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DEPARTMENT OF AGRICULTURE

Commodity Credit Corporation

7 CFR Part 1470

[Docket No. NRCS–2019–0020]

RIN 0578–AA67

Conservation Stewardship Program (CSP) Interim Rule

AGENCY: Commodity Credit Corporation, United States Department of Agriculture.

ACTION: Interim rule.

SUMMARY: This interim rule with request for comment amends the existing regulation for CSP to incorporate programmatic changes as authorized by amendments in the Agriculture Improvement Act of 2018 (2018 Farm Bill).

DATES:

Effective: November 12, 2019.

Comment date: Submit comments on or before January 13, 2020.

Comment date for Environmental Review: Submit comments on the draft Environmental Analysis (EA) and Finding of No Significant Impact (FONSI) on or before December 12, 2019.

ADDRESSES: We invite you to submit comments on this rule. In your comments, include the date, volume, and page number of this issue of the **Federal Register**, and the title of notice. You may submit comments by the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov/* and search for Docket ID NRCS–2019–0020. Follow the online instructions for submitting comments.

All written comments received will be publicly available on *http://www.regulations.gov*.

A copy of the draft Environmental Assessment (EA) and Finding of No Significant Impact (FONSI) may be obtained from either of the following websites: *www.regulations.gov* or *https://www.nrcs.usda.gov/wps/portal/nrcs/detail/national/technical/ecosciences/ec*. A hard copy may also be requested in one of the following ways:

- *Via mail: karen.fullen@usda.gov* with ''Request for EA'' in the subject line; or
- *A written request:* Karen Fullen, Environmental Compliance Specialist, Natural Resources Conservation Service, 9173 W Barnes Dr., Suite C, Boise, ID 83709.

FOR FURTHER INFORMATION CONTACT: Sarah Brooks; phone: (720) 544–2825; or email: *sarah.brooks@usda.gov*. Persons with disabilities who require alternative means for communication should contact the USDA Target Center at (202) 720–2600 (voice).

SUPPLEMENTARY INFORMATION:

Discussion of Conservation Stewardship Program (7 CFR Part 1470)

The Food, Conservation, and Energy Act of 2008 (2008 Farm Bill) amended the Food Security Act of 1985 to establish CSP and authorize the program in fiscal years (FY) 2009 through 2013. The Agricultural Act of 2014 (2014 Farm Bill) reauthorized and revised CSP through FY 2018. NRCS promulgated an interim rule on November 5, 2014, and subsequently made final those changes on March 10, 2016, through issuance of a final rule. The Agriculture Improvement Act of 2018 (2018 Farm Bill) moved CSP from subchapter B of chapter 2 of subtitle D of title XII of the Food Security Act of 1985 to a new subchapter B of chapter 4 of subtitle D of title XII of the Food Security Act of 1985, and then repealed subchapter B of chapter 2 as amended.

The purpose of CSP is to encourage producers to address priority resource concerns and improve and conserve the quality and condition of the natural resources in a comprehensive manner by: (1) Undertaking additional conservation activities; and (2) improving, maintaining, and managing existing conservation activities. The Secretary of Agriculture delegated authority to the Chief, Natural Resources Conservation Service (NRCS), to administer CSP.

Through CSP, NRCS provides financial and technical assistance to eligible producers to conserve and enhance soil, water, air, and related natural resources on their land. Eligible lands include private or Tribal cropland, grassland, pastureland, rangeland, nonindustrial private forest lands, and other land in agricultural areas (including cropped woodland, marshes, and agricultural land or land capable of being used for the production of livestock) on which resource concerns related to agricultural production could be addressed. Eligible lands also include lands associated with these private or Tribal agricultural lands on which a priority resource concern can be addressed through a CSP contract. Participation in the program is voluntary.

CSP encourages land stewards to improve their conservation performance by installing and adopting additional conservation activities, and improving, maintaining, and managing existing conservation activities on eligible land. NRCS accepts applications for CSP at any time, but specifically identifies one batching cutoff period in the first quarter of each fiscal year. NRCS then ranks and makes funding decisions based on the applications received on or before the established cutoff date. Depending upon the availability of funds or whether there existed sufficient competition amongst high quality applications during the first ranking and selection period, NRCS can establish additional ranking and selection periods during the remainder of the fiscal year.

NRCS continues to streamline and coordinate administration of both CSP and the Environmental Quality Incentives Program (EQIP) as directed by the 2018 Farm Bill. Through this effort, NRCS has evaluated several administrative processes in order to establish standard methodologies for both programs. Some examples include: Using payment schedules to develop the payment rates for all conservation practices and activities used by the programs; tying all enhancements to NRCS conservation practice standards; using Farm Service Agency (FSA) records to ensure that program participants represent themselves the same way across all USDA programs; aligning payment and modification processes to the greatest extent possible recognizing that CSP has certain statutory requirements for annual payment timing; and requiring implementation of at least one new conservation practice or activity within the first 12 months of the contract.

In addition, CSP and EQIP work in a complementary manner to address conservation issues associated with agricultural operations. While EQIP focuses on the implementation of conservation practices at the field level to address specific natural resource concerns, CSP emphasizes the use of conservation activities, which include practices, enhancements, and bundles, implemented at the agricultural operation level. Conservation practices have a conservation practice physical effect (CPPE) score that provides a measure of the positive or negative effect of the practice on any given resource concern. Similarly, NRCS has developed enhancement physical effect (EPE) scores for each enhancement that provide a measure of environmental benefit for each resource concern.

NRCS also recognizes that not all enhancements will achieve the same benefit with respect to a specific resource concern and the agency continues to move toward quantifying the benefits based upon scientific information made available through Conservation Effects and Assessment Project (CEAP) studies. A producer who installs conservation practices under EQIP to meet one or more resource concerns is then better positioned to meet the CSP stewardship threshold. NRCS encourages a producer enrolled in CSP to achieve increased environmental benefits through the adoption of conservation activities that focus on increased positive impacts to a specific resource concern as documented by the EPE score. In this way, CSP builds upon the conservation efforts initiated under EQIP and expands upon them to a new level of conservation performance.

Summary of CSP Provisions

The CSP regulation is organized into three subparts: (1) Subpart A—General Provisions, (2) Subpart B—Contracts, and (3) Subpart C—General Administration. Below is a summary of the changes made to each subpart based upon the changes made to CSP by the 2018 Farm Bill.

The 2018 Farm Bill made the following changes to CSP program requirements:

- Confirms validity of CSP contracts entered into prior to 2018 Farm Bill enactment, authorizes the ability to extend contracts that are due to expire on or before December 31, 2019, and authorizes renewal of such contracts through the new CSP authority.
- Defines new terms and adjusts existing terms, such as expanding the definition of ''conservation activities'' and defining the term ''comprehensive conservation plan.''
- Simplifies CSP ranking criteria and requires that both new contracts and contract renewals be ranked based on those criteria.
- Requires that if two or more applications receive the same ranking, they be ranked on the extent to which actual and anticipated conservation benefits from each contract are provided at the lowest cost relative to other similarly beneficial offers.
- Provides opportunity for participants to renew their contracts in the first half of the fifth year of the 5-year contract.
- Bases program allocations on funds rather than acres and eliminates the requirement that NRCS administer the program at $18 per acre average nationally.
- Incentivizes certain activities, including authorizing payment for cover crop activities at not less than 125 percent of the annual payment amount, and authorizes a supplemental payment for advanced grazing management or resource-conserving crop rotations at not less than 150 percent of the annual payment amount.
- Provides a one-time payment to participants who agree to develop a comprehensive conservation plan.
- Continues a $200,000 payment limitation for individuals and legal entities for all contracts entered into during FY 2019 through 2023.
- Requires that States be given an allocation to support organic production based on the certified and transitioning organic operations of the State and the number of certified and transitioning organic acres of the State.
- Requires that CSP be streamlined and aligned with EQIP, including applications, contracting, conservation planning, conservation practices, and related administrative procedures.
- Requires that to the greatest extent practicable, the program should be managed to enhance soil health.
- Requires NRCS to submit an annual report to Congress on payment rates along with an analysis of whether payment rates can be reduced for the most expensive conservation activities.
- Authorizes a CSP-Grasslands Conservation Initiative to help producers with certain base acres in protecting grazing land uses, conserving and improving soil, water and wildlife resources and waives several program requirements to facilitate enrollment under the initiative.
- Authorizes funding for CSP at—
  - $700 million for FY 2019.
  - $725 million for FY 2020.
  - $750 million for FY 2021.
  - $800 million for FY 2022.
  - $1 billion for FY 2023.

NRCS is making the following mandatory and discretionary changes to the CSP regulation based upon these changes made by the 2018 Farm Bill:

Mandatory Changes—

- Removes regulatory language that addressed CSP implementation under the Regional Conservation Partnership Program (RCPP) since the 2018 Farm Bill removed the requirement that RCPP be implemented through CSP and the other ''covered programs.'' (See § 1470.2(b).)
- Removes reference to acreage cap and dollar amount per acre limit (See § 1470.2(d).)
- Adds the following definitions to reflect statutory changes: Advanced grazing management, *comprehensive* conservation plan, and management-intensive rotational grazing. (See § 1470.3.)
- Adds a new paragraph to address State organic allocations which will be based on the number of organic and transitioning-to-organic operations in a State and the number of organic and transitioning-to-organic acres in a State. (See § 1470.4(b).)
- Requires that if two or more applications receive the same ranking, they be ranked on the extent to which actual and anticipated conservation benefits from each contract are provided at the lowest cost relative to other similarly beneficial offers. (See § 1470.24(c).)
- Adds advanced grazing management as another type of supplemental payment. (See § 1470.24(b).)
- Includes language for the one-time payment option for development of a comprehensive conservation plan. (See § 1470.24(c).)
- Incorporates language about opportunity for participants to renew their contracts in the first half of the fifth year of the 5-year contract. (See § 1470.26(a).)
- Outlines the requirements and parameters of CSP–GCI. (See § 1470.28.)

Discretionary Changes—

- Removes identification of Chief as a Vice President of the Commodity Credit Corporation. (See § 1470.2(a).)
- Modifies existing terms to reflect changes in terminology, to more closely align CSP program administration with EQIP, and for clarity. (See § 1470.3.) These include, but are not limited to—
  - Modifying ''eligible land'' to include public land when the land is a working component of the participant's agricultural or forestry operation.

○ Modifying the definition of ''veteran farmers or ranchers'' to cite the statutory reference in the 2018 Act.

○ Clarifying ''enhancement'', ''participant'', and ''stewardship threshold.''

• Specifies eligibility requirements for all applicants sharing in the risk and participating in day-to-day activities. (See § 1470.6(a).)

• Expands the potential scope of bundles and provides NRCS with discretionary authority for offering bundles. (See § 1470.7(c).)

• Removes the requirements associated with an operation crossing ranking pool boundaries to increase applicant flexibility. (See § 1470.20(d).)

• Adds organic producers or producers transitioning to organic as a category of producer with a targeted ranking pool. (See § 1470.20(d).)

• Clarifies the annual payment structure and adjusted the timeframe for implementing the first conservation activity to align with EQIP. (See § 1470.24(a).)

• Adds language stating that, unless a waiver is granted, participants will not receive payment for conservation activities initiated or implemented prior to contract approval. (See § 1470.24(f).)

• Expands the regulatory $400,000 contract limit for all joint operations. (See § 1470.24(h).)

• Adds language to allow for contract increases due to minor adjustments made to conservation activities at the discretion of NRCS. (See § 1470.25(c).)

• Modifies language to provide greater consideration to a participant's circumstances with respect to operational changes. (See § 1470.25(b).)

Adds language to address contract changes that arise due to the death, incompetence, or disappearance of a program participant. (See § 1470.25(h).)

• Includes an eligibility restriction for renewal-eligible participants who choose not to renew in favor of competing for a new contract. (See § 1470.26(c).)

• Removes language related to training NRCS staff. (See § 1470.8(c).)

• Adjusts definitions to conform to those in other NRCS or Department regulations. (See § 1470.3.)

USDA 2018 Farm Bill Listening Session

On February 14, 2019, the Farm Service Agency (FSA), NRCS, and the Risk Management Agency (RMA) published a notice in the **Federal Register** (84 FR 4041–4044) announcing a listening session for initial public input on the changes to existing programs implemented by the agencies. Each agency will take into account stakeholder input when making discretionary decisions on program implementation. The agencies also announced an opportunity for the public to make written statements through March 1, 2019. The listening session was held on February 26, 2019. The Commodity, Credit, and Crop Insurance titles, and parts of the Conservation, Energy, and Miscellaneous titles were covered during the listening session.

FSA, NRCS, and RMA received 183 written comments from individuals, trade groups, other organizations, and State entities. All written comments are available to the public for review at: *https://www.regulations.gov/document?D=USDA-2019-0001-0001.* In addition to program-specific comments, there were recurring overarching comments about placing a priority on information sharing between agencies for data collection regarding soil health and conservation practices.

Among the comments submitted concerning CSP, NRCS received 20 comments related to program delivery and administration. Numerous comments called for the immediate start of the sign-up period for CSP and for more flexibility on eligibility requirements involving land control, lower-cost practices, and past participation in other conservation programs. Some comments emphasized consideration of local priorities and protection of treaty-reserved resources in identifying resource concerns. Other comments focused on increased payments for practices associated with soil health, cover crops, resource-conserving crop rotations, and advanced grazing management.

NRCS also received five comments that underlined the adoption of robust conservation management activities under the initiative. Other comments sought for clear guidance on program eligibility and effective outreach to producers regarding enrollment options.

NRCS received three comments on the funding allocation to support organic production and transition to organic production. Two of the comments recommended that the allocation formula be based on the current Farm Bill and on feedback from States regarding projected demand from organic and transitioning farmers. The other comment stressed the need for additional financial support and technical assistance among transitioning organic farmers.

NRCS received a couple comments on reevaluating the definition of resource-conserving crop rotation to include the required use of perennial grass or legume and rotations of annual crops, such as sorghum. Another comment recommended that the resource-conserving crop rotation be included in the FY 2019 sign up.

Finally, NRCS received two comments on prioritizing incentives for practices that improve soil health: One comment supporting the development of conservation enhancements for advanced grazing management, and one comment requesting guidance on practices that can be implemented under CSP that will help in coping with weather volatility.

NRCS evaluated the changes made by the 2018 Farm Bill and the comments received during the listening session and is hereby promulgating this interim rule with request for comments to incorporate the 2018 Farm Bill changes to CSP program administration and make other adjustments based on public comment. This action is pursuant to section 1246 of the Food Security Act of 1985 which requires implementation of title XII of the Food Security Act through an interim rule with request for comments. Section 2504 of the 2018 Farm Bill states that NRCS may implement the Farm Bill conservation provisions under their current regulations to the extent that such regulations are consistent with the 2018 Farm Bill provisions. This interim authority enabled NRCS to hold CSP program enrollment in FY 2019. It expires September 30, 2019.

Subpart A—General Provisions

§ 1470.1 Applicability

This section sets forth the policies, procedures, and requirements of CSP. In paragraph (a), NRCS clarifies that contracts entered into prior to the 2018 Farm Bill are administered according to the CSP regulation in effect prior to enactment, and that contracts entered into after enactment of the 2018 Farm Bill will be administered under these regulations.

§ 1470.2 Administration

This section describes the roles of NRCS at the National and State levels. Paragraph (a) was changed to remove reference to the NRCS Chief being an officer of the Commodity Credit Corporation. When USDA established the Farm Production and Conservation (FPAC) Mission Area, officer positions were delegated to the mission area Under Secretary and the FPAC Business Center Chief Operating Officer.

Paragraph (b) is revised to remove any reference to the Regional Conservation Partnership Program, which will have its own regulations and fiscal allocations consistent with the 2018

Farm Bill. NRCS removed paragraph (d) because CSP no longer has an acreage cap, nor is it limited to any dollar amount per acre. Subsequent paragraphs were redesignated accordingly. NRCS amended redesignated paragraph (d)(2) to remove the ''applicable'' modifier for priority resource concerns to improve readability. NRCS added paragraph (d)(4) to cover new information related to advanced grazing management.

§ 1470.3 Definitions

This section sets forth definitions for terms used throughout this regulation. The following definitions have been added to reflect changes made by the 2018 Farm Bill: Advanced grazing management, comprehensive conservation plan, and management-intensive rotational grazing.

The term conservation activities was modified to include several additional examples consistent with the 2018 Farm Bill.

The term conservation practice was modified to reflect the technical definition used in other NRCS manuals.

The term effective control was modified for clarity.

The term eligible land was modified to include privately controlled public land when the land is a working component of the participant's agricultural or forestry operation. The CSP statute identifies that eligible land includes lands associated with the producer's private or Tribal agricultural or forestry operation provided that priority resource concerns could be addressed through a contract under the program on that associated land. NRCS has interpreted that this language regarding associated lands allows producers to enroll the public land components of their overall agricultural or forestry operation, if such land is managed as part of the private or Tribal producer's operation pursuant to a long-term lease from a public agency and the enrollment of the land will contribute to an improvement in an identified priority resource concern. NRCS makes this change to align CSP program administration more closely with EQIP as required by the 2018 Farm Bill.

The terms enhancement and field office technical guide were modified to reflect a change in terminology from ''quality criteria'' to ''planning criteria''.

The term historically underserved producer was modified to include veteran farmers or ranchers.

The term participant was modified to clarify that a participant must first apply and be accepted into the program to qualify as a participant.

The term priority resource concern was simplified by removing the additional qualifiers of ''applicable'' and ''other'' and thus aligns the term more closely with the statutory definition and improves readability of the regulation.

The term resource-conserving crop rotation was modified to add ''building soil organic matter'' as a requirement. The term resource-conserving crop was modified to clarify that NRCS determines whether a crop is resource conserving, and expanded the definition to include a small grain or ''other resource-demanding'' crop grown in combination with a grass, legume, forbs, or grass-forbs mixture.

The definition of stewardship threshold was modified to delineate the means by which the stewardship threshold may be reached.

The definition of technical assistance was modified to remove the specific reference to development of forest stewardship plans. The intent was simply to broaden the language to encompass all plans, including the new plans authorized under the 2018 Farm Bill, and the development of forest stewardship plans remains encompassed within the definition of technical assistance.

The definition of technical service provider was modified to be consistent with the potential for a technical service provider to be certified through a third-party certifying organization.

The definition of veteran farmer or rancher was modified to correctly cite the statutory reference as amended by the 2018 Farm Bill.

§ 1470.4 Allocation and Management

This section addresses national allocations and how the proportion of eligible land will be used as the primary means to distribute CSP funds among States. The NRCS Chief has discretionary authority to adjust the weighting of the statutorily prescribed allocation factors to better distribute funds and address program purposes. NRCS seeks public comment on the weighting of the statutory factors and whether other factors should be considered to achieve equitable geographic distribution of program funds or enhance environmental benefits realized through the program. This section has been modified to address the change in the CSP program from an acre-based program to a dollar-based program by the 2018 Farm Bill. References to acreage have been removed from this section and language has been modified to clarify that allocations of funding are not tied to any acreage cap. NRCS removed paragraph (d) that identified veteran farmer or rancher priority since veteran farmer or rancher access, which includes prioritization, is addressed through § 1470.20. NRCS revised paragraph (b) to address State organic allocations as required by statute which will be based on the number of organic and transitioning-to-organic operations in a State and the number of organic and transitioning-to-organic acres in a State.

§ 1470.5 Outreach Activities

This section addresses NRCS outreach activities. NRCS has made minor editorial adjustments to this section to improve clarity by using the term historically underserved producers.

§ 1470.6 Eligibility Requirements

This section sets forth the criteria for determining applicant and land eligibility. The CSP statute identifies that producers with effective control of the land are eligible to participate. Since 2010, the CSP regulation required that the producer be the operator of record in the Farm Service Agency (FSA) farm records system but allowed NRCS to waive the operator of record requirements. While this regulatory requirement seemed to provide a clear standard for determining producer eligibility, given the variety of agricultural operations and land tenancy it resulted in creating unnecessary administrative hurdles for many otherwise eligible producers to participate. Therefore, NRCS expanded paragraph (a)(1) to include owners and other tenants as identified in the FSA farm records system as potential eligible applicants and removed the operator of record waiver authority as the waiver is no longer needed. NRCS believes that this change will improve customer service, simplify the application and contracting process, and reduce the burden on field office staff.

Further, NRCS redesignated paragraphs (a)(2) through (5) as paragraphs (a)(3) through (6) and inserted a new paragraph (a)(2) to specify eligibility requirements for all applicants related to sharing in the risk and participating in the day-to-day management of the operation. In paragraph (a)(6), NRCS removed the reference to veteran farmers or ranchers as redundant since the term farmer and rancher is incorporated into the term historically underserved producer. NRCS removed reference to Conservation Security Program contracts as there are no longer any active contracts under the repealed program.

The CSP statute defines eligible land as ''private or tribal land on which agricultural commodities, livestock, or forest-related products are produced'' and includes ''associated lands.''

Western producers often lease or have a permit to use public land as part of their operation and have been discouraged from participating in CSP even though such lands are an integral part of their operation. NRCS has amended the CSP regulatory definition of eligible land to allow the enrollment of public lands that are associated with eligible land under the effective control of the producer as part of their private agricultural operation. This change provides consistency with EQIP program administration since EQIP currently allows public lands that are part of a private producer's operation to be enrolled in an EQIP contract. Because of the inclusion of public land under the definition of eligible land, NRCS removed paragraph (c)(4) which previously identified public lands as ineligible. In paragraph (c)(3), the dates were modified to address the scope of the 2018 Farm Bill.

§ 1470.7 Conservation Activities

This section describes the range of activities and practices covered by CSP. The name of this section was updated for simplification to incorporate conservation practices, enhancements and bundles. Previously, § 1470.7 identified that NRCS will make available bundled suites of conservation enhancements for participants to select voluntarily to include as part of their conservation stewardship plans. These ''bundled suites of conservation enhancements'' included multiple enhancements whose installation as a group was designed to improve conservation performance and address resource concerns in a more comprehensive and cost-effective manner. NRCS modified paragraph (c) to expand the potential scope of bundles to include both practices and enhancements by using the term ''conservation activity'' as defined in § 1470.3. NRCS also adjusted the language to allow the agency discretion in offering bundles as there may be particular contexts where bundling of activities will not improve conservation performance. NRCS removed paragraph (d) that encouraged the use of other NRCS programs to implement conservation practices to meet agreed-upon stewardship levels, though not compensated under CSP, due to programmatic changes that now allow broader practice implementation and compensation under CSP.

§ 1470.8 Technical and Other Assistance

This section explains that NRCS or other technical service providers (TSPs) not directly affiliated with NRCS could provide the technical consultation for installing conservation activities under CSP. NRCS modified paragraph (c) to remove language related to training NRCS staff as this is an internal agency administrative matter.

Subpart B—Contracts and Payments

§ 1470.20 Application for Contracts and Selecting Offers From Applicants

This section identifies procedures associated with contract application requirements, the application evaluation process, and application acceptance. NRCS intends to continue evaluating applications based on the level of expected environmental benefit achieved through adoption of additional conservation activities. Currently, NRCS provides higher ranking points to applicants who agree to adopt more conservation activities in order to meet or exceed the stewardship threshold of a higher number of resource concerns, agree to adopt the additional conservation activities over a greater percentage of their operation, adopt bundles, and adopt conservation activities that target wildlife habitat improvement and soil health. NRCS also uses an efficiency score component in the ranking which considers the environmental benefit associated with an applicant's planned additional conservation activities and the costs associated with implementing these activities. In this way, NRCS prioritizes applications that will provide higher levels of conservation and environmental benefits across the agricultural or forestry operation. NRCS amended paragraph (c) to incorporate the new criteria established in the 2018 Farm Bill. NRCS removed the discretionary provision related to weighting of ranking factors as this determination is more administrative rather than regulatory in nature. NRCS incorporated the language regarding national, state and local priorities into paragraph (c)(2)(iii). In paragraph (d), NRCS removed the requirements associated with an operation crossing ranking pool boundaries to increase applicant flexibility. NRCS establishes ranking pools based on watersheds, geographic areas, or other high priority areas within a State or region. Nationally, NRCS requires States to establish separate ranking pools for beginning farmer or ranchers, socially disadvantaged farmer or ranchers, and through the 2018 Farm Bill, organic producers or producers transitioning to organic. In addition, NRCS may establish national or State initiatives which would have a unique ranking pool. NRCS continues to provide priority to veteran farmers or ranchers within the beginning farmer or rancher or socially disadvantaged farmer or rancher ranking pools. NRCS modified paragraph (e) to authorize NRCS to make application determinations throughout the fiscal year to provide additional flexibility to program administration. Similarly, NRCS modified paragraph (f) to use consistent terminology with respect to CSP contracts.

§ 1470.21 Contract Requirements

This section identifies elements contained within a contract and the responsibilities of a CSP participant. A participant must enter into a CSP contract, including a conservation stewardship plan, to enroll their eligible land and to receive payment. NRCS modifies this section only to improve the clarity of language.

§ 1470.22 Conservation Stewardship Plan

This section describes that NRCS will use the conservation planning process to encourage producers to address priority resource concerns in a comprehensive manner. The conservation stewardship plan contains a record of the participant's decisions on the schedule of conservation activities to be implemented, managed, and improved under CSP. NRCS modifies this section to consolidate duplicative information and to ensure consistent language is used throughout this part. This section was also modified to remove reference to documentation that is addressed as part of NRCS actions, including documentation related to meeting or exceeding the applicable stewardship thresholds.

§ 1470.23 Conservation Activity Operation and Maintenance

This section addresses the participant's responsibility for managing and maintaining existing conservation activities on the agricultural operation to at least the level of conservation performance identified at the time of application for the conservation stewardship contract period. Additional activities installed and adopted over the term of the conservation stewardship contract also need to be maintained. NRCS simplifies the language in this section.

§ 1470.24 Payments

This section describes the types of payments issued under CSP, how payments will be derived, and payment limitations. NRCS modified paragraph (a) to consolidate duplicative information, remove outdated

information, and to improve clarity by using the active voice. Specifically, NRCS clarified the annual payment structure and adjusted the timeframe for implementing the first conservation activity to align with EQIP. NRCS added language requiring a higher payment percentage for cover crop activities as stipulated in the 2018 Farm Bill.

The 2018 Farm Bill added advanced grazing management as another type of supplemental payment and included payment for development of a comprehensive conservation plan. NRCS incorporated advanced grazing management in paragraph (b) and added language for supplemental payment rates as prescribed in the 2018 Farm Bill. NRCS inserted paragraph (c) to incorporate a one-time payment option for development of a comprehensive conservation plan.

Under paragraph (f), ''Noncompensatory Matters,'' NRCS describes situations in which a participant may not receive payment. To avoid duplicate payments, participants are required to certify on the payment application that they have not received payment under any other USDA program for the same conservation activity(ies) as discussed in paragraph (f)(1). Paragraph (f)(4) includes an additional noncompensatory matter stating that participants will not receive payment for conservation activities initiated or implemented prior to contract approval, unless NRCS grants a waiver prior to the participant starting the activity. NRCS maintains the statutory payment limitation but removed the annual payment limitation from paragraph (g) and the annual contract payment limitation from paragraph (h).

The CSP statute has an aggregate $200,000 payment limitation for persons and legal entities for all CSP contracts entered into between FY 2019 through 2023. In addition to the statutory aggregate payment limitation, NRCS retains the $200,000 contract limitation for individual and entity participants in paragraph (h) and expands the higher $400,000 contract limit to include all joint operations, regardless of whether the joint operation uses an Employer Identification Number (EIN) or member Social Security Numbers (SSNs). This policy prohibits large joint operations from entering into multimillion-dollar CSP contracts while still offering a contract limit that does not discourage them from participating in CSP.

§ 1470.25 Voluntary Contract Modifications and Transfers of Land

This section identifies the actions that NRCS might take to modify or terminate a contract and the notice and process requirements for transfers of land under a CSP contract. Because CSP was previously subject to a national average rate of $18 per acre, NRCS restricted the extent to which a CSP contract could be modified to ensure that subsequent contract actions would not result in NRCS exceeding the statutory limit. The 2018 Farm Bill removes the $18 per acre restriction and encourages more coordination between how contracts are administered under both CSP and EQIP. Therefore, NRCS made several changes to § 1470.25 to incorporate the new flexibility provided through the 2018 Farm Bill. Specifically, NRCS modified paragraph (b)(2) to add clarification that participant requests to take land out of production or convert an area under contract to a different land use do not include changes made to a land use as a result of involuntary loss of land. NRCS moved and simplified language related to conservation activity substitution from § 1470.24, Payments, and inserted this as paragraph (b)(3) of this section. NRCS added language to paragraph (c) to allow for contract increases due to minor adjustments made to conservation activities at the discretion of NRCS. The above referenced changes align CSP contract administration with EQIP contract administration as encouraged by the 2018 Farm Bill. NRCS modified paragraphs (d) and (e) to change language from mandatory to discretionary to provide greater consideration to a participant's circumstances with respect to operational changes and to provide greater consistency with other provisions in this section and throughout the part.

NRCS added a new paragraph (h) at the end of § 1470.25 to address contract changes in the cases of death, incompetency, or disappearance of any participant. The new paragraph helps to streamline contract matters at a difficult time for a participant's family and provides greater consistency between how NRCS and FSA addresses these sensitive issues.

§ 1470.26 Contract Renewal

In this section, NRCS may allow a participant to renew the contract for one additional 5-year period if they meet specific criteria. NRCS updates this section to incorporate language from the 2018 Farm Bill, including that renewals will now be ranked and compete for available funding. Consistent with the 2018 Farm Bill, NRCS included a provision that participants may be given the opportunity to renew in the first half of the fifth year of their existing contract period. NRCS added paragraph (c) to include an eligibility restriction for renewal-eligible participants who elect not to renew in favor of competing for a new contract under the general program provisions. NRCS also updated this section to ensure consistent language and to remove the reference to the acreage cap.

§ 1470.27 Contract Violations and Termination

This section addresses the procedures that NRCS will take when a violation has occurred or a contract termination is needed. NRCS made changes throughout the section to align violation procedures with EQIP, consolidate duplicative information, eliminate redundancy, and improve clarity.

§ 1470.28 Grassland Conservation Initiative Contracts

This section is added to incorporate this new initiative authorized through the 2018 Farm Bill. The grassland conservation initiative will assist producers in protecting grazing uses; conserving and improving soil, water, and wildlife resources; and achieving related conservation values by conserving eligible land through grassland conservation contracts. Paragraph (b) explains that the initiative is applicable on eligible cropland for which base acres have been maintained by the Secretary under section 1112(d)(3) of the Agricultural Act of 2014 (7 U.S.C. 9012(d)(3)). NRCS will allow a GCI participant to plant crops on land enrolled in GCI if the participant meets specific resource conditions analogous to if the land were planted or maintained to grass. Conditions include development of a conservation plan and the participant must adopt the identified conservation activities to receive the $18 per acre payment to ensure that the resource concerns associated with grassland are met.

Paragraph (c) identifies that the producer with eligible land is provided one opportunity to enroll in the initiative during FY 2019 through 2023; however, a producer has the option to defer enrollment to any year within this period. Producers with land eligible for the initiative may not have the same land enrolled under the initiative and the general CSP at the same time. Through paragraph (d), participants enrolled in the initiative must agree to meet or exceed the stewardship threshold for at least one priority resource concern before the end of the contract. Paragraph (e) defines the contract period as one 5-year term. Initiative contracts are not subject to

renewal at the end of the initial 5-year term. Initiative contracts will receive payment of $18 per acre not to exceed the acres enrolled in the initiative contract per paragraph (f). Paragraph (f) also provides that initiative contracts are not subject to the payment limitations or contract limits provided in § 1470.24(f) and (g), nor are they eligible for supplemental payments as provided in § 1470.24(b). The participant may request to terminate their initiative contract at any time and retain payments already received under the contract in accordance with paragraph (g).

Subpart C—General Administration

§ 1470.30 Fair Treatment of Tenants and Sharecroppers

This section specifies that any CSP payments received must be divided in the manner specified in the contract. Where conflicts arise between an operator and landowner, NRCS may refuse to enter into a CSP contract.

§ 1470.33 Access to Agricultural Operation

This section notifies potential CSP applicants and CSP participants that an authorized NRCS representative may enter an operating unit for the purpose of determining eligibility, ascertaining accuracy of any representations, and confirming compliance with the program requirements during the term of the contract.

§ 1470.34 Equitable Relief

This section notifies a participant that he or she may be eligible for equitable relief in accordance with 7 CFR part 635, if the participant relied upon the advice or action of NRCS and did not know that the action or advice was erroneous.

§ 1470.37 Environmental Credits for Conservation Improvements

This section is changed to conform its language to section 1244(o) of the Food Security Act of 1985, as amended by clarifying that environmental benefits achieved through participation in the CSP program may qualify for environmental credits under an environmental credit-trading program, and that NRCS asserts no direct or indirect interest in these credits. Further, any requirements or standards of such environmental market program to receive credits must be compatible with the purposes of the CSP contract.

Effective Date, Notice and Comment, and Paperwork Reduction Act

In general, the Administrative Procedure Act (APA) (5 U.S.C. 553) requires that a notice of proposed rulemaking be published in the **Federal Register** and interested persons be given an opportunity to participate in the rulemaking through submission of written data, views, or arguments with or without opportunity for oral presentation, except when the rule involves a matter relating to public property, loans, grants, benefits, or contracts. This rule involves matters relating to benefits and therefore is exempt from the APA requirements. Further, the regulations to implement the programs of chapter 58 of title 16 of the U.S. Code, as specified in 16 U.S.C. 3846, and the administration of those programs, are:

- To be made as an interim rule effective on publication, with an opportunity for notice and comment,
- Exempt from the Paperwork Reduction Act (44 U.S.C. ch. 35), and
- To use the authority under 5 U.S.C. 808 related to Congressional review and any potential delay in the effective date.

For major rules, the Congressional Review Act requires a delay in the effect date of 60-days after publication to allow for Congressional Review. This rule is a major under the Congressional Review Act, as defined by 5 U.S.C. 804(2). The authority in 5 U.S.C. 808 provides that when an agency finds for good cause that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, that the rule may take effect at such time as the agency determines. Due to the nature of the rule, the mandatory requirements of the 2018 Farm Bill, and the need to implement the CSP regulations expeditiously to provide assistance to producers, NRCS and CCC find that notice and public procedure are contrary to the public interest. Therefore, even though this rule is a major rule for purposes of the Congressional Review Act of 1996, NRCS and CCC are not required to delay the effective date for 60 days from the date of publication to allow for Congressional review. Therefore, this rule is effective on the date of publication in the **Federal Register**

NRCS invites interested persons to participate in this rulemaking by submitting written comments or views about the changes made by this interim rule. The most helpful comments reference a specific portion of the regulation, explain the reason for any recommended changes, and include supporting data and references to relevant section of either the 2018 Farm Bill or the 1985 Farm Bill. All comments received on or before the closing date for comments will be considered. NRCS will review and respond to the public comments in the CSP final rule.

Executive Orders 12866, 13563, 13771, and 13777

Executive Order 12866, ''Regulatory Planning and Review,'' and Executive Order 13563, ''Improving Regulation and Regulatory Review,'' 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 emphasized the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Executive Order 13777, ''Enforcing the Regulatory Reform Agenda,'' established a federal policy to alleviate unnecessary regulatory burdens on the American people.

The Office of Management and Budget (OMB) designated this rule as economically significant under Executive Order 12866, and therefore, OMB has reviewed this rule. The costs and benefits of this proposed rule are summarized below. The full cost benefit analysis is available on *https://www.regulations.gov/.* Executive Order 13771, ''Reducing Regulation and Controlling Regulatory Costs,'' requires that, to manage the private costs required to comply with federal regulations for every new significant or economically significant regulation issued, the new costs must be offset by the elimination of at least two prior regulations. This rule involves transfer payments and does not rise to the level required to comply with Executive Order 13771.

Clarity of the Regulation

Executive Order 12866, as supplemented by Executive Order 13563, requires each agency to write all rules in plain language. In addition to your substantive comments on this rule, we invite your comments on how to make the rule easier to understand. For example:

- Are the requirements in the rule clearly stated? Are the scope and intent of the rule clear?
- Does the rule contain technical language or jargon that is not clear?
- Is the material logically organized?
- Would changing the grouping or order of sections or adding headings make the rule easier to understand?
- Could we improve clarity by adding tables, lists, or diagrams?

• Would more, but shorter, sections be better? Are there specific sections that are too long or confusing?

• What else could we do to make the rule easier to understand?

Cost Benefit Analysis Summary

Compared to CSP as authorized under the 2014 Farm Bill, Congress significantly reduced the program's size in the 2018 Farm Bill—from $9 billion [1] to $3.975 billion over 5 years—but left much of CSP's underlying structure intact. With fewer dollars available, fewer contracts will be funded under the 2018 Farm Bill. However, CSP will continue to fund high-ranking applications across all States, with the aim of improving cost effectiveness based on dollars per additional unit of conservation effect.

Funds for all activities conducted under the CSP contract are obligated up front and funds for contract renewals will come from the available funds at the time of contract renewal. The 2018 Farm Bill also eliminated the 10-million-acre cap on enrollment and the annual $18 per acre cap on program costs, moving to an annual funding level for new CSP contracts similar to EQIP.

Regarding changes beyond funding and the elimination of the acreage cap, only revised CSP contract renewal conditions are expected to generate impacts that are moderately different from the 2014 Farm Bill. CSP contracts continue to run for 5 years and include the potential for a 1-time renewal option for an additional 5 years. Under the 2014 Farm Bill, renewals were non-competitive and at the request of the contract holder. Under the 2018 Farm Bill, contract renewals will be ranked against other contract renewals and funded based on the availability of funds in the year of renewal. The requirement to compete against other applicants for funds will reduce the number of contracts renewed and reduce the funding available for new contracts, reducing the number of conservation activities undertaken. Cost-effectiveness of CSP may increase as lower ranked applications will not be funded.

The 2018 Farm Bill also mandates the establishment of the Grassland Conservation Initiative for eligible producers with base acres where the entire farm was planted to grass or pasture, or was idle or fallow, from January 1, 2009 to December 31, 2017. Beginning in FY 2019, the Secretary provided a 1-time election for a producer to enroll eligible land for a 5-year non-renewable term. Participants must meet CSP eligibility conditions, but do not go through the ranking process. Participating producers must agree to meet or exceed the stewardship threshold for not less than 1 priority resource concern by the date on which the contract expires. The annual payment is limited to $18 per acre, and enrolled acreage cannot exceed the number of base acres on a farm.

An estimated 2.4 million acres meet the 2009 to 2017 criterion noted above and are eligible for the Grassland Conservation Initiative. Although these eligible acres are concentrated in Texas, Oklahoma, and Kansas, there is eligible acreage throughout most of the country. The Grassland Conservation Initiative is expected to cost $214.9 million over 5 years, representing 5.5-percent of total authorized CSP funding under the 2018 Farm Bill. Cost-effectiveness may be affected marginally as fewer funds will be available for higher ranked applications and contract renewals.

In implementing the 2018 Farm Bill, USDA is following legislative intent to maximize conservation impacts, address natural resource concerns, establish an open participatory process, and provide flexible assistance to producers who apply appropriate conservation measures to comply with Federal, State, and Tribal environmental requirements. Participation in CSP is voluntary. Hence, CSP participation is not expected to negatively impact program participants and nonparticipants.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601–612), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), generally requires an agency to prepare a regulatory analysis of any rule whenever an agency is required by APA or any other law to publish a proposed rule, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. This rule is not subject to the Regulatory Flexibility Act because no law requires that a proposed rule be published for this rulemaking initiative. Despite the Regulatory Flexibility Act not applying to this rule, the action only affects those entities who voluntarily participate in CSP and in doing so receive its benefits. Compliance with the provisions of CSP regulations is only required for those entities who choose to participate in this voluntary program.

Environmental Review

The environmental impacts of this rule have been considered in a manner consistent with the provisions of the National Environmental Policy Act (NEPA, 42 U.S.C. 4321–4347), the regulations of the Council on Environmental Quality (40 CFR parts 1500–1508), and the NRCS regulations for compliance with NEPA (7 CFR part 650). The 2018 Farm Bill requires minor changes to NRCS conservation programs, and there are no changes to the basic structure of the programs. NRCS conducted an analysis of the CSP interim rule and the analysis has determined there will not be a significant impact to the human environment and as a result, an environmental impact statement (EIS) is not required to be prepared (40 CFR 1508.13). While OMB has designated this rule as ''economically significant'' under Executive Order 12866, ''. . . economic or social effects are not intended by themselves to require preparation of an environmental impact statement'' (40 CFR 1508.14), when not interrelated to natural or physical environmental effects. The Environmental Assessment (EA) and Finding of No Significant Impact (FONSI) are available for review and comment for 30 days from the date of publication of this interim rule in the **Federal Register**. NRCS will consider this input and determine whether there is any new information provided that is relevant to environmental concerns and bearing on the proposed action or its impacts that warrant supplementing or revising the current available draft of the CSP EA and FONSI.

Executive Order 12372

Executive Order 12372, ''Intergovernmental Review of Federal Programs,'' requires consultation with State and local officials that would be directly affected by proposed Federal financial assistance. The objectives of the Executive order are to foster an intergovernmental partnership and a strengthened federalism, by relying on State and local processes for State and local government coordination and review of proposed Federal financial assistance and direct Federal development. For reasons specified in the final rule related notice regarding 7 CFR part 3015, subpart V (48 FR 29115, June 24, 1983), the programs and activities in this rule are excluded from the scope of Executive Order 12372.

Executive Order 12988

This rule has been reviewed under Executive Order 12988, ''Civil Justice Reform.'' This rule will not preempt State or local laws, regulations, or policies unless they represent an irreconcilable conflict with this rule.

[1] This includes funding for renewing contracts for an additional five years.

Before any judicial actions may be brought regarding the provisions of this rule, the administrative appeal provisions of 7 CFR part 11 are to be exhausted.

Executive Order 13132

This rule has been reviewed under Executive Order 13132, ''Federalism.'' The policies contained in this rule do not have any substantial direct effect on States, on the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government, except as required by law. Nor does this rule impose substantial direct compliance costs on State and local governments. Therefore, consultation with the States is not required.

Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, ''Consultation and Coordination with Indian Tribal Governments.'' Executive Order 13175 requires Federal agencies to consult and coordinate with Tribes on a Government-to-Government basis on policies that have Tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects 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.

The USDA's Office of Tribal Relations (OTR) has assessed the impact of this rule on Indian Tribes and determined that this rule does not have Tribal implication that requires Tribal consultation under Executive Order 13175. If a Tribe requests consultation, NRCS and CCC will work with OTR to ensure meaningful consultation is provided where changes, additions, and modifications identified in this rule are not expressly mandated by the 2018 Farm Bill.

Separate from Tribal consultation, communication and outreach efforts are in place to assure that all producers, including Tribes (or their members), are provided information about the regulation changes. Specifically, NRCS obtains input through Tribal Conservation Advisory Councils. A Tribal Conservation Advisory Council may be an existing Tribal committee or department and may also constitute an association of member Tribes organized to provide direct consultation to NRCS at the State, regional, and national levels to provide input on NRCS rules, policies, programs, and impacts on Tribes. Tribal Conservation Advisory Councils provide a venue for agency leaders to gather input on Tribal interests. Additionally, NRCS will be holding several sessions with Indian Tribes and Tribal entities across the country to describe the 2018 Farm Bill changes to NRCS conservation programs, obtain input about how to improve Tribal and Tribal member access to NRCS conservation assistance, and make any appropriate adjustments to the regulations that will foster such improved access.

Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4), requires Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal governments or the private sector. Agencies generally must prepare a written statement, including cost-benefits analysis, for proposed and final rules with Federal mandates that may result in expenditures of $100 million or more in any 1 year for State, local, or Tribal governments, in the aggregate, or to the private sector. UMRA generally requires agencies to consider alternatives and adopt the more cost-effective or least burdensome alternative that achieves the objectives of the rule. This rule contains no Federal mandates, as defined under title II of UMRA, for State, local, and Tribal governments or the private sector. Therefore, this rule is not subject to the requirements of UMRA.

Federal Assistance Programs

The title and number of the Federal Domestic Assistance Programs in the Catalog of Federal Domestic Assistance to which this rule applies is 10.924—Conservation Stewardship Program.

E-Government Act Compliance

NRCS and CCC are committed to complying with the E-Government Act, to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to government information and services, and for other purposes.

List of Subjects in 7 CFR Part 1470

Agricultural operation, Conservation activities, Natural resources, Priority resource concern, Resource-conserving crop rotation, Soil and water conservation, Soil quality, Stewardship threshold, Water quality and water conservation, Wildlife and forest management.

■ For the reasons stated in the preamble, part 1470 of title 7 of the Code of Federal Regulations is revised to read as follows:

PART 1470—CONSERVATION STEWARDSHIP PROGRAM

Subpart A—General Provisions

Sec.
1470.1 Applicability.
1470.2 Administration.
1470.3 Definitions.
1470.4 Allocation and management.
1470.5 Outreach activities.
1470.6 Eligibility requirements.
1470.7 Conservation activities.
1470.8 Technical and other assistance.

Subpart B—Contracts and Payments

1470.20 Application for contracts and selecting offers from applicants.
1470.21 Contract requirements.
1470.22 Conservation stewardship plan.
1470.23 Conservation activity operation and maintenance.
1470.24 Payments.
1470.25 Contract modifications and transfers of land.
1470.26 Contract renewal.
1470.27 Contract violations and termination.
1470.28 Grassland conservation initiative contracts.

Subpart C—General Administration

1470.30 Fair treatment of tenants and sharecroppers.
1470.31 Appeals.
1470.32 Compliance with regulatory measures.
1470.33 Access to agricultural operation.
1470.34 Equitable relief.
1470.35 Offsets and assignments.
1470.36 Misrepresentation and scheme or device.
1470.37 Environmental credits for conservation improvements.

Authority: 16 U.S.C. 3839aa–21–3839aa–25.

Subpart A—General Provisions

§ 1470.1 Applicability.

(a) This part sets forth the policies, procedures, and requirements for the Conservation Stewardship Program (CSP) as administered by the Natural Resources Conservation Service (NRCS), for enrollment during fiscal year (FY) 2019 and thereafter. Contracts entered into prior to FY 2019 will use the regulations and policies in effect prior to December 20, 2018.

(b) The purpose of CSP is to encourage producers to address priority resource concerns and improve and conserve the quality and condition of natural resources in a comprehensive manner by—

(1) Undertaking additional conservation activities; and

(2) Improving, maintaining, and managing existing conservation activities.

(c) CSP is applicable in any of the 50 States, District of Columbia, Commonwealth of Puerto Rico, Guam, Virgin Islands of the United States, American Samoa, and Commonwealth of the Northern Mariana Islands.

(d) NRCS provides financial and technical assistance to eligible producers.

§ 1470.2 Administration.

(a) The regulations in this part will be administered under the general supervision and direction of the Chief, NRCS.

(b) No delegation in the administration of this part to lower organizational levels will preclude the Chief from making any determinations under this part, redelegating to other organizational levels, or from reversing or modifying any determination made under this part. The Chief may modify or waive a nonstatutory, discretionary provision of this part if the Chief determines the application of that provision to a particular limited situation is inappropriate and inconsistent with the purposes of the program.

(c) To achieve the conservation goals of CSP, NRCS will—

(1) Make the program available nationwide to eligible applicants on a continuous application basis with one or more ranking periods to determine enrollments. One of the ranking periods will occur in the first quarter of each fiscal year to the extent practicable.

(2) Establish a science-based stewardship threshold for each priority resource concern at the level of management required to conserve and improve the quality and condition of a natural resource. To the extent practicable, NRCS will use scientifically developed assessment tools and guides including, but not limited to, soil erosion prediction tools, wildlife habitat assessment tools, rangeland health assessments, and soil health assessments, to establish the stewardship threshold and measure the level of improvement once the participant applies additional conservation activities to meet or exceed a resource concern.

(d) NRCS will develop State-level technical, outreach, and program materials, with the advice of the State technical committee and local working groups, including:

(1) Establishment of ranking pools appropriate for the conduct of CSP within the State to ensure program availability and better distribution of the funds. Ranking pools may be based on watersheds, geographic areas, or other appropriate regions within a State and may consider high-priority regional and State-level priority resource concern areas;

(2) Identification of not less than five priority resource concerns in particular geographic areas or other appropriate regions within a State;

(3) Identification of resource-conserving crops that will be part of resource-conserving crop rotations; and

(4) Identification of combinations of grazing conservation activities that will be part of an advanced grazing management system.

(e) NRCS may enter into agreements with Federal, State, and local agencies, conservation districts, Indian Tribes, private entities, and individuals to assist NRCS with program implementation including, but not limited to, planning activities, outreach, and providing other forms of technical assistance.

§ 1470.3 Definitions.

The following definitions will apply to this part and all documents issued in accordance with this part, unless specified otherwise:

Advanced grazing management means the use of a combination of grazing conservation activities, as determined by NRCS, which may include management-intensive rotational grazing, that provide for—

(1) Improved soil health and carbon sequestration;

(2) Drought resilience;

(3) Wildlife habitat;

(4) Wildfire mitigation;

(5) Control of invasive plants; and

(6) Water quality improvement.

Agricultural operation means all eligible land, as determined by NRCS, whether contiguous or noncontiguous that is—

(1) Under the effective control of a producer at the time of enrollment in the program; and

(2) Operated by the producer with equipment, labor, management, and production or cultivation practices that are substantially separate from other agricultural operations.

Applicant means a producer who has requested in writing to participate in CSP.

Beginning farmer or rancher means a person or legal entity who—

(1) Has not operated a farm, ranch, or nonindustrial private forest land (NIPF); or who has operated a farm, ranch, or NIPF for not more than 10 consecutive years. The requirement in this paragraph (1) applies to all members of a legal entity who will materially and substantially participate in the operation of the farm or ranch.

(2) In the case of a contract with an individual, individually, or with the immediate family, material and substantial participation requires that the individual provide substantial day-to-day labor and management of the farm or ranch, consistent with the practices in the county or State where the farm is located.

(3) In the case of a contract with a legal entity or joint operation, all members must materially and substantially participate in the operation of the farm or ranch. Material and substantial participation requires that each of the members provide some amount of the management or labor and management necessary for day-to-day activities, such that if each of the members did not provide these inputs, operation of the farm or ranch would be seriously impaired.

Chief means the Chief of NRCS, United States Department of Agriculture (USDA), or designee.

Comprehensive conservation plan means a conservation plan that meets or exceeds the stewardship threshold for each priority resource concern identified by NRCS across all land uses included in the operation.

Conservation activities mean conservation systems, practices, enhancements, or management measures, as determined by NRCS, and may include—

(1) Structural measures, vegetative measures, and land management measures, including agricultural drainage management systems as determined by NRCS;

(2) Planning needed to address a priority resource concern;

(3) Development of a comprehensive conservation plan;

(4) Soil health planning, including planning to increase soil organic matter; and

(5) Activities that will assist a producer to adapt to, or mitigate against, increasing weather volatility.

Conservation district means any district or unit of State, Tribal, or local government formed under State, Tribal, or territorial law for the express purpose of developing and carrying out a local soil and water conservation program. Such district or unit of government may be referred to as a ''conservation district,'' ''soil conservation district,'' ''soil and water conservation district,'' ''resource conservation district,'' ''land conservation committee,'' ''natural resource district,'' or similar name.

Conservation practice means a specified treatment, such as a structural, vegetative, or management technique commonly used to meet a specific need in planning and carrying out

conservation programs for which standards and specifications have been developed. Conservation practices are in the Field Office Technical Guide (FOTG).

Conservation stewardship plan means a plan developed in accordance with the requirements of § 1470.22.

Conservation system means a combination of conservation practices, management measures, and enhancements used to address natural resource and environmental concerns in a comprehensive, holistic, and integrated manner.

Contract means a legal document that specifies the rights and obligations of any participant who has been accepted into the program. A CSP contract is a binding agreement under this part for the transfer of assistance from NRCS to the participant for installing, adopting, improving, managing, and maintaining conservation activities.

Effective control means possession of the land by ownership, written lease, or other legal agreement and authority to act as decision maker for the day-to-day management of the operation both at the time the applicant enters into a stewardship contract and for the duration of the contract.

Eligible land means:

(1) Private and Tribal land upon which:

(i) Agricultural commodities, livestock, or forest-related products are produced; and

(ii) Priority resource concerns could be addressed through a contract under the program. Eligible land includes cropland, grassland, rangeland, pastureland, nonindustrial private forest land, and other agricultural lands including cropped woodland, marshes, and agricultural land used or capable of being used for the production of livestock as determined by the Chief; and

(2) Publicly owned land where the—

(i) Land is associated with the land described in paragraph (1) of this definition and is a working component of the producer's agricultural or forestry operation;

(ii) Producer has control of the land for the term of the contract; and

(iii) Conservation activities the producer will implement on the public land are necessary and will address an identified priority resource concern.

Enhancement means a type of conservation activity used to treat natural resources and improve conservation performance. Enhancements are equal to or greater than the performance level for the planning criteria identified for a given resource concern. Planning criteria are defined for each resource concern in Section III—Conservation Management Systems, Field Office Technical Guide.

Field Office Technical Guide (FOTG) means the official local NRCS source of resource information and interpretations of guidelines, planning criteria, and standards for planning and implementation of conservation practices. The FOTG contains detailed information on the planning standard to achieve conservation of soil, water, air, plant, energy, and animal resources applicable to the local area for which it is prepared. (See *https://www.nrcs.usda.gov/wps/portal/nrcs/main/national/technical/fotg/* to access your State FOTG.)

Historically underserved producer means a person, joint operation, legal entity, or Indian Tribe who is a beginning farmer or rancher, socially disadvantaged farmer or rancher, limited resource farmer or rancher, or veteran farmer or rancher.

Indian lands mean land held in trust by the United States for individual Indians or Indian Tribes, or all land titles held by individual Indians or Tribes, subject to Federal restrictions against alienation or encumbrance, or land which is subject to the rights of use, occupancy, and/or benefit of certain Indian Tribes. This term also includes lands for which the title is held in fee status by an Indian, Indian family, or Indian Tribe.

Indian Tribe means any Indian Tribe, band, nation, pueblo, or other organized group or community, including any Alaska Native village or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (43 U.S.C. 1601 *et seq.*), which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians.

Joint operation means, as defined in 7 CFR part 1400, a general partnership, joint venture, or other similar business organization in which the members are jointly and severally liable for the obligations of the organization.

Legal entity means, as defined in 7 CFR part 1400, an entity created under Federal or State law that owns land or an agricultural commodity, product, or livestock; or produces an agricultural commodity, product, or livestock.

Limited resource farmer or rancher means:

(1) A person with direct or indirect gross farm sales not more than the current indexed value in each of the previous 2 fiscal years (adjusted for inflation using Prices Paid by Farmer Index as compiled by the National Agricultural Statistical Service); and

(2) Has a total household income at or below the national poverty level for a family of four, or less than 50 percent of county median household income in each of the previous 2 years (to be determined annually using Department of Commerce Data).

(3) A limited resource farmer or rancher also includes a legal entity or joint operation if all individual members independently qualify under paragraphs (1) and (2) of this definition.

Liquidated damages means a sum of money stipulated in the CSP contract that the participant agrees to pay NRCS if the participant fails to fulfill the terms of the contract. The sum represents an estimate of the technical assistance expenses incurred to service the contract and reflects the difficulties of proof of loss and the inconvenience or nonfeasibility of otherwise obtaining an adequate remedy.

Management-intensive rotational grazing means a strategic, adaptively managed multipasture grazing system in which animals are regularly and systematically moved to a fresh pasture in a manner that, as determined by NRCS:

(1) Maximizes the quantity and quality of forage growth;

(2) Improves manure distribution and nutrient cycling;

(3) Increases carbon sequestration from greater forage harvest;

(4) Improves the quality and quantity of cover for wildlife;

(5) Provides permanent cover to protect the soil from erosion; and

(6) Improves water quality.

Management measure means one or more specific actions that is not a conservation practice, but which has the effect of alleviating problems or improving the treatment of the natural resources.

National Organic Program means the program established under the Organic Foods Production Act of 1990 (7 U.S.C. 6501 *et seq.*), administered by the Agricultural Marketing Service, which regulates the standards for any farm, wild crop harvesting, or handling operation that wants to market an agricultural product as organically produced.

Natural Resources Conservation Service means an agency of USDA which has responsibility for administering CSP using the funds, facilities, and authorities of the Commodity Credit Corporation.

Nonindustrial private forest land means rural land, as determined by NRCS, that has existing tree cover or is suitable for growing trees, and is owned

by any nonindustrial private individual, group, association, corporation, Indian Tribe, or other private legal entity that has definitive decision-making authority over the land.

Operation and maintenance means work performed by the participant to maintain existing conservation activities to at least the level of conservation performance identified at the time of enrollment, and maintain additional conservation activities installed and adopted over the contract period. Operation includes the administration, management, and performance of nonmaintenance actions needed to keep the completed activity functioning as intended. Maintenance includes work to prevent deterioration of the activity, repairing damage, and replacement or restoration of the activity to its original condition if one or more components fail.

Participant means a producer that has applied for participation and has entered into a CSP contract and is receiving payment or is responsible for implementing the terms and conditions of a CSP contract.

Payment means financial assistance provided to the participant under the terms of the CSP contract.

Person means, as defined in 7 CFR part 1400, an individual, natural person and does not include a legal entity.

Priority resource concern means a natural resource concern or problem, as determined by NRCS, that is likely to be addressed successfully through implementation of conservation activities under this program.

Producer means a person, legal entity, joint operation, or Indian Tribe who either has an interest in the agricultural operation or who NRCS determines is engaged in agricultural production or forestry management on the agricultural operation.

Resource-conserving crop means a crop that is one of the following, as determined by NRCS:

(1) A perennial grass;

(2) A legume grown for use as forage, seed for planting, or green manure;

(3) A legume-grass mixture; or

(4) A small grain or other resource-demanding crop grown in combination with a grass, legume, forbs, grass-forbs mixture, whether interseeded or planted in rotation.

Resource-conserving crop rotation means a crop rotation that—

(1) Includes at least one resource-conserving crop as determined by NRCS;

(2) Reduces erosion;

(3) Improves soil fertility and tilth;

(4) Interrupts pest cycles;

(5) Builds soil organic matter; and

(6) In applicable areas, reduces depletion of soil moisture or otherwise reduces the need for irrigation.

Secretary means the Secretary of the USDA.

Socially disadvantaged farmer or rancher means a producer who is a member of a group whose members have been subjected to racial or ethnic prejudices without regard to its members' individual qualities.

State technical committee means a committee established by the NRCS in a State pursuant to 7 CFR part 610, subpart C.

Stewardship threshold means the level of management required, as determined by NRCS, to conserve and improve the quality and condition of a natural resource through the use of—

(1) Planning criteria under a resource management system;

(2) Predictive analytics tools or models developed or approved by NRCS;

(3) Data from past and current enrollment in the program; and

(4) Other methods that measure conservation and improvement in priority resource concerns, as determined by the Chief.

Technical assistance means technical expertise, information, and tools necessary for the conservation of natural resources on land active in agricultural, forestry, or related uses. The term includes the following:

(1) Technical services provided directly to farmers, ranchers, Indian Tribes, forest producers, and other eligible entities, such as conservation planning, technical consultation, and assistance with the design and implementation of conservation activities; and

(2) Technical infrastructure, including processes, tools, and agency functions needed to support delivery of technical services; such as technical standards, resource inventories, training, data, technology, monitoring, and effects analyses.

Technical service provider (TSP) means an individual, private-sector entity, Indian Tribe, or public agency certified pursuant to 7 CFR part 652 and placed on the approved list to provide technical services to participants; or selected by USDA to assist USDA in the implementation of conservation programs covered by this part through a procurement contract, contribution agreement, or cooperative agreement with USDA.

Veteran farmer or rancher means a producer who meets the definition in section 2501(a)(7) of the Food, Agriculture, Conservation, and Trade Act of 1990, as amended (7 U.S.C. 2279).

§ 1470.4 Allocation and management.

(a) The Chief will allocate funds to States, and may adjust the weighting of the following allocation factors to provide for equitable geographic distribution and meet enrollment goals, based on the consideration of—

(1) Each State's proportion of eligible land to the total acreage of eligible land in all States;

(2) The extent and magnitude of the conservation needs associated with agricultural production in each State;

(3) The degree to which implementation of the program in the State is, or will be, effective in helping producers address those needs; and

(4) Other considerations determined by the Chief to achieve equitable geographic distribution of program funds.

(b) The Chief will allocate funding to the States to support organic production and transition to organic production based on—

(1) The number of certified and transitioning organic operations within the State; and

(2) The number of acres of certified and transitioning organic production within the State.

(c) Of the funds made available for each of fiscal years 2019 through 2023 to carry out CSP, NRCS will use, as a minimum:

(1) Five percent to assist beginning farmers or ranchers; and

(2) Five percent to assist socially disadvantaged farmers or ranchers.

(d) NRCS may adjust State allocations or reallocate funds in any fiscal year if a State cannot use their full allocation.

§ 1470.5 Outreach activities.

(a) NRCS will establish program outreach activities at the national, State, and local levels to inform potential applicants who control eligible land that they may be eligible to apply for program assistance.

(b) NRCS will specifically conduct outreach to historically underserved producers.

(c) NRCS will provide outreach so as not to limit producer participation because of size or type of operation or production system, including specialty crop and organic production.

§ 1470.6 Eligibility requirements.

(a) *Eligible applicant.* To apply for CSP, a producer must—

(1) Be the operator, owner, or other tenant of an agricultural operation in the Farm Service Agency (FSA) farm records management system. Applicants

must establish or update records with FSA before NRCS will consider an applicant as eligible;

(2) Share in the risk of producing a crop; share in the crop available for marketing from the farm (or would have shared had the crop been produced); and participate in the daily management, administration, and performance of the operation for the land included in the contract;

(3) Have effective control of the land unless an exception is made by the Chief in the case of land administered by the Bureau of Indian Affairs, Indian lands, or other instances in which NRCS determines that there is sufficient assurance of control;

(4) Be in compliance with the highly erodible land and wetland conservation provisions found at 7 CFR part 12;

(5) Be in compliance with adjusted gross income provisions found at 7 CFR part 1400;

(6) Supply information, as required by NRCS, to determine eligibility for the program, including but not limited to, information related to eligibility requirements and ranking factors; conservation activity and production system records; information to verify the applicant's status as an historically underserved producer, if applicable; and payment eligibility as established by 7 CFR part 1400; and

(7) Provide a list of all members of the legal entity or joint operation, as applicable, and embedded entities along with members' tax identification numbers and percentage interest in the legal entity or joint operation. Where applicable, American Indians, Alaska Natives, and Pacific Islanders may use another unique identification number for each individual eligible for payments.

(b) *Eligible land.* A contract application must include all of the eligible land on an applicant's agricultural operation. A participant may submit an application(s) to enter into an additional contract(s) for newly acquired or newly eligible land, which would then compete with other applications in a subsequent ranking period.

(c) *Ineligible land.* The following lands (even if covered by the definition of eligible land in § 1470.3) are part of the agricultural operation, but are not eligible for enrollment in CSP:

(1) Land enrolled in the Conservation Reserve Program (CRP), 7 CFR part 1410, unless—

(i) The conservation reserve contract will expire at the end of the fiscal year in which the land is to be enrolled in the program; and

(ii) Conservation reserve program payments for land enrolled in the program cease before the first program payment is made to the applicant under this subchapter;

(2) Land enrolled in a wetland reserve easement through the Agricultural Conservation Easement Program, 7 CFR part 1468; and

(3) Land used for crop production after December 20, 2018, that had not been planted, considered to be planted, or devoted to crop production for at least 4 of the 6 years preceding that date, unless the land does not meet such requirements because that land—

(i) Had previously been enrolled in CRP;

(ii) Has been maintained using long-term crop rotation practices as determined by the NRCS; or

(iii) Is incidental land needed for efficient operation of the farm or ranch as determined by NRCS.

§ 1470.7 Conservation activities.

(a) NRCS will record in the conservation stewardship plan the additional conservation activities the participant agrees to implement under the conservation stewardship contract.

(b) NRCS will make available to the public the list of conservation activities an applicant may choose to implement and manage through the CSP.

(c) NRCS may make available bundles of conservation activities that when implemented together address resource concerns in a more comprehensive and cost-effective manner.

§ 1470.8 Technical and other assistance.

(a) NRCS may provide technical assistance to an eligible applicant or participant either directly or through a TSP as set forth in 7 CFR part 652.

(b) NRCS retains approval authority over certification of work done by non-NRCS personnel for the purpose of approving CSP payments.

(c) NRCS will ensure that technical assistance is available and program specifications are appropriate so as not to limit producer participation because of size or type of operation or production system, including specialty crop and organic production.

(d) NRCS will assist potential applicants dealing with the requirements of certification under the National Organic Program and CSP requirements concerning how to coordinate and simultaneously meet eligibility standards under each program.

(e) NRCS may utilize the services of State foresters and existing technical assistance programs such as the Forest Stewardship Program of the U.S. Forest Service, in coordinating assistance to NIPF owners.

Subpart B—Contracts and Payments

§ 1470.20 Application for contracts and selecting offers from applicants.

(a) *Submission of contract applications.* Applicants may submit an application for CSP at any time to enroll all of the eligible land included in their agricultural operation.

(b) *Stewardship threshold requirement.* To be eligible to participate in CSP, an applicant must submit to NRCS for approval, a contract offer for the agricultural operation that—

(1) Demonstrates that the applicant's conservation activities, at the time of contract offer, meet or exceed the stewardship threshold for at least two priority resource concerns; and

(2) Would, at a minimum, meet or exceed the stewardship threshold for at least one additional priority resource concern by the end of the conservation stewardship contract by:

(i) Installing and adopting additional conservation activities; and

(ii) Improving, maintaining, and managing existing conservation activities across the entire agricultural operation in a manner that increases or extends the conservation benefits in place at the time the contract application is accepted by NRCS; and

(3) Provides a map, aerial photograph, or overlay that—

(i) Identifies the applicant's agricultural operation; and

(ii) Delineates eligible land with associated acreage amounts.

(c) *Evaluation of contract applications.* NRCS will conduct one or more ranking periods each fiscal year.

(1) To the extent practicable, one ranking period will occur in the last quarter of the previous fiscal year or the first quarter of the current fiscal year.

(2) In evaluating CSP applications for new enrollment or for renewal, NRCS will rank applications based on the following factors:

(i) The natural resource conservation and environmental benefits that result from the conservation treatment on all State identified priority resource concerns at the time of submission of the application;

(ii) The degree to which the proposed conservation activities increase natural resource conservation and environmental benefits; and

(iii) Other consistent criteria, as determined by NRCS, including criteria the Chief determines are necessary to ensure that national, State, and local priority resource concerns are effectively addressed.

(3) In the event that two or more applications receive the same ranking under paragraph (c)(2) of this section, NRCS shall rank those contracts based on the extent to which the actual and anticipated conservation benefits from each contract are provided at the lowest cost relative to other similarly beneficial contract offers.

(4) NRCS may not assign a higher priority to any application because the applicant is willing to accept a lower payment than the applicant would otherwise be eligible to receive.

(d) *Ranking pools.* States will establish ranking pools in accordance with § 1470.2(d)(1).

(1) Nonindustrial private forest land (NIPF) applications will compete in separate ranking pools. An applicant with both NIPF and other eligible land may submit one application for NIPF and one application for all other eligible land.

(2) Within each State or established ranking pool, NRCS will address conservation access for certain farmers or ranchers, including—

(i) Socially disadvantaged farmers or ranchers;

(ii) Beginning farmers or ranchers;

(iii) Producers who are veteran farmers or ranchers; and

(iv) Organic producers or producers who are transitioning to organic.

(e) *Application preapproval.* NRCS will make application preapproval determinations throughout the fiscal year based on eligibility and ranking score.

(f) *Field verification.* NRCS will conduct onsite field verification prior to entering into a conservation stewardship contract to substantiate the accuracy of the information provided by applicants during the application process and to verify applicability of planned conservation activities.

§ 1470.21 Contract requirements.

(a) After NRCS approves the application and develops the conservation stewardship plan in accordance with § 1470.22, NRCS will enter into a conservation stewardship contract with the participant to enroll the participant's agricultural operation in the program.

(b) The conservation stewardship contract will—

(1) Be for a period of 5 years;

(2) Incorporate by reference the conservation stewardship plan;

(3) State the payment amount NRCS agrees to make to the participant annually, subject to the availability of funds;

(4) Incorporate all provisions as required by law or statute, including requirements that the participant will—

(i) Implement the conservation stewardship plan as described in § 1470.22;

(ii) Operate and maintain conservation activities on the agricultural operation consistent with § 1470.23;

(iii) Comply with the terms of the contract or documents incorporated by reference into the contract;

(iv) Refund as determined by NRCS, any program payments received with interest, and forfeit any future payments under the program, upon the violation of a term or condition of the contract, consistent with § 1470.27;

(v) Refund as determined by NRCS, all program payments received with interest, upon the transfer of the right and interest of the participant, in land subject to the contract, unless the transferee of the right and interest agrees to assume all obligations of the contract, consistent with § 1470.25;

(vi) Maintain and supply information as requested by NRCS, to determine compliance with the conservation stewardship plan and any other requirements of the program; and

(vii) Not conduct any activities on the agricultural operation that would tend to defeat the purposes of the program, as determined by NRCS;

(5) Permit all economic uses of the eligible land that—

(i) Maintain the agricultural or forestry nature of the land; and

(ii) Are consistent with the conservation purposes of the contract;

(6) Include a provision to ensure that NRCS will not consider a participant in violation of the contract for failure to comply with the contract due to circumstances beyond the control of the participant, including a disaster or related condition, as determined by NRCS; and

(7) Include such other provisions as NRCS determines necessary to ensure the purposes of the program are achieved.

§ 1470.22 Conservation stewardship plan.

(a) NRCS will use the conservation planning process as outlined in the NRCS ''National Planning Procedures Handbook'' to encourage participants to address resource concerns in a comprehensive manner.

(b) The conservation stewardship plan will contain a record of the participant's objectives and decisions to meet or exceed stewardship thresholds for identified resource concerns through implementation or adoption of one or more conservation activities. The plan will document the schedule of conservation activities to be implemented, managed, or improved under the conservation stewardship contract.

(c) Supporting documentation for the participant's plan will include—

(1) Identification and inventory of priority resource concerns;

(2) Establishing benchmark data on the condition of existing conservation activities at the time of enrollment;

(3) A plan map delineating the agricultural operation included in the program contract with associated acreage amounts;

(4) For organic producers or producers transitioning to organic production, documentation that supports the participant's transition to or participation in the National Organic Program; and

(5) Other information as determined appropriate by NRCS.

§ 1470.23 Conservation activity operation and maintenance.

Throughout the conservation stewardship contract period, the participant will maintain and manage existing conservation activities across the entire agricultural operation to at least the benchmark level of conservation performance identified at the time of enrollment for the conservation stewardship contract period. The participant will also maintain and manage additional activities installed and adopted under the conservation stewardship contract.

§ 1470.24 Payments.

(a) *Annual payments.* Subject to the availability of funds, NRCS will provide, as appropriate, annual payments under the program to compensate a participant for installing and adopting additional conservation activities, and for improving, maintaining, and managing existing conservation activities across the entire agricultural operation in a manner that increases or extends the conservation benefits in place at the time NRCS accepts the contract offer. A split-rate annual payment structure is used to provide separate payments for additional and existing conservation activities in order to place emphasis on implementing additional conservation.

(1) NRCS will make equal annual payments for the existing activity portion of the payment, specific to the operation, based on the land uses and NRCS assessment of existing stewardship. NRCS will make payments for the additional conservation activities based on the complexity and extent of the individual activities completed by the participant during the previous fiscal year. Additional activities implemented may vary from year to

year, so the total annual payment may fluctuate;

(2) In order to receive an annual payment for a land use, participants must schedule, install, and adopt at least one additional conservation activity on the land use type;

(3) At least one additional conservation activity must be implemented on one land use type within the first 12 months of the contract. NRCS may extend this timeframe if NRCS determines that the participant is unable to complete the conservation activity for reasons beyond their control;

(4) NRCS will base the annual payment rates, to the maximum extent practicable, on the following factors:

(i) Costs incurred by the participant associated with planning, design, materials, installation, labor, management, maintenance, or training;

(ii) Income foregone by the participant;

(iii) Expected conservation benefits;

(iv) The extent to which priority resource concerns will be addressed through the installation and adoption of conservation activities on the agricultural operation;

(v) The level of stewardship in place at the time of application and maintained over the term of the contract;

(vi) The degree to which the conservation activities will be integrated across the entire agricultural operation for all State identified priority resource concerns over the term of the contract; and

(vii) Such other factors as determined by the Chief; and

(5) Participants will receive payments for cover crop activities at not less than 125 percent of the annual payment amount, as determined by NRCS.

(b) *Supplemental payments.* Subject to the availability of funds, NRCS will provide a supplemental payment to a participant receiving annual payments, who also agrees to adopt or improve a resource-conserving crop rotation or adopt advanced grazing management, as defined by NRCS, to achieve beneficial crop or grazing rotations as appropriate for the eligible land of the participant.

(1) NRCS will determine whether a resource-conserving crop rotation or advanced grazing management is eligible for supplemental payments based on whether the resource-conserving crop rotation or advanced grazing management is designed to provide natural resource conservation and production benefits;

(2) A participant must adopt or improve the resource-conserving crop rotation or adopt advanced grazing management during the term of the contract to be eligible to receive a supplemental payment;

(3) Supplemental payments will be based, to the maximum extent practicable, on the factors from paragraph (a)(4) of this section; and

(4) Supplemental payments will be not less than 150 percent of the annual payment amount, as determined by NRCS.

(c) *Comprehensive conservation plan.* Participants choosing to develop a comprehensive conservation plan through their conservation stewardship contract will receive a one-time payment for this activity. NRCS will determine the payment based on the number of priority resource concerns addressed in the comprehensive conservation plan and the number of types of land uses included in the plan. Participants will not be eligible to receive payment for plans developed prior to their enrollment in a conservation stewardship contract.

(d) *Minimum contract payment.* NRCS may make a minimum contract payment to a participant in any fiscal year in which the contract's payment amount total is less than a rate determined equitable by the Chief based upon the effort required by a participant to comply with the terms of the contract.

(e) *Timing of payments.* NRCS will make payments as soon as practicable after October 1 of each fiscal year for activities carried out in the previous fiscal year. For newly enrolled contracts, NRCS will make payments as soon as practicable after October 1 following the fiscal year of enrollment.

(f) *Noncompensatory matters.* NRCS will not provide a CSP payment to a participant for—

(1) New conservation activities applied with financial assistance through other USDA conservation programs;

(2) The design, construction, or maintenance of animal waste storage or treatment facilities, or associated waste transport or transfer devices for animal feeding operations;

(3) Conservation activities for which there is no cost incurred or income foregone by the participant; or

(4) Conservation activities initiated or implemented prior to contract approval, unless NRCS granted a waiver prior to the participant starting the activity.

(g) *Payment limits.* A person or legal entity may not receive, directly or indirectly, payments that, in the aggregate, exceed $200,000 under all CSP contracts entered into during fiscal years 2019 through 2023, excluding funding arrangements with Indian Tribes, regardless of the number of contracts entered into under the CSP by the person or legal entity.

(h) *Contract limits.* Each conservation stewardship contract will be limited to $200,000 over the term of the contract period, except that conservation stewardship contracts with any joint operation will be limited to $400,000 over the term of the contract period.

(i) *Scope of payment and contract limitations for Indian Tribes and individual Tribal members.* Contracts with Indian Tribes are not subject to payment or contract limitations but payment limitations in paragraph (f) of this section apply to individual Tribal member(s). Indian Tribes and the Bureau of Indian Affairs will certify in writing that no one individual, directly or indirectly, will receive more than the payment limitation. Certification provided at the time of enrollment will cover the entire contract period. The Tribal entity must also provide, upon request from NRCS, a listing of individuals and payment made, by Social Security number or other unique identification number, during the previous year for calculation of overall payment limitations.

(j) *Tax Identification Number.* To be eligible to receive a CSP payment, all applicants must provide a tax identification number. In accordance with 7 CFR part 1400, applicants who participate as a legal entity or joint operation must provide a list of all members of the legal entity or joint operation and associated embedded entities, along with the members' Social Security numbers and percentage interest in the legal entity or joint operation. NRCS attributes payments directly to legal entity members for the purpose of complying with paragraph (f) of this section.

(k) *Unique identification numbers.* American Indians, Alaska Natives, and Pacific Islanders may use another unique identification number for each individual eligible for payment. Any participant that uses a unique identification number as an alternative to a tax identification number will use that identifier for all CSP contracts in which they participate.

§ 1470.25 Contract modifications and transfers of land.

(a) NRCS may modify a conservation stewardship contract, if—

(1) The participant agrees to the modification; and

(2) NRCS determines the modification is in the public interest.

(b) NRCS may allow modification to a conservation stewardship contract to

accommodate certain changes in the agricultural operation, including—

(1) Removing contract acres the participant will enroll in CRP, protect with a wetland reserve easement through the Agricultural Conservation Easement Program (ACEP), or enroll in other Federal or State programs that offer greater natural resource protection through an easement, long-term contract, land use restrictions, or similar authority as determined by NRCS. NRCS may reduce payments for such modified contracts to reflect the modified acreage and performance. Participants will not be subject to liquidated damages or refund of payments received for enrolling land in these programs.

(2) Accommodating other limited changes, in response to a participant's request made prior to implementing the change, that would take land out of production or convert an area under contract to a different land use. These situations apply only to land for which the participant has and will retain effective control, and not for situations of involuntary loss of land.

(3) Allowing a participant to substitute a conservation activity as long as the level of conservation performance agreed to at the time of enrollment remains the same or is improved with implementation of the substitute activity.

(i) Adjustments to existing activities may occur consistent with conservation performance requirements from § 1470.23.

(ii) [Reserved]

(4) Prior to approval, NRCS must determine that any modification under this section is authorized by the provisions of 16 U.S.C. 3838d–3838g.

(c) A contract modification under this section will not increase the scheduled annual payments under the program, except to make minor adjustments to a conservation activity, as determined by NRCS; implement an appeal determination; correct an administrative error as approved by NRCS; or to adjust payment limitations. Contracts transferred from an individual or entity to a joint operation will retain the original contract limit outlined in § 1470.24(g).

(d) Within the time specified in the contract, a participant must provide NRCS with written notice regarding any voluntary or involuntary loss of control of any acreage under the CSP contract, which includes changes in a participant's ownership structure or corporate form. Failure to provide timely notice may result in termination of the entire contract.

(e) Unless NRCS approves a transfer of contract rights under this paragraph (e), a participant losing control of any acreage may constitute a violation of the CSP contract and NRCS may terminate the contract and require a participant to refund all or a portion of any financial assistance provided. NRCS may approve a transfer of the contract if—

(1) NRCS receives written notice that identifies the new producer who will take control of the acreage, as required in paragraph (d) of this section;

(2) The new producer meets program eligibility requirements within a reasonable time frame, as specified in the CSP contract;

(3) The new producer agrees to assume the rights and responsibilities for the acreage under the contract; and

(4) NRCS determines that the purposes of the program will continue to be met despite the original participant's losing control of all or a portion of the land under contract.

(f) Until NRCS approves the transfer of contract rights, the new producer is not a participant in the program and may not receive payment for conservation activities commenced prior to approval of the contract transfer.

(g) NRCS may not approve a contract transfer and may terminate the contract in its entirety if NRCS determines that the loss of control of the land was voluntary, the new producer is not eligible or willing to assume responsibilities under the contract, or the purposes of the program cannot be met.

(h) In the case of death, incompetency, or disappearance of any participant, NRCS may, as identified in the CSP contract—

(i) Terminate the contract;

(ii) Make any payments due under this part pursuant to guidance under applicable provisions of 7 CFR parts 707 and 1400 (including payment to successor(s)); or

(iii) Take any further action that the Chief determines is fair and reasonable in light of all of the circumstances.

§ 1470.26 Contract renewal.

(a) During the first half of the fifth year of the initial contract period, NRCS may allow a participant to apply and compete for the opportunity under § 1470.20 to renew the contract to receive payments for one additional 5-year period, subject to the availability of funds, if the participant meets criteria from paragraph (b) of this section.

(b) To be considered for contract renewal, the participant must—

(1) Be in compliance with the terms of their existing contract as determined by NRCS;

(2) Add any newly acquired eligible land that is part of the agricultural operation that NRCS determines must be included in the renewal contract;

(3) Agree to adopt and continue to integrate new or improved conservation activities across the entire agricultural operation, demonstrating continued improvement during the additional 5-year period, as determined by NRCS; and

(4) By the end of the renewal contract period, agree to meet or exceed the stewardship threshold of at least two additional priority resource concerns on the agricultural operation; or to adopt or improve conservation activities, as determined by NRCS, to achieve higher levels of conservation performance with respect to not less than two existing priority resource concerns that are specified by the Chief in the initial contract.

(c) Participants eligible for renewal who choose not to renew will be ineligible for a new contract on land previously enrolled under a conservation stewardship contract for 2 years following expiration of their initial contract.

§ 1470.27 Contract violations and termination.

(a) NRCS may terminate a contract:

(1) Without the consent of the participant where NRCS determines that the participant—

(i) Violated the contract; or

(ii) Is unable to comply with the terms of the contract as the result of conditions beyond their control.

(2) With the consent of the participant if NRCS determines that the termination is in the public interest. NRCS will not assess liquidated damages for contracts terminated under this basis.

(b) When NRCS terminates a contract in accordance with paragraph (a) of this section, NRCS may allow a participant to retain payments already received based on—

(1) The level of effort the participant has made to comply with the contract. NRCS may require a participant to provide only a partial refund of the payments received if a previously installed conservation activity has achieved the expected conservation performance improvement, is not adversely affected by any contract violation or the absence of other conservation activities that would have been installed under the contract, and has met the associated operation and maintenance requirement of the activity; or

(2) Hardship situations where circumstances beyond the participant's control prevented the participant from complying with the contract. Any hardship affecting the participant's

ability to comply with the contract must not have existed at the time the contract was executed by the participant. Participants may submit a written request to NRCS, along with additional supporting documentation, for NRCS to consider granting a waiver of any requested repayment and/or assessment of liquidated damages.

(c) If NRCS determines that a participant is out of compliance with the contract terms or incorporated documents, NRCS will notify the participant to explain what the participant must do to regain compliance and the consequences for not correcting the violation. NRCS will give the participant reasonable time to complete all necessary corrective actions, not to exceed one year. NRCS may authorize additional time for the participant to complete the corrective actions if, during the initial period, the participant was unable to complete the corrective actions due to circumstances beyond their control. If a participant's contract continues in violation, NRCS may:

(1) Terminate the contract in accordance with paragraph (e) of this section; or

(2) Where NRCS determines the violation does not warrant termination, NRCS may require the participant to:

(i) Refund all or a portion of the payments provided; or

(ii) Agree to such adjustments to the contact terms as determined appropriate by NRCS.

(d) Notwithstanding the provisions of paragraph (c) of this section, NRCS will terminate a contract, effective immediately, upon a determination by NRCS that the participant:

(1) Has submitted false information or filed a false claim;

(2) Engaged in any act, scheme, or device for which NRCS found the participant ineligible for payments as provided in § 1470.36; or

(3) Incurred a contract violation that the participant cannot correct in a timeframe established by NRCS.

(e) If NRCS terminates a contract, the participant will forfeit all rights to future payments under the contract, pay liquidated damages, and refund all or part of the payments received, plus interest, except as otherwise noted in paragraph (b) of this section.

§ 1470.28 Grassland conservation initiative contracts.

(a) The purpose of the grassland conservation initiative (GCI) is to assist producers in protecting grazing uses, conserving and improving soil, water, and wildlife resources, and achieving related conservation values by conserving eligible land through grassland conservation contracts.

(b) The GCI is applicable on eligible cropland for which base acres have been maintained by the FSA under section 1112(d)(3) of the Agricultural Act of 2014 (7 U.S.C. 9012(d)(3)).

(c) Producers with eligible land will have one-time election to enroll in the GCI during fiscal years 2019 through 2023. A producer may elect to enroll eligible acres in the GCI or under a general CSP contract. A producer with land eligible for the GCI may not have the same land enrolled under both a GCI and general CSP contract at the same time.

(d) Participants enrolled in the GCI must agree to meet or exceed the stewardship threshold for at least one priority resource concern before the end of the contract.

(e) A GCI plan shall:

(1) Encompass all enrolled land;

(2) Require adoption of conservation activities to address grassland resource concerns; and

(3) If crops are grown, require adoption of conservation activities that achieve conservation stewardship levels analogous to the land being planted or maintained in grass.

(f) The GCI contract will be for one 5-year term and will not be subject to renewal.

(g) GCI annual payments will be $18 per acre, not to exceed the acres enrolled in the GCI contract.

(1) GCI contracts are not subject to the payment limitations or contract limits provided in § 1470.24(f) and (g).

(2) GCI contracts are not eligible for supplemental payments as provided in § 1470.24(b).

(h) The participant may request to terminate their GCI contract at any time and retain payments already received under the contract.

Subpart C—General Administration

§ 1470.30 Fair treatment of tenants and sharecroppers.

Participants must divide payments received under this part in the manner specified in the applicable contract. NRCS will ensure that tenants and sharecroppers who have an interest in acreage being enrolled receive equitable treatment, as determined by NRCS. NRCS may refuse to enter into a contract when joint applicants seeking enrollment disagree on an applicant's eligibility to participate in the contract as a tenant.

§ 1470.31 Appeals.

A participant may obtain administrative review of an adverse decision under this part in accordance with 7 CFR parts 11 and 614. Determinations in matters of general applicability, such as payment rates, payment limits, the designation of identified priority resource concerns, and eligible conservation activities are not subject to appeal.

§ 1470.32 Compliance with regulatory measures.

Participants will be responsible for obtaining the authorities, rights, easements, permits, or other approvals or legal compliance necessary for the implementation, operation, and maintenance associated with the conservation stewardship plan. Participants will be responsible for compliance with all laws and for all effects or actions resulting from the implementation of the contract.

§ 1470.33 Access to agricultural operation.

NRCS, or its authorized representative, will have the right to enter an agricultural operation to ascertain the accuracy of any representations, including natural resource information provided by an applicant to evaluate a contract application. Access will include the right to provide technical assistance, determine eligibility, assess natural resource conditions, inspect any work undertaken under the contract, and collect information necessary to evaluate the implementation of conservation activities in the contract. NRCS, or its authorized representative, will try to contact the participant prior to the exercise of the provision in this section.

§ 1470.34 Equitable relief.

(a) If a participant relied upon the advice or action of NRCS and did not know, or have reason to know, that the action or advice was improper or erroneous, the participant may be eligible for equitable relief under 7 CFR part 635. NRCS will not assume the financial or technical liability for any action by a participant that was taken based on the advice of a TSP. This liability will remain with the TSP.

(b) If NRCS finds that a participant is in violation of a provision of the conservation stewardship contract or any incorporated document through failure to comply fully with that provision, the participant may be eligible for equitable relief under 7 CFR part 635.

§ 1470.35 Offsets and assignments.

(a) Any payment or portion thereof due to any participant under this part will be allowed without regard to any claim or lien in favor of any creditor,

except agencies of the United States Government. The regulations governing offsets and withholdings found at 7 CFR part 1403 will be applicable to contract payments.

(b) Any participant entitled to any payment may assign such payments in accordance with regulations governing assignment of payment found at 7 CFR part 1404.

§ 1470.36 Misrepresentation and scheme or device.

(a) If NRCS determines that an applicant intentionally misrepresented any fact affecting a CSP determination, the application will be determined ineligible immediately.

(b) A participant who is determined to have erroneously represented any fact affecting a program determination made in accordance with this part will not be entitled to contract payments and must refund to NRCS all payments, plus interest determined in accordance with 7 CFR part 1403.

(c) A participant will refund to NRCS all payments, plus interest determined in accordance with 7 CFR part 1403, received by such participant with respect to all CSP contracts if they are determined to have—

(1) Adopted any scheme or device that tends to defeat the purpose of the program;

(2) Made any fraudulent representation;

(3) Adopted any scheme or device for the purpose of depriving any tenant or sharecropper of the payments to which such person would otherwise be entitled under the program; or

(4) Misrepresented any fact affecting a program determination.

(d) Participants determined to have committed actions identified in paragraph (c) of this section will have their interest in all CSP contracts terminated.

§ 1470.37 Environmental credits for conservation improvements.

(a) NRCS will not prohibit a participant under this part from participating in, and receiving compensation from, an environmental services market if one of the purposes of the market is the facilitation of additional conservation benefits that are consistent with CSP purposes, as determined by NRCS. CSP participation may create environmental benefits that qualify for environmental credits under an environmental credit-trading program. NRCS will not prohibit a participant under this part from participating in, or receiving compensation from, an environmental credit-trading program, and NRCS asserts no direct or indirect interest in these credits. However, in addition, any requirements or standards of an environmental market program in which a CSP participant simultaneously enrolls to receive environmental credits must be compatible with the purposes and requirements of the CSP contract and with this part. NRCS retains the authority to ensure that CSP purposes are met and that one of the purposes of the market is the facilitation of additional conservation benefits that are consistent with CSP purposes.

(b) The participant must meet all operation and maintenance requirements for CSP-funded activities, consistent with §§ 1470.21 and 1470.23. Where activities required under an environmental credit agreement may affect the land and conservation activities under a CSP contract, NRCS recommends that CSP participants request assistance with the development of a compatibility assessment prior to entering into any credit agreement. The CSP contract may be modified in accordance with policies outlined in § 1470.25 provided the modifications meet CSP purposes and is in compliance with this part.

(c) CSP participants may not use CSP funds to implement conservation practices and activities that the participant is required to establish because of a court order.

Kevin Norton,

Associate Chief, Natural Resources Conservation Service.

Robert Stephenson,

Executive Vice President, Commodity Credit Corporation.

[FR Doc. 2019–24367 Filed 11–8–19; 8:45 am]

BILLING CODE 3410–16–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2019–0583; Product Identifier 2019–NM–063–AD; Amendment 39–19780; AD 2019–22–01]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain The Boeing Company Model 787–8 airplanes. This AD was prompted by a report of an escapement from the wing spar terminal fitting supplier indicating that the engineering requirements provided by Boeing for controlling machine mismatch were incorrect for part faying surfaces, which can result in a reduced fatigue capability at the interface of the side of body (SOB) rib. This AD requires repetitive inspections for fatigue cracking and applicable on-condition actions for the SOB rib webs where fastener locations attach the terminal fittings. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 17, 2019.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 17, 2019.

ADDRESSES: For service information identified in this final rule, 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 service information at the FAA, Transport Standards 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–2019–0583.

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–2019–0583; 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, the regulatory evaluation, 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: Allen Rauschendorfer, Aerospace Engineer, Airframe Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3528; email: *Allen.Rauschendorfer@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would

apply to certain The Boeing Company Model 787–8 airplanes. The NPRM published in the **Federal Register** on August 9, 2019 (84 FR 39239). The NPRM was prompted by a report of an escapement from the wing spar terminal fitting supplier indicating that the engineering requirements provided by Boeing for controlling machine mismatch were incorrect for part faying surfaces, which can result in a reduced fatigue capability at the interface of the SOB rib. The NPRM proposed to require repetitive inspections for fatigue cracking and applicable on-condition actions for the SOB rib webs where fastener locations attach the terminal fittings.

The FAA is issuing this AD to address fatigue cracks in the left and right SOB rib webs common to the front and rear wing spar terminal fittings. Undetected fatigue cracks can grow to weaken primary wing structure where it cannot sustain limit load, which could adversely affect the structural integrity of the airplane.

Comments

The FAA gave the public the opportunity to participate in developing this final rule. The FAA has considered the comment received. Boeing indicated its support for the NPRM.

Conclusion

The FAA reviewed the relevant data, considered the comment 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

The FAA reviewed Boeing Alert Requirements Bulletin B787–81205–SB570036–00 RB, Issue 001, dated December 14, 2018. The service information describes procedures for repetitive high frequency eddy current or ultrasonic inspections for fatigue cracking and applicable on-condition actions for the SOB rib webs where fastener locations attach the terminal fittings. On-condition actions include 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.

Costs of Compliance

The FAA estimates that this AD affects 1 airplane 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
Inspection	Up to 32 work-hours × $85 per hour = Up to $2,720 per inspection cycle.	$960	Up to $3,680 per inspection cycle.	Up to $3,680 per inspection cycle.

The FAA has received no definitive data that would enable the agency to provide cost estimates for the on-condition actions specified in this AD.

According to the manufacturer, some or all of the costs of this 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 our 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.

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

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 adding the following new airworthiness directive (AD):

2019–22–01 The Boeing Company: Amendment 39–19780; Docket No. FAA–2019–0583; Product Identifier 2019–NM–063–AD.

(a) Effective Date

This AD is effective December 17, 2019.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model 787–8 airplanes, certificated in any category, as identified in Boeing Alert Requirements Bulletin B787–81205–SB570036–00 RB, Issue 001, dated December 14, 2018.

(d) Subject

Air Transport Association (ATA) of America Code 57, Wings.

(e) Unsafe Condition

This AD was prompted by a report of an escapement from the wing spar terminal fitting supplier indicating that the engineering requirements provided by Boeing for controlling machine mismatch were incorrect for part faying surfaces, which can result in a reduced fatigue capability at the interface of the side of body (SOB) rib. The FAA is issuing this AD to address fatigue cracks in the left and right SOB rib webs common to the front and rear wing spar terminal fittings. Undetected fatigue cracks can grow to weaken primary wing structure where it cannot sustain limit load, which could adversely affect the structural integrity 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 B787–81205–SB570036–00 RB, Issue 001, dated December 14, 2018, do all applicable actions identified in, and in accordance with, the Accomplishment Instructions of Boeing Alert Requirements Bulletin B787–81205–SB570036–00 RB, Issue 001, dated December 14, 2018.

Note 1 to paragraph (g): Guidance for accomplishing the actions required by this AD can be found in Boeing Alert Service Bulletin B787–81205–SB570036–00, Issue 001, dated December 14, 2018, which is referred to in Boeing Alert Requirements Bulletin B787–81205–SB570036–00 RB, Issue 001, dated December 14, 2018.

(h) Exception to Service Information Specifications

Where Boeing Alert Requirements Bulletin B787–81205–SB570036–00 RB, Issue 001, dated December 14, 2018, specifies contacting Boeing for repair instructions: This AD requires doing the repair using a method approved in accordance with the procedures specified in paragraph (i) 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 local Flight Standards District 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) 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 local flight standards district office/certificate holding district 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

For more information about this AD, contact Allen Rauschendorfer, Aerospace Engineer, Airframe Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3528; email: *Allen.Rauschendorfer@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 the AD specifies otherwise.

(i) Boeing Alert Requirements Bulletin B787–81205–SB570036–00 RB, Issue 001, dated December 14, 2018.

(ii) [Reserved]

(3) 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.*

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

(5) 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 in Des Moines, Washington, on October 29, 2019.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–24501 Filed 11–8–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2019–0436; Product Identifier 2019–NM–014–AD; Amendment 39–19744; AD 2019–19–08]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc., Airplanes

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

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Bombardier, Inc., Model CL–600–2B19 (Regional Jet Series 100 & 440), CL–600–2C10 (Regional Jet Series 700, 701 & 702), CL–600–2D15 (Regional Jet Series 705), CL–600–2D24 (Regional Jet Series 900), and CL–600–2E25 (Regional Jet Series 1000) airplanes. This AD was prompted by reports of power control unit (PCU) rod end fractures due to pitting corrosion. This AD requires revising the existing maintenance or inspection program, as applicable, to incorporate new maintenance tasks. This AD also requires detailed inspections of the elevator PCU rod ends and applicable corrective actions. This AD also prohibits using certain aircraft maintenance manual tasks. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 17, 2019.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of December 17, 2019.

ADDRESSES: For service information identified in this final rule, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; Widebody Customer Response Center North America toll-free telephone 1–866–538–1247 or direct-dial telephone 1–514–855–2999; fax 514–855–7401; email *ac.yul@aero.bombardier.com;* internet *http://www.bombardier.com.* You may view this service information at the FAA, Transport Standards 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–2019–0436.

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–2019–0436; 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, the regulatory evaluation, 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: Darren Gassetto, Aerospace Engineer, Mechanical Systems and Admin Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7323; fax 516–794–5531; email *9-avs-nyaco-cos@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued Canadian AD CF–2018–29, dated November 2, 2018 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Bombardier, Inc., Model CL–600–2B19 (Regional Jet Series 100 & 440), CL–600–2C10 (Regional Jet Series 700, 701 & 702), CL–600–2D15 (Regional Jet Series 705), CL–600–2D24 (Regional Jet Series 900), and CL–600–2E25 (Regional Jet Series 1000) airplanes. You may examine the MCAI in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0436.

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Bombardier, Inc., Model CL–600–2B19 (Regional Jet Series 100 & 440), CL–600–2C10 (Regional Jet Series 700, 701 & 702), CL–600–2D15 (Regional Jet Series 705), CL–600–2D24 (Regional Jet Series 900), and CL–600–2E25 (Regional Jet Series 1000) airplanes. The NPRM published in the **Federal Register** on June 21, 2019 (84 FR 29108). The NPRM was prompted by reports of PCU rod end fractures due to pitting corrosion. The NPRM proposed to require revising the existing maintenance or inspection program, as applicable, to incorporate new maintenance tasks. The NPRM also proposed to require detailed inspections of the elevator PCU rod ends and applicable corrective actions, and prohibit using certain aircraft maintenance manual tasks.

The FAA is issuing this AD to address PCU rod end fractures due to pitting corrosion, which, if not detected and corrected, could lead to a disconnect between the PCU and the control surface, resulting in potential loss of the control surface function or inadequate flutter suppression. 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 comment received. The commenter, Patrick Imperatrice, stated that he supports the NPRM.

Conclusion

The FAA reviewed the relevant data, considered the comment 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

Bombardier has issued the following service information.

Bombardier Service Bulletin 670BA–27–074, dated June 22, 2017. This service information describes procedures for detailed inspections for pitting and corrosion of the left and right rod ends of the elevator PCUs and to make sure that the spherical ball and inner race of the rod ends move freely, and applicable corrective actions. Corrective actions include installing a new PCU.

The following tasks describe operational checks of the elevator and rudder control systems, and a detailed inspection of the rudder PCU rod end spherical ball.

- Task 27–20–00–13, Operational Check of the Rudder Control System of Section 3—Systems and Powerplant Program, of the Bombardier Model CL–600–2B19 Series 100/200/440 Maintenance Planning Manual, Low Utilization Maintenance Program (MRLUMP–001), CSP A–054–009, Revision 37, dated July 10, 2018 (''MRLUMP–001, Revision 37'').
- Task 27–23–01–01, Detailed Inspection of the Rudder PCU Rod End Spherical Ball, of MRLUMP–001, Revision 37.
- Task 27–31–00–05, Operational Check of the Elevator Control System, of MRLUMP–001, Revision 37.

The following tasks describe operational tests of the elevator and rudder control systems, and a detailed inspection of the rudder PCU rod end spherical ball.

- Task 27–20–00–13, Operational Test of the Rudder Control System, of Section 3—Systems and Powerplant Program, of the Bombardier Model CL–600–2B19 Series 100/200/440 Maintenance Planning Manual, Low Utilization Maintenance Program (MRLUMP–002), CSP A–054–060, Revision 37, dated July 10, 2018 (''MRLUMP–002, Revision 37'').
- Task 27–23–01–01, Detailed Inspection of the Rudder PCU Rod End Spherical Ball, of MRLUMP–002, Revision 37.
- Task 27–31–00–05, Operational Test of the Elevator Control System, of MRLUMP–002, Revision 37.

The following tasks describe operational tests of the elevator and rudder PCUs, and a detailed inspection of the elevator PCU rod end spherical ball.

- Task 27–20–00–106, Operational Test of the Rudder PCUs (Duplicate CMR 27–20–00–106), of Section 3—Systems/Power Plant Tasks, of the Bombardier Model CL–600–2C10, CL–600–2D15, CL–600–2D24, Series 700/705/900 Maintenance Planning Manual, Low Utilization Maintenance Program (LUMP), CSP BC–116, Revision 15, dated May 25, 2017 (''LUMP, Revision 15'').
- Task 273000–207, Operational Test of the Elevator Power-Control Units (PCUs), of LUMP, Revision 15.
- Task 273000–215, Detailed Inspection of the Elevator PCU Rod End Spherical Ball, of LUMP, Revision 15.

The following task describes an operational check of each elevator PCU.

- Task 273000–207, Operational Check of each Elevator PCU, of Subject 1–27, of Section 1, Systems and Powerplant Program, Volume 1 of Part 1, Maintenance Review Board Report, Revision 18, dated July 25, 2018, of the Bombardier Model CL–600–2C10, CL–600–2D15, CL–600–2D24, and CL–600–2E25 Series 700/705/900/1000 Maintenance Requirements Manual, CSP B–053.

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.

Costs of Compliance

The FAA estimates that this AD affects 1,008 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS *

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
9 work-hours × $85 per hour = $765	$0	$765	$771,120

* Table does not include estimated costs for revising the maintenance or inspection program.

The FAA has determined that revising the existing maintenance or inspection program takes an average of 90 work-hours per operator, although the FAA recognizes that this number may vary from operator to operator. In the past, the FAA has estimated that this action takes 1 work-hour per airplane. Since operators incorporate maintenance or inspection program changes for their affected fleet(s), the FAA has determined that a per-operator estimate is more accurate than a per-airplane estimate. Therefore, the FAA estimates the total cost per operator to be $7,650 (90 work-hours × $85 per work-hour).

The FAA has received no definitive data that would enable the agency to provide cost estimates for the on-condition actions specified in this AD.

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.

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

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 adding the following new airworthiness directive (AD):

2019–19–08 Bombardier, Inc.: Amendment 39–19744; Docket No. FAA–2019–0436; Product Identifier 2019–NM–014–AD.

(a) Effective Date

This AD is effective December 17, 2019.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Bombardier, Inc., airplanes, certificated in any category, as identified in paragraphs (c)(1) through (4) of this AD.

(1) Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes, serial numbers 7003 and subsequent.

(2) Model CL–600–2C10 (Regional Jet Series 700, 701 & 702) airplanes, serial numbers 10002 through 10999 inclusive.

(3) Model CL–600–2D15 (Regional Jet Series 705) and CL–600–2D24 (Regional Jet Series 900) airplanes, serial numbers 15001 through 15990 inclusive.

(4) Model CL–600–2E25 (Regional Jet Series 1000) airplanes, serial numbers 19001 through 19990 inclusive.

(d) Subject

Air Transport Association (ATA) of America Code 27, Flight controls.

(e) Reason

This AD was prompted by reports of power control unit (PCU) rod end fractures due to pitting corrosion. The FAA is issuing this AD to address this condition, which, if not detected and corrected, could lead to a disconnect between the PCU and the control surface, resulting in potential loss of the control surface function or inadequate flutter suppression.

(f) Compliance

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

(g) Maintenance or Inspection Program Revision for Certain Airplanes Operating Under the Low Utilization Maintenance Program (LUMP)

(1) For Model CL–600–2B19 airplanes operating under the LUMP: Within 90 days after the effective date of this AD, revise the existing maintenance or inspection program, as applicable, to incorporate the information specified in paragraphs (g)(1)(i) through (vi) of this AD. The initial compliance time for accomplishing the actions is within 90 days after the effective date of this AD; or within the applicable interval specified in Section 3—Systems and Powerplant Program, of the Bombardier Model CL–600–2B19 Series 100/200/440 Maintenance Planning Manual, Low Utilization Maintenance Program (MRLUMP–001), CSP A–054–009, Revision 37, dated July 10, 2018 (''MRLUMP–001, Revision 37''); or Section 3—Systems and Powerplant Program, of the Bombardier Model CL–600–2B19 Series 100/200/440 Maintenance

Planning Manual, Low Utilization Maintenance Program (MRLUMP–002), CSP A–054–060, Revision 37, dated July 10, 2018 (''MRLUMP–002, Revision 37''), after the effective date of this AD; whichever occurs later.

(i) Task 27–20–00–13, Operational Check of the Rudder Control System, of MRLUMP–001, Revision 37.

(ii) Task 27–23–01–01, Detailed Inspection of the Rudder PCU Rod End Spherical Ball, of MRLUMP–001, Revision 37.

(iii) Task 27–31–00–05, Operational Check of the Elevator Control System, of MRLUMP–001, Revision 37.

(iv) Task 27–20–00–13, Operational Test of the Rudder Control System, of MRLUMP–002, Revision 37.

(v) Task 27–23–01–01, Detailed Inspection of the Rudder PCU Rod End Spherical Ball, of MRLUMP–002, Revision 37.

(vi) Task 27–31–00–05, Operational Test of the Elevator Control System, of MRLUMP–002, Revision 37.

(2) For Model CL–600–2C10 airplanes having serial numbers 10004, 10040, 10043, 10052, 10100, 10164, 10183, 10187, 10204, 10206, 10217, 10247, 10289, 10332, and 10343 operating under the LUMP; and Model CL–600–2D15 and CL–600–2D24 airplanes having serial numbers 15158, 15278, and 15370 operating under the LUMP: Within 30 days after the effective date of this AD, revise the existing maintenance or inspection program, as applicable, to incorporate the information specified in paragraphs (g)(2)(i) through (iii) of this AD. The initial compliance time for accomplishing the actions is within 30 days after the effective date of this AD; or within the applicable interval specified in Section 3—Systems/Power Plant Tasks, of the Bombardier Model CL–600–2C10, CL–600–2D15, CL–600–2D24, Series 700/705/900 Maintenance Planning Manual, Low Utilization Maintenance Program (LUMP), CSP BC–116, Revision 15, dated May 25, 2017 (''LUMP, Revision 15''), after the effective date of this AD; whichever occurs later.

(i) Task 27–20–00–106, Operational Test of the Rudder PCUs (Duplicate CMR 27–20–00–106), of LUMP, Revision 15.

(ii) Task 273000–207, Operational Test of the Elevator Power-Control Units (PCUs), of LUMP, Revision 15.

(iii) Task 273000–215, Detailed Inspection of the Elevator PCU Rod End Spherical Ball, of LUMP, Revision 15.

(h) Maintenance or Inspection Program Revision for Certain Airplanes That Are Not Operating Under the LUMP

For Model CL–600–2C10, CL–600–2D15, CL–600–2D24, and CL–600–2E25 airplanes that are not operating under the LUMP: Within 30 days after the effective date of this AD, revise the existing maintenance or inspection program, as applicable, to incorporate the information specified in task 273000–207, Operational Check of each Elevator PCU, of Subject 1–27, of Section 1, Systems and Powerplant Program, Volume 1 of Part 1, Maintenance Review Board Report, Revision 18, dated July 25, 2018, of the Bombardier Model CL–600–2C10, CL–600–2D15, CL–600–2D24, and CL–600–2E25 Series 700/705/900/1000 Maintenance Requirements Manual, CSP B–053, (''CSP B–053, Revision 18''). The initial compliance time for accomplishing the actions is within 30 days after the effective date of this AD; or within the applicable interval specified in CSP B–053, Revision 18, after the effective date of this AD; whichever occurs later.

(i) No Alternative Actions or Intervals

After the existing maintenance or inspection program has been revised as required by paragraph (g) or (h) of this AD, no alternative actions (*e.g.,* inspections) or intervals may be used unless the actions and intervals are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (n)(1) of this AD.

(j) First Inspection of the Elevator PCU Rod End for Certain Airplanes

For Model CL–600–2C10, CL–600–2D15, CL–600–2D24, and CL–600–2E25 airplanes that are not operating under the LUMP, and that have accumulated less than 6,000 total flight hours as of the effective date of this AD: Within the compliance time specified in figure 1 to paragraph (j) of this AD, perform a detailed inspection for pitting and corrosion of the left and right rod ends of the elevator PCUs and to make sure that the spherical ball and inner race of the rod ends move freely, and do all applicable corrective actions, in accordance with paragraph 2.B. of the Accomplishment Instructions of Bombardier Service Bulletin 670BA–27–074, dated June 22, 2017. Do all applicable corrective actions before further flight.

Figure 1 to paragraph (j) – *First Inspection Compliance Times*

Total Flight Hours as of the Effective Date of this AD	Compliance Time
Less than 800 total flight hours	After the airplane accumulates 1,000 total flight hours, but not to exceed 1,400 total flight hours
800 or more total flight hours and less than 6,000 total flight hours	Within 880 flight hours from the effective date of this AD

(k) Second Inspection of the Elevator PCU Rod End for Certain Airplanes

(1) For Model CL–600–2C10, CL–600–2D15, CL–600–2D24, and CL–600–2E25 airplanes that are not operating under the LUMP, and that have accumulated 2,600 total flight hours or less at the time of the inspection required by paragraph (j) of this AD: Before the accumulation of 3,400 total flight hours, perform an additional detailed inspection for pitting and corrosion of the left and right rod ends of the elevator PCUs and to make sure that the spherical ball and inner race of the rod ends move freely, and do all applicable corrective actions, in accordance with paragraph 2.B. of the Accomplishment Instructions of Bombardier Service Bulletin 670BA–27–074, dated June 22, 2017. Do all applicable corrective actions before further flight.

(2) For airplanes that have accumulated more than 2,600 total flight hours at the time of the inspection required by paragraph (j) of this AD: A second inspection is not required.

(l) No Inspection for Certain Airplanes

The requirements of paragraphs (j) and (k) of this AD are not applicable to airplanes that have accumulated 6,000 total flight hours or more as of the effective date of this AD.

(m) Service Information Prohibition for Certain Airplanes

For all Model CL–600–2B19 airplanes: After 30 days from the effective date of this AD, this AD prohibits the use of the aircraft maintenance manual (AMM) tasks specified in paragraphs (m)(1) through (3) of this AD.

(1) Task 10–12–00–550–804, Short-Term Storage Return-to-Service Maintenance Checks, of the Bombardier CL–600–2B19 Series 100/200/440 AMM, CSP A–001, Revision 55, dated April 10, 2017, or earlier revisions of this task.

(2) Task 27–23–01–220–801, Detailed Inspection of the Rudder PCU Rod End Spherical Ball, of the Bombardier CL–600–

2B19 Series 100/200/440 AMM, CSP A–001, Revision 54, dated October 10, 2016, or earlier revisions of this task.

(3) Task 27–33–01–220–801, Detailed Inspection of the Elevator PCU Rod End Spherical Ball, of the Bombardier CL–600–2B19 Series 100/200/440 AMM, CSP A–001, Revision 54, dated October 10, 2016, or earlier revisions of this task.

(n) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York 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 manager of the certification office, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; fax 516–794–5531. 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.

(2) Contacting the Manufacturer: For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, New York ACO Branch, FAA; or Transport Canada Civil Aviation (TCCA); or Bombardier, Inc.'s TCCA Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(o) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) Canadian AD CF–2018–29, dated November 2, 2018, for related information, for related information. This MCAI may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0436.

(2) For more information about this AD, contact Darren Gassetto, Aerospace Engineer, Mechanical Systems and Admin Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7323; fax 516–794–5531; email *9-avs-nyaco-cos@faa.gov.*

(p) 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) Bombardier Service Bulletin 670BA–27–074, dated June 22, 2017.

(ii) Section 3—Systems and Powerplant Program, of the Bombardier Model CL–600–2B19 Series 100/200/440 Maintenance Planning Manual, Low Utilization Maintenance Program (MRLUMP–001), CSP A–054–009, Revision 37, dated July 10, 2018.

(A) Task 27–20–00–13, Operational Check of the Rudder Control System.

(B) Task 27–23–01–01, Detailed Inspection of the Rudder PCU Rod End Spherical Ball.

(C) Task 27–31–00–05, Operational Check of the Elevator Control System.

(iii) Section 3—Systems and Powerplant Program, of the Bombardier Model CL–600–2B19 Series 100/200/440 Maintenance Planning Manual, Low Utilization Maintenance Program (MRLUMP–002), CSP A–054–060, Revision 37, dated July 10, 2018.

(A) Task 27–20–00–13, Operational Test of the Rudder Control System.

(B) Task 27–23–01–01, Detailed Inspection of the Rudder PCU Rod End Spherical Ball.

(C) Task 27–31–00–05, Operational Test of the Elevator Control System.

(iv) Section 3—Systems/Power Plant Tasks, of the Bombardier Model CL–600–2C10, CL–600–2D15, CL–600–2D24, Series 700/705/900 Maintenance Planning Manual, Low Utilization Maintenance Program (LUMP), CSP BC–116, Revision 15, dated May 25, 2017.

(A) Task 27–20–00–106, Operational Test of the Rudder PCUs (Duplicate CMR 27–20–00–106).

(B) Task 273000–207, Operational Test of the Elevator Power-Control Units (PCUs).

(C) Task 273000–215, Detailed Inspection of the Elevator PCU Rod End Spherical Ball.

(v) Task 273000–207, Operational Check of each Elevator PCU, of Subject 1–27, of Section 1, Systems and Powerplant Program, Volume 1 of Part 1, Maintenance Review Board Report, Revision 18, dated July 25, 2018, of the Bombardier Model CL–600–2C10, CL–600–2D15, CL–600–2D24, and CL–600–2E25 Series 700/705/900/1000 Maintenance Requirements Manual, CSP B–053.

(3) For service information identified in this AD, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; Widebody Customer Response Center North America toll-free telephone 1–866–538–1247 or direct-dial telephone 1–514–855–2999; fax 514–855–7401; email *ac.yul@aero.bombardier.com;* internet *http://www.bombardier.com.*

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

(5) 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 in Des Moines, Washington, on September 19, 2019.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–24495 Filed 11–8–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0807; Product Identifier 2018–NM–003–AD; Amendment 39–19674; AD 2019–13–01]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

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

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Airbus SAS Model A330–200, A330–300, A340–200, and A340–300 series airplanes. This AD was prompted by a report that revealed the wheel axles of the main landing gear (MLG) were machined with a certain radius and a determination that the life limit for the affected wheel axles of the MLG must be reduced. This AD requires an inspection to determine the part number and serial number of each MLG wheel axle and replacement of affected parts prior to exceeding the reduced life limits. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 17, 2019.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of December 17, 2019.

ADDRESSES: For service information identified in this final rule, contact Airbus SAS, Airworthiness Office—EAL, Rond-Point Emile Dewoitine No: 2, 31700 Blagnac Cedex, France; phone: +33 5 61 93 36 96; fax: +33 5 61 93 45 80; email: *airworthiness.A330-A340@airbus.com;* internet: *http://www.airbus.com.* You may view this service information at the FAA, Transport Standards 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–2018–0807.

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–2018–0807; 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, the regulatory evaluation, 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:

Vladimir Ulyanov, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3229.

SUPPLEMENTARY INFORMATION:

Discussion

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Airbus SAS Model A330–200, A330–300, A340–200, and A340–300 series airplanes. The NPRM published in the **Federal Register** on October 15, 2018 (83 FR 51889). The NPRM was prompted by a report that revealed the wheel axles of the MLG were machined with a radius as small as 0.4 millimeters (mm) and a determination that the life limit for the affected wheel axles of the MLG must be reduced. The NPRM proposed to require an inspection to determine the part number and serial number of each MLG wheel axle and replacement of affected parts prior to exceeding the reduced life limits.

The FAA issued a supplemental notice of proposed rulemaking (SNPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Airbus SAS Model A330–200, A330–300, A340–200, and A340–300 series airplanes. The SNPRM published in the **Federal Register** on April 15, 2019 (84 FR 15154). The FAA issued the SNPRM to add certain airplanes to certain compliance time tables.

The FAA is issuing this AD to address fatigue of the wheel axles of the MLG, which could result in reduced structural integrity of the airplane.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2018–0150, dated July 16, 2018 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Airbus SAS Model A330–200, A330–300, A340–200, and A340–300 series airplanes.

This AD was prompted by a report that revealed the wheel axles of the MLG were machined with a radius as small as 0.4 millimeters and a determination that the life limit for the affected wheel axles of the MLG must be reduced. The FAA is issuing this AD to address fatigue of the wheel axles of the MLG, which could result in reduced 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 considered the comments received. An anonymous commenter and Laith Ibrahim stated 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

Airbus has issued Service Bulletin A330–32–3282, Revision 03, dated October 24, 2017; and Service Bulletin A340–32–4311, Revision 03, dated October 24, 2017. This service information describes procedures for inspecting the MLG wheel axles to determine the part number and serial number, and replacing the affected MLG wheel axles. This service information also specifies reduced life limits for the affected MLG wheel axles. These documents are distinct since they apply to different airplane models.

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.

Costs of Compliance

The FAA estimates that this AD affects 29 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
2 work-hours × $85 per hour = $170	$0	$170	$4,930

The FAA estimates the following costs to do any necessary on-condition replacements that would be required based on the results of any required actions. The FAA has no way of determining the number of aircraft that might need these on-condition replacements:

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Labor cost (per part)	Parts cost (per part)	Cost per product (per part)
16 work-hours × $85 per hour = $1,360	$40,000	$41,360

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.

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

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 adding the following new airworthiness directive (AD):

2019–13–01 Airbus SAS: Amendment 39–19674; Docket No. FAA–2018–0807; Product Identifier 2018–NM–003–AD.

(a) Effective Date

This AD is effective December 17, 2019.

(b) Affected ADs

This AD affects AD 2013–08–03, Amendment 39–17420 (78 FR 23105, April 18, 2013) (''AD 2013–08–03'').

(c) Applicability

This AD applies to the Airbus SAS airplanes, certificated in any category, specified in paragraphs (c)(1) through (5) of this AD.

(1) Model A330–201, –202, –203, –223, and –243 airplanes, all manufacturer serial numbers (MSNs), except those on which Airbus Modification 54500 has been embodied in production.

(2) Model A330–301, –302, –303, –321, –322, –323, –341, –342, and –343 airplanes, all manufacturer serial numbers, except MSNs 0896, 0905, and 0913 (which are specified in paragraph (c)(3) of this AD), and except those on which Airbus Modification 54500 has been embodied in production.

(3) Model A330–343 airplanes, MSNs 0896, 0905, and 0913, except those on which the actions in Airbus Service Bulletin A330–32–3273 have been embodied in service.

(4) Model A340–211, –212, and –213 airplanes, all manufacturer serial numbers, except those on which Airbus Modification 54500 has been embodied in production.

(5) Model A340–311, –312, and –313 airplanes, all manufacturer serial numbers, except those on which Airbus Modification 54500 has been embodied in production.

(d) Subject

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

(e) Reason

This AD was prompted by a report that revealed the wheel axles of the main landing gear (MLG) were machined with a radius as small as 0.4 millimeters and a determination that the life limit for the affected wheel axles of the MLG must be reduced. The FAA is issuing this AD to address fatigue of the wheel axles of the MLG, which could result in reduced structural integrity of the airplane.

(f) Compliance

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

(g) Definitions

(1) For the purpose of this AD, the affected MLG wheel axles are listed by part number and serial number in Appendix 01 (Maintenance Repair Organization (MRO) 001), Appendix 02 (MRO 002), and Appendix 03 (MRO 003) of Airbus Service Bulletin A330–32–3282, Revision 03, dated October 24, 2017; and Airbus Service Bulletin A340–32–4311, Revision 03, dated October 24, 2017; as applicable.

(2) For the purpose of this AD, a serviceable MLG wheel axle is an affected MLG wheel axle that has not exceeded the applicable post-repair life limit values as specified in table 1 to paragraphs (g)(2), (g)(3), and (i) of this AD, table 2 to paragraphs (g)(2), (g)(3), and (i) of this AD, or table 3 to paragraphs (g)(2), (g)(3), and (i) of this AD; or a part that is not an affected MLG wheel axle.

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Table 1 to paragraphs (g)(2), (g)(3), and (i) – *MRO 001 Post-Repair Life Limits*

Affected Airplane(s)	Weight Variant (WV) (series)	Compliance Time/Post-Repair Life Limits (flight cycles (FC) or flight hours (FH), whichever occurs first, as defined by paragraph (g)(3) of this AD for post-repair life limits)
A340-211, A340-212 and A340-213	WV00x	4,600 FC or 29,000 FH
A340-311, A340-312 and A340-313	WV00x	4,700 FC or 22,250 FH
A340-313	WV02x and WV05x	3,950 FC or 16,900 FH
A330-301, A330-321, A330-322, A330-341, and A330-342	WV00x and WV01x	5,050 FC or 15,200 FH
A330-201, A330-202, A330-203, A330-223, and A330-243	WV02x, WV05x, and WV06x	4,450 FC or 17,900 FH
A330-301, A330-302, A330-303, A330-323, A330-342, and A330-343	WV02x and WV05x	5,150 FC or 13,450 FH

Table 2 to paragraphs (g)(2), (g)(3), and (i) – *MRO 002 Post-Repair Life Limits*

Affected Airplane(s)	WV (series)	Compliance Time/Post-Repair Life Limits A or B, whichever occurs later (FC or FH, whichever occurs first, as defined by paragraph (g)(3) of this AD for post-repair life limits)
A340-211, A340-212, A340-213, A340-311, A340-312, and A340-313	WV00x	**A:** 25,000 FC or 100,000 FH **B:** 12 months after the effective date of this AD
A340-311, A340-312, and A340-313	WV02x and WV05x	**A:** 25,000 FC or 83,100 FH **B:** 12 months after the effective date of this AD, but not to exceed 25,000 FC or 100,000 FH
A330-301, A330-302, A330-303, A330-321, A330-322, A330-323, A330-341, A330-342, and A330-343	WV00x, WV01x, WV02x, and WV05x	**A:** 50,000 FC or 75,000 FH **B:** 12 months after the effective date of this AD
A330-201, A330-202, A330-203, A330-223, and A330-243	WV02x, WV05x (except WV058), and WV06x	**A:** 50,000 FC or 75,000 FH **B:** 12 months after the effective date of this AD
A330-201, A330-202, A330-203, A330-223, and A330-243	WV058	**A:** 50,000 FC or 70,950 FH **B:** 12 months after the effective date of this AD, but not to exceed 50,000 FC or 75,000 FH

Table 3 to paragraphs (g)(2), (g)(3), and (i) – *MRO 003 Post-Repair Life Limits*

Affected Airplane(s)	WV (series)	Compliance Time/Post-Repair Life Limits A or B, whichever occurs later (FC or FH, whichever occurs first, as defined by paragraph (g)(3) of this AD for post-repair life limits)
A340-211, A340-212, A340-213, A340-311, A340-312, and A340-313	WV00x	**A:** 25,000 FC or 100,000 FH **B:** 12 months after the effective date of this AD
A340-311, A340-312, and A340-313	WV02x and WV05x	**A:** 25,000 FC or 68,800 FH **B:** 12 months after the effective date of this AD, but not to exceed 25,000 FC or 100,000 FH
A330-301, A330-302, A330-303, A330-321, A330-322, A330-323, A330-341, A330-342, and A330-343	WV00x and WV01x	**A:** 50,000 FC or 73,400 FH **B:** 12 months after the effective date of this AD, but not to exceed 50,000 FC or 75,000 FH
A330-301, A330-302, A330-303, A330-321, A330-322, A330-323, A330-341, A330-342, and A330-343	WV02x and WV05x	**A:** 50,000 FC or 64,100 FH **B:** 12 months after the effective date of this AD, but not to exceed 50,000 FC or 75,000 FH
A330-201, A330-202, A330-203, A330-223, and A330-243	WV02x, WV05x (except WV058), and WV06x	**A:** 50,000 FC or 62,950 FH **B:** 12 months after the effective date of this AD, but not to exceed 50,000 FC or 75,000 FH
A330-201, A330-202, A330-203, A330-223, and A330-243	WV058	**A:** 50,000 FC or 59,350 FH **B:** 12 months after the effective date of this AD, but not to exceed 50,000 FC or 75,000 FH

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(3) For the purpose of this AD, the term ''post-repair life limits'' represents the time-in-service, flight cycles, or flight hours, whichever occurs first, accumulated since repair by the affected MRO specified in table 1 to paragraphs (g)(2), (g)(3), and (i) of this AD, table 2 to paragraphs (g)(2), (g)(3), and (i) of this AD, or table 3 to paragraphs (g)(2), (g)(3), and (i) of this AD.

(h) Inspection To Determine Part Number and Serial Number

Within 90 days after the effective date of this AD: Do an inspection of each MLG wheel axle (left-hand and right-hand sides) to determine the part number and serial number. A review of airplane delivery or maintenance records is acceptable to make this determination, in lieu of inspecting a MLG wheel axle, provided those records can be relied upon for that purpose and the part number and serial number of the affected part can be positively identified from that review.

(i) Replacement of Affected MLG Wheel Axles

If any affected MLG wheel axle is found: Within the compliance time specified in table 1 to paragraphs (g)(2), (g)(3), and (i) of this AD, table 2 to paragraphs (g)(2), (g)(3), and (i) of this AD, or table 3 to paragraphs (g)(2), (g)(3), and (i) of this AD; replace each repaired MLG wheel axle with a serviceable MLG wheel axle, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A330–32–3282, Revision 03, dated October 24, 2017; or Airbus Service Bulletin A340–32–4311, Revision 03, dated October 24, 2017; as applicable. Post-repair life limits specified in tables 1, 2, and 3 to paragraphs (g)(2), (g)(3), and (i) of this AD may not exceed the applicable ALS Part 1 life limits in the existing maintenance or inspection program.

(j) Parts Installation Limitation

As of the effective date of this AD, any affected MLG wheel axle repaired using MRO 001, MRO 002, or MRO 003 may be installed

on an airplane, provided the MLG wheel axle is a serviceable part as defined in paragraph (g)(2) of this AD.

(k) Terminating Action for AD 2013–08–03

Accomplishing the inspection and replacement required by paragraphs (h) and (i) of this AD terminates all requirements of AD 2013–08–03.

(l) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Section, Transport Standards 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 International Section, send it to the attention of the person identified in paragraph (m)(2) of this AD. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* 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.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or the European Aviation Safety Agency (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):* 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.

(m) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA AD 2018–0150, dated July 16, 2018, for related information. This MCAI may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0807.

(2) For more information about this AD, contact Vladimir Ulyanov, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3229.

(n) 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) Airbus Service Bulletin A330–32–3282, Revision 03, dated October 24, 2017.

(ii) Airbus Service Bulletin A340–32–4311, Revision 03, dated October 24, 2017.

(3) For service information identified in this AD, contact Airbus SAS, Airworthiness Office—EAL, Rond-Point Emile Dewoitine No: 2, 31700 Blagnac Cedex, France; phone: +33 5 61 93 36 96; fax: +33 5 61 93 45 80; email: *airworthiness.A330-A340@airbus.com;* internet: *http://www.airbus.com.*

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

(5) 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 in Des Moines, Washington, on July 3, 2019.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–24492 Filed 11–8–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

Bureau of Economic Analysis

15 CFR Part 801

[Docket No. 191104–0074]

RIN 0691–AA89

Direct Investment Surveys: BE–10, Benchmark Survey of U.S. Direct Investment Abroad

AGENCY: Bureau of Economic Analysis, Commerce.

ACTION: Final rule.

SUMMARY: This final rule amends regulations of the Department of Commerce's Bureau of Economic Analysis (BEA) to set forth the reporting requirements for the 2019 BE–10, Benchmark Survey of U.S. Direct Investment Abroad (''BE–10 survey''). The BE–10 survey is conducted every five years; the prior survey covered 2014. The BE–10 survey covers the universe of U.S. direct investment abroad and is BEA's most comprehensive survey of such investment. For the 2019 BE–10 survey, BEA will make changes in data items collected, the design of the survey forms, and the reporting requirements for the survey to satisfy changing data needs and improve data quality and the effectiveness and efficiency of data collection.

DATES: This final rule will be effective December 12, 2019.

FOR FURTHER INFORMATION CONTACT: Ricardo Limes, Chief, Multinational Operations Branch (BE–69), Bureau of Economic Analysis, U.S. Department of Commerce, Washington, DC 20233; phone (301) 278–9659; or via email *ricardo.limes@bea.gov.*

SUPPLEMENTARY INFORMATION: The BE–10, Benchmark Survey of U.S. Direct Investment Abroad, is a mandatory survey and is conducted once every five years by BEA under the authority of the International Investment and Trade in Services Survey Act (22 U.S.C. 3101–3108).

The BE–10 survey covers the U.S. direct investment abroad universe and is BEA's most comprehensive survey of such investment. U.S. direct investment abroad is defined as the ownership or control, directly or indirectly, by one U.S. person of 10 percent or more of the voting securities of an incorporated foreign business enterprise or an equivalent interest in an unincorporated foreign business enterprise, including a branch.

The purpose of the BE–10 survey is to obtain universe data on the financial and operating characteristics of, and on positions and transactions between, U.S. parent companies and their foreign affiliates. The data are needed to measure the size and economic significance of U.S. direct investment abroad, measure changes in such investment, and assess its impact on the U.S. and foreign economies. Such data are generally found in enterprise-level accounting records of respondent companies. The benchmark data provide a baseline for subsequent sample-based estimates in non-benchmark years. In particular, they serve as benchmarks for the quarterly direct investment estimates included in the U.S. international transactions, international investment position, and national income and product accounts, and for annual estimates of the U.S. direct investment abroad position and of the activities of U.S. multinational enterprises.

On August 7, 2019, BEA published a notice of proposed rulemaking that set forth the reporting requirements for the BE–10, Benchmark Survey of U.S. Direct Investment Abroad (84 FR 38583). Two

comments on the proposed rule were received.

The Global Legal Entity Identifier Foundation (GLEIF), an international organization supporting the implementation and use of the Legal Entity Identifier (LEI), expressed support for BEA's proposal to collect the 20-digit LEI of each U.S. parent and foreign affiliate on the BE–10A, BE–10B, and BE–10C forms. Collecting the LEI on the BE–10 survey will assist in matching entities across internal and external databases, enabling better verification of data and linking to other surveys and publicly available information.

The Bank Policy Institute (BPI) expressed support for the survey and BEA's efforts to measure the digital economy. BPI requested clarification on several aspects of the proposed questions on the digital economy and regional headquarters. BEA will include definitions of new terms and guidance for survey respondents in the final version of the survey forms. BPI also recommended that BEA not change the reporting requirements for the BE–10 Claim for Not Filing because of concerns about burden. BEA clarified that a BE–10 Claim For Not Filing only needs to be filled out for those foreign affiliates that do not meet the reporting requirements of the survey and for which BEA contacts the reporter. By providing a standard form for notifying BEA that a foreign affiliate no longer meets the survey requirements, BEA is reducing respondent burden.

This final rule amends 15 CFR part 801 to set forth the reporting requirements for the BE–10, Benchmark Survey of U.S. Direct Investment Abroad. Under this final rule, persons subject to the reporting requirements of the BE–10 survey would be required to respond, whether or not they are contacted by BEA.

Description of Changes

The final rule amends the regulations (15 CFR part 801) and the survey forms for the BE–10 survey. These amendments include changes in data items collected, the design of the survey forms, and the reporting requirements for the survey.

BEA will change the reporting requirements for certain private funds that file the BE–10 survey. BEA, in cooperation with the U.S. Department of the Treasury, will instruct reporters of investments in private funds that meet the definition of direct investment (that is, ownership by one person of 10 percent or more of the voting interest of a business enterprise) but display characteristics of portfolio investment (specifically, investors who do not intend to control or influence the management of an operating company) to report through the Treasury International Capital (TIC) reporting system. Reporting through TIC is more efficient because other related portfolio investments are already being reported there. Such private funds should not report on the BE–10 survey and BEA's other direct investment surveys. Direct investment in operating companies, including investment by and through private funds, will continue to be reported to BEA. This change has already been implemented on BEA's other surveys of U.S. direct investment abroad: The BE–577, Quarterly Survey of U.S. Direct Investment Abroad; and the BE–11, Annual Survey of U.S. Direct Investment Abroad. Additional information on the change in reporting requirements for investments in private funds can be found in the *Direct Investment Surveys: BE–577, Quarterly Survey of U.S. Direct Investment Abroad-Transactions of U.S. Reporter With Foreign Affiliate, and Changes to Private Fund Reporting on Direct Investment Surveys* **Federal Register** notice issued in 2016 (81 FR 33658).

BEA will add, delete, and modify some items on the BE–10 survey forms. Most of the additions are in response to suggestions from data users and to provide more information about U.S. direct investment abroad. The following items will be added or modified on the BE–10 survey:

(1) The form of organization question for the U.S. reporter (item 2 on the BE–10A form, the form that collects information on the domestic operations of U.S. parent companies) will be modified to include more options: Corporations (except for S corporations); partnerships; S corporations; limited liability companies (LLCs); individual, estate, or trust; and other (specify). This information will help BEA to produce economic statistics by sector.

(2) A question will be added to collect the 20-digit Legal Entity Identifier of each U.S. parent and foreign affiliate on the BE–10A, BE–10B, and BE–10C forms (the BE–10B and BE–10C forms collect information on foreign affiliate operations). This information will assist in matching entities across databases, enabling better verification of data and linking to other surveys and publicly available data.

(3) For each publicly traded company, the stock exchange on which it is listed and the ticker symbol will be collected on the BE–10A form. This information will assist in matching entities across databases, enabling better verification of data and linking to other surveys and publicly available data.

(4) The income statement item on income from equity investments (item 44) on the BE–10A form will be modified to separately collect income from unconsolidated U.S. investments and from foreign investments. This will aid in resolving discrepancies between the BE–10 and the BE–577 surveys.

(5) Item 73 on the BE–10A and item 127 on the BE–10B forms collect the amount of restatement in a company's property, plant, and equipment. This question will be modified to separately collect restatement due to ''change in entity'' and due to ''change in accounting methods or principles.'' A checkbox question will be added to the BE–10A and BE–10B forms asking if the change due to accounting methods or principles is due in whole or in part to implementation of FASB ASU No. 2016–02, Leases (Topic 842). This information will allow BEA to assess the impact on BEA's statistics of the change in accounting standards on leases.

(6) Questions will be added to collect sales, employment, and costs and expenses (excluding compensation) on the BE–10A form, and sales on the BE–10B form, related to the provision of selected services generally recognized as prevalent in the digital economy. These selected services are (1) cloud computing, (2) digital intermediation services on both the BE–10A and BE–10B forms, and (3) advertising on the BE–10B form. In addition, checkboxes will be added to the BE–10A and BE–10B forms to collect the percentage of the respondent's sales of services delivered remotely, sales of services that were digitally ordered, and sales of goods that were digitally ordered, along with checkboxes to identify if this information was sourced from accounting records or from recall/general knowledge. These questions will contribute to BEA's efforts to measure the digital economy.

(7) A checkbox question will be added to the BE–10B and BE–10C forms to capture whether the affiliate serves as a regional headquarters. This information will support research into the role and impact of regional headquarters in the operations of multinational enterprises.

(8) A checkbox question will be added to the BE–10B forms to collect information on the value of R&D performed by the U.S. parent for the foreign affiliate under a collaborative R&D agreement, such as a cost-sharing agreement. This question will help BEA follow the production and use of intellectual property in global value chains and their impacts on economic statistics.

(9) A section will be added to the BE–10 Claim for Not Filing to be filled out for those foreign affiliates for which BEA contacts the reporter but do not meet the reporting requirements of the survey. This section will make it easier for reporters to indicate to BEA which affiliates should be removed from the survey.

a. The section will include a private funds exemption option. This is a change to prior reporting requirements described above.

b. There will also be an option to select if the U.S. reporter no longer owns the foreign affiliate and if this was due to the affiliate being sold or liquidated, or because the U.S. reporter's ownership interest in the affiliate fell below 10 percent.

The final rule will also eliminate or consolidate the following items from the BE–10 survey:

(1) Item 8 on the BE–10A, which asks if the U.S. reporter is a bank, will be removed. This question was used in the past when reporting requirements for direct investment surveys were different for banks than other industries but is no longer needed.

(2) Questions on contract manufacturing services will be deleted (items 33–35 on the BE–10A form). The data collected have been burdensome for companies to provide and have not been widely used by data users. Alternative methods are being developed to measure and study contract manufacturing.

(3) The petroleum and mining exploration and development expenditures item will be removed from the BE–10A form (item 80) and BE–10B form (item 135). This item was used to calculate the current cost adjustment to the direct investment statistics in the international transactions accounts (ITAs) but is not used in the current methodology.

(4) The trade in goods by world region questions (items 99–104 and 109–114) on the BE–10A form will be removed. The data collected have been burdensome for companies to provide and have not been widely used by data users. BEA is exploring alternative methods to produce geographical detail on trade by U.S. multinational companies.

(5) Option 2 of item 11 on the BE–10B form and item 8 on the BE–10C form, which collect information on why the affiliate will no longer report on the survey, will be removed. This information will now be captured on the BE–10 Claim for Not Filing (as discussed in item 9 of the additions and modifications section above). U.S. reporters will no longer be required to complete the rest of the BE–10B or BE–10C form with partial year information for foreign affiliates that were sold, merged, reorganized, liquidated, seized, or otherwise ceased to exist at some point during, but before the end of, their fiscal year that ended in the calendar year covered by the BE–10 survey.

(6) Items 18 and 19 on the BE–10B form, and 14 and 15 on the BE–10C form, which collect the direct ownership interest held by ''foreign persons in this affiliate's country of location'' and by ''all other foreign persons,'' will be combined into one item on each of the forms.

(7) Questions collecting information on sales by world region (items 105–110) and on sales to the top five countries outside of the country of location of the affiliate (items 111–116) on the BE–10B form will be removed. The data collected have been burdensome for companies to provide and have not been widely used by data users. BEA will continue to collect items 101–104, which allow sales to be disaggregated into goods and services and by whether the sales are to the United States, to the host country, or to other foreign countries. These items are more widely used.

(8) Several items of Part V of the BE–10B form and Part III of the BE–10C form will be removed, except for the items noted below. These data were used to validate the information collected on the quarterly survey, but data reported elsewhere in the BE–10 forms are sufficient for this purpose. The following items will be retained:

a. A question on reverse investment (item 167 on the BE–10B form).

b. Intercompany debt balances (items 63–65 on the BE–10C form) for foreign affiliates with less than $60 million in assets, sales, or net income.

Executive Order 12866

This final rule has been determined to be not significant for purposes of E.O. 12866.

Executive Order 13132

This final rule does not contain policies with federalism implications sufficient to warrant preparation of a federalism assessment under E.O. 13132.

Paperwork Reduction Act

The collection of information in this final rule was submitted to the Office of Management and Budget (OMB) pursuant to the requirements of the Paperwork Reduction Act (PRA). OMB approved the information collection under OMB control number 0608–0049.

Notwithstanding any other provisions of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA unless that collection displays a currently valid OMB control number.

The BE–10 survey is expected to result in the filing of reports from approximately 18,000 respondents. A complete response includes a BE–10A form for the U.S. parent's domestic operation and one or more BE–10B, BE–10C, or BE–10D forms for its foreign affiliates. BEA estimates that U.S. parents will submit 18,000 BE–10A forms, 19,100 BE–10B forms, 14,500 BE–10C forms, 18,000 BE–10D forms, and 2,000 BE–10 Claims for Not Filing. Total annual burden is calculated by multiplying the estimated number of submissions of each form by the average hourly burden per form, which is 10 hours for the BE–10A form, 19 hours for the BE–10B form, 6 hours for the BE–10C form, 3 hours for the BE–10D form, and 0.5 hours for the BE–10 Claim for Not Filing. The estimated total respondent burden for this survey is estimated at 684,900 hours. The respondent burden for this collection of information is expected to vary considerably among respondents because of differences in company structure, size, and complexity. The burden includes time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. The average respondent burden is 38 hours per response (684,900 hours/18,000 respondents), compared to an average burden of 144 hours and total burden of 561,100 hours for the previous (2014) BE–10 survey. The increase in the estimated total respondent burden reflects an increase in the respondent universe of U.S. and foreign entities that are required to file the BE–10 survey. The average burden decreased because the newer respondents on average file fewer and more abbreviated forms and because the changes to the survey will result in a net decrease in the amount of information collected on the survey.

Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in the final rule should be sent to both BEA via email at *Ricardo.Limes@bea.gov,* and OMB, OIRA, Paperwork Reduction Project 0608–0049, Attention PRA Desk Officer for BEA, via email at *OIRA_Submission@omb.eop.gov.*

Regulatory Flexibility Act

The Chief Counsel for Regulation, Department of Commerce, certified to the Chief Counsel for Advocacy, Small Business Administration, under the provisions of the Regulatory Flexibility Act (RFA), 5 U.S.C. 605(b), that this action will not have a significant economic impact on a substantial number of small entities. The factual basis for the certification was published in the proposed rule and is not repeated here. No final regulatory flexibility analysis was prepared, as no comments were received regarding the determination that this action will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 15 CFR Part 801

Economic statistics, International transactions, Multinational companies, Penalties, Reporting and record keeping requirements, U.S. direct investment abroad.

Paul W. Farello,

Associate Director of International Economics, Bureau of Economic Analysis.

For reasons set forth in the preamble, BEA amends 15 CFR part 801 as follows:

PART 801—SURVEY OF INTERNATIONAL TRADE IN SERVICES BETWEEN U.S. AND FOREIGN PERSONS AND SURVEYS OF DIRECT INVESTMENT

■ 1. The authority citation for 15 CFR part 801 continues to read as follows:

Authority: 5 U.S.C. 301; 15 U.S.C. 4908; 22 U.S.C. 3101–3108; E.O. 11961 (3 CFR, 1977 Comp., p. 86), as amended by E.O. 12318 (3 CFR, 1981 Comp. p. 173); and E.O. 12518 (3 CFR, 1985 Comp. p. 348).

■ 2. Revise § 801.8 to read as follows:

§ 801.8 Rules and regulations for the BE–10, Benchmark Survey of U.S. Direct Investment Abroad.

A BE–10, Benchmark Survey of U.S. Direct Investment Abroad, will be conducted every five years and covers years ending in 4 and 9. All legal authorities, provisions, definitions, and requirements contained in §§ 801.1 and 801.2 and 801.4 through 801.6 are applicable to this survey. Specific additional rules and regulations for the BE–10 survey are given in paragraphs (a) through (d) of this section. More detailed instructions are given on the report forms and instructions.

(a) *Response required.* A response is required from persons subject to the reporting requirements of the BE–10, Benchmark Survey of U.S. Direct Investment Abroad, contained in this section, whether or not they are contacted by BEA. Also, a person, or their agent, contacted in writing by BEA about reporting in this survey must respond by filing a properly completed BE–10 report (BE–10A and BE–10B, BE–10C, BE–10D, and/or BE–10 Claim for Not Filing).

(b) *Who must report.* A BE–10 report is required of any U.S. person that had a foreign affiliate—that is, that had direct or indirect ownership or control of at least 10 percent of the voting stock of an incorporated foreign business enterprise, or an equivalent interest in an unincorporated foreign business enterprise, including a branch—at the end of the U.S. person's fiscal year that ended in the calendar year covered by the survey. Foreign affiliates that are private funds and meet certain criteria are exempt from the BE–10 survey. Specifically, if a foreign affiliate meets all of the criteria in paragraphs (b)(1) though (3) of this section, the U.S. reporter is not required to file a BE–10 form for that affiliate except to indicate exemption from the survey if contacted by BEA:

(1) The foreign affiliate is a private fund; and

(2) The private fund foreign affiliate does not own, directly or indirectly through another business enterprise, an ''operating company''—*i.e.,* a business enterprise that is not a private fund or a holding company—in which the consolidated U.S. reporter owns at least 10 percent of the voting interest; and

(3) If the U.S. reporter owns the private fund indirectly (through one or more other business enterprises), there are no ''operating companies'' between the consolidated U.S. reporter and the indirectly-owned foreign private fund.

(c) *Forms to be filed.* (1) Form BE–10A must be completed by a U.S. reporter. Form BE–10A is required to cover the fully consolidated U.S. domestic business enterprise. It must also file Form(s) BE–10B, BE–10C, and/or BE–10D for its foreign affiliates, whether held directly or indirectly.

(2) Form BE–10B must be filed for each majority-owned foreign affiliate (for purposes of this survey, a ''majority-owned'' foreign affiliate is one in which the combined direct and indirect ownership interest of all U.S. parents of the foreign affiliate exceeds 50 percent) for which any of the items in paragraph (c)(2)(i) through (iii) of this section (not just the U.S. reporter's share) was greater than $80 million (positive or negative) at the end of, or for, its fiscal year that ended in the calendar year covered by the survey:

(i) Total assets (without netting liabilities);

(ii) Sales or gross operating revenues, excluding sales taxes; or

(iii) Net income after provision for foreign income taxes.

(3) Form BE–10C must be filed:

(i) For each majority-owned foreign affiliate for which any one of the three items listed in paragraph (c)(2) of this section was greater than $25 million but for which none of these items was greater than $80 million (positive or negative) at the end of, or for, its fiscal year that ended in the calendar year covered by the survey; and

(ii) For each minority-owned foreign affiliate (for purposes of this survey, a ''minority-owned'' foreign affiliate is one in which the combined direct and indirect ownership interest of all U.S. parents of the foreign affiliate is 50 percent or less) for which any one of the three items listed in paragraph (c)(2) of this section was greater than $25 million (positive or negative) at the end of, or for, its fiscal year that ended in the calendar year covered by the survey.

(4) Form BE–10D must be filed for majority- or minority-owned foreign affiliates for which none of the three items listed in paragraph (c)(2) of this section was greater than $25 million (positive or negative) at the end of, or for, its fiscal year that ended in the calendar year covered by the survey. Form BE–10D is a schedule; a U.S. reporter would submit one or more pages of the form depending on the number of affiliates that are required to be filed on this form.

(5) BE–10 Claim for Not Filing will be provided for response by:

(i) Persons that are not subject to the reporting requirements of the BE–10 survey but have been contacted by BEA concerning their reporting status; or

(ii) U.S. reporters that have been contacted by BEA concerning their reporting status for foreign affiliates that are no longer subject to the reporting requirements of the BE–10 survey.

(d) *Due date.* A fully completed and certified BE–10 report comprising Form BE–10A and Form(s) BE–10B, BE–10C, BE–10D, and/or BE–10 Claim for Not Filing (as required) is due to be filed with BEA not later than May 31 of the year after the year covered by the survey, for those U.S. reporters filing fewer than 50, and June 30, for those U.S. reporters filing 50 or more, foreign affiliate Forms BE–10B, BE–10C, and/or BE–10D.

[FR Doc. 2019–24414 Filed 11–8–19; 8:45 am]

BILLING CODE 3510–06–P

DEPARTMENT OF DEFENSE

Department of the Army

32 CFR Part 584

[Docket ID: USA–2018–HQ–0008]

RIN 0702–AA84

Family Support, Child Custody, and Paternity

AGENCY: Department of the Army, DoD.

ACTION: Final rule.

SUMMARY: This final rule removes the Army's regulation governing support and nonsupport of family members; child custody involving a soldier; paternity complaints against soldiers; and adoption proceedings involving children of soldiers. This part does not impose obligations on members of the public that are not already imposed by statute. This part is obsolete and unnecessary. Therefore, this part can be removed from the CFR.

DATES: This rule is effective on November 12, 2019.

FOR FURTHER INFORMATION CONTACT: John Meixell, 571–256–7865.

SUPPLEMENTARY INFORMATION: It has been determined that publication of this CFR part removal for public comment is impracticable, unnecessary, and contrary to public interest since it is based on removing DoD internal policies and procedures that are publically available on the Department's website.

Army internal guidance governing support and nonsupport of family members; child custody involving a soldier; paternity complaints against soldiers; and adoption proceedings involving children of soldiers will continue to be published in Army Regulation 608–99 available at *http://www.apd.army.mil/epubs/DR_pubs/DR_a/pdf/web/r608_99.pdf.*

This rule is not significant under Executive Order (E.O.) 12866, ''Regulatory Planning and Review,'' therefore, E.O. 13771, ''Reducing Regulation and Controlling Regulatory Costs'' does not apply.

List of Subjects in 32 CFR Part 584

Adoption and foster care, Child support, Military personnel, Wages.

PART 584—[REMOVED]

■ Accordingly, by the authority of 5 U.S.C. 301, 32 CFR part 584 is removed.

Brenda S. Bowen,

Army Federal Register Liaison Officer.

[FR Doc. 2019–24550 Filed 11–8–19; 8:45 am]

BILLING CODE 5001–03–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2019–0821]

RIN 1625–AA09

Drawbridge Operation Regulation; Kissimmee River, Fort Basinger, FL

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is removing the existing drawbridge operation regulation for the DSX Railroad Bridge (CSX Railroad Bridge) across the Kissimmee River, mile 37 near Fort Basinger, Florida. The drawbridge was converted to a fixed bridge in 2016 and the operating regulation is no longer applicable or necessary.

DATES: This rule is effective November 12, 2019.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2019–0821. In the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rulemaking.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Mr. Eddie Lawrence, Bridge Administration Branch, United States Coast Guard District Seven: Telephone 305–415–6946, email *Eddie.H.Lawrence@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
FL Florida
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this final 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), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because DSX Railroad Bridge that once required draw operations in 33 CFR 117.295, was converted to a fixed bridge in 2016. Therefore, the regulation is no longer applicable and shall be removed from publication. It is unnecessary to publish an NPRM because this regulatory action does not purport to place any restrictions on mariners but rather removes a restriction that has no further use or value.

We are issuing this 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**. The bridge has been a fixed bridge for three years and this rule merely requires an administrative change to the **Federal Register** in order to omit a regulatory requirement that is no longer applicable or necessary. The modification has already taken place and the removal of the regulation will not affect mariners currently operating on this waterway. Therefore, a delayed effective date is unnecessary.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority of The Bridge Act of 1894, 33 U.S.C. 499.

The DSX Railroad Bridge was converted to a fixed bridge in 2016. The regulation for the previously existing drawbridge was not removed subsequent to the bridge's conversion to a fixed bridge. The conversion of this bridge necessitates the removal of the drawbridge operation regulation, 33 CFR 117.295, because this drawbridge regulation governs a bridge that is no longer able to be opened.

IV. Discussion of Final Rule

The Coast Guard is changing the regulation in 33 CFR 117.295 by removing restrictions and the regulatory burden related to the draw operations for this bridge, which is no longer a drawbridge. The change removes 33 CFR 117.295 in its entirety since the bridge has been converted to a fixed bridge. This Final Rule seeks to update the Code of Federal Regulations by removing language that governs the operation of the DSX Railroad Bridge, which in fact is no longer a drawbridge. This change does not affect waterway or land traffic.

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 protesters.

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, it 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 fact that the bridge was converted to a fixed bridge and no longer operates as a drawbridge. The removal of the operating schedule from 33 CFR 117 Subpart B will have no effect on the movement of waterway or land traffic.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 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.

For the reasons stated in section V.A above this final rule would 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 (Pub. L. 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**, above.

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 calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Government

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.

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 Management Directive 023–01, U.S. Coast Guard Environmental Planning Policy COMDTINST 5090.1 (series) and U.S. Coast Guard Environmental Planning Implementation Procedures (series) which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f). We have made a determination 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 promulgates the operating regulations or procedures for drawbridges. This action is categorically excluded from further review, under paragraph L49, of Chapter 3, Table 3–1 of the U.S. Coast Guard Environmental Planning Implementation Procedures.

A preliminary Record of Environmental Consideration and a Memorandum for the Record are not required for this rule.

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 117

Bridges.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

■ 1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 33 CFR 1.05–1; Department of Homeland Security Delegation No. 0170.1.

§ 117.295 [Removed]

■ 2. Remove § 117.295.

Dated: November 5, 2019.

Eric C. Jones,

Rear Admiral, U.S. Coast Guard, Commander, Seventh Coast Guard District.

[FR Doc. 2019–24467 Filed 11–8–19; 8:45 am]

BILLING CODE 9110–04–P

LIBRARY OF CONGRESS

Copyright Office

37 CFR Parts 201 and 202

[Docket No. 2017–16]

Group Registration of Newspapers

AGENCY: U.S. Copyright Office, Library of Congress.

ACTION: Final rule.

SUMMARY: The U.S. Copyright Office is amending its regulation governing the group registration option for newspapers. Under the current regulation, applicants are required to upload a complete copy of each newspaper issue through the Office's electronic registration system. Applicants may also submit their newspaper issues on microfilm on a voluntary basis (in addition to and at the same time as submitting the required digital files), provided the microfilm is received by December 31, 2019. The microfilm option expires at the end of this year; therefore, today's final rule eliminates the reference to that option.

DATES: Effective January 1, 2020.

FOR FURTHER INFORMATION CONTACT: Regan A. Smith, General Counsel and Associate Register of Copyrights, or Robert J. Kasunic, Associate Register of Copyrights and Director of Registration Policy and Practice, or Erik Bertin, Deputy Director of Registration Policy and Practice, by email at *regans@copyright.gov, rkas@copyright.gov,* and *ebertin@copyright.gov* or by telephone at (202) 707–8350.

SUPPLEMENTARY INFORMATION: When Congress enacted the Copyright Act of 1976 (the ''Act''), it authorized the Register of Copyrights to specify by regulation the administrative classes of works for the purpose of seeking a registration, and the nature of the deposits required for each such class. In addition, Congress granted the Register the discretion to allow groups of related works to be registered with one application and one filing fee. *See* 17 U.S.C. 408(c)(1). Congress cited ''the various editions or issues of a daily newspaper'' as a specific example of a ''group of related works'' that would be suitable for a group registration. H.R. Rep. No. 94–1476, at 153–54 (1976); S. Rep. No. 94–473, at 136 (1975).

On January 30, 2018, the Copyright Office (the ''Office'') issued a final rule amending the regulation governing the group registration option for newspapers (''GRNP''). 83 FR 4144 (Jan. 30. 2018). The 2018 final rule modified the requirements for this group registration option in several respects, including the deposit requirements. Applicants are now required to upload their newspaper issues in digital form through the Office's electronic registration system. In addition, applicants may submit microfilm containing a complete copy of each issue on a voluntary basis, provided the Office receives the microfilm by December 31, 2019.

The Office made these changes to improve the efficiency of the registration system and encourage broader participation in the registration system by reducing the burden on applicants. To that end, the Office provided a one-year phase out period for microfilm deposits to give publishers time to develop quality assurance testing for their digital submissions.

These amendments went into effect on March 1, 2018. Since then, the number of microfilm submissions has steadily declined. For example, in March 2018 the Office received electronic deposits (without any microfilm) for 78% of the applications submitted under this group registration option. That number increased to 87% by the end of December 2018. The trend continued through July 2019, where digital deposit copies accounted for 92% of all GRNP applications. In fact, from May through July 2019 the Office received no microfilm submissions and compliance with the digital deposit requirement has been 100%.

The microfilm option will expire at the end of this year, and based on the submissions received since March 2018, the Office sees no need to extend the phase out period. Accordingly, the Office is amending its regulations to remove the reference to the microfilm option.

Because the updates are technical and non-substantive changes that do not ''alter the rights or interests of parties,'' they are not subject to the notice and comment requirements of the Administrative Procedure Act.[1] Furthermore, the Office finds good cause that providing notice and comment is ''unnecessary'' because the changed requirements and phase-out period were adopted in a previous public proceeding; this final rule merely removes related obsolete language.[2]

List of Subjects

37 CFR Part 201

Copyright, General provisions.

37 CFR Part 202

Copyright, Preregistration and registration of claims to copyright.

Final Regulations

For the reasons set forth in the preamble, the Copyright Office amends 37 CFR parts 201 and 202 as follows:

[1] *See Nat'l Mining Ass'n* v. *McCarthy,* 758 F.3d 243, 250 (D.C. Cir. 2014); 5 U.S.C. 553(b) (notice and comment not required for ''interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice'').

[2] *See* 5 U.S.C. 553(b).

PART 201—GENERAL PROVISIONS

■ 1. The authority citation for part 201 continues to read as follows:

Authority: 17 U.S.C. 702.

§ 201.1 [Amended]

■ 2. Amend § 201.1(c)(6) by removing '', and newspaper microfilm copies submitted under § 202.4(e) of this chapter,''.

PART 202—PREREGISTRATION AND REGISTRATION OF CLAIMS TO COPYRIGHT

■ 3. The authority citation for part 202 continues to read as follows:

Authority: 17 U.S.C. 408(f), 702.

§ 202.4 [Amended]

■ 4. Amend § 202.4 by removing paragraph (e)(6)(ii)(B) and redesignating paragraph (e)(6)(ii)(A) as paragraph (e)(6)(ii).

Dated: October 23, 2019.

Karyn A. Temple,

Register of Copyrights and Director of the U.S. Copyright Office.

Approved by:

Carla D. Hayden,

Librarian of Congress.

[FR Doc. 2019–24450 Filed 11–8–19; 8:45 am]

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LIBRARY OF CONGRESS

U.S. Copyright Office

37 CFR Part 202

[Docket No. 2018–2]

Group Registration of Serials

AGENCY: U.S. Copyright Office, Library of Congress.

ACTION: Final rule.

SUMMARY: The U.S. Copyright Office is amending its regulation governing the group registration option for serials. Under the current regulation, applicants may complete and submit the online application designated for a group of serial issues, or they may complete and submit a paper application using Form SE/Group, provided the Office receives the paper form by December 30, 2019. Applicants submitting Form SE/Group may submit a physical copy of each issue in the group; applicants using the online application may upload one electronic copy of each issue through the Office's electronic registration system or they may submit one physical copy, provided the Office receives the physical copy by December 30, 2019.

This final rule eliminates the reference to paper applications and physical deposit copies. Beginning December 31, 2019, the Office will no longer accept a paper application or a physical deposit for this group registration option.

DATES: Effective December 31, 2019.

FOR FURTHER INFORMATION CONTACT: Regan A. Smith, General Counsel and Associate Register of Copyrights, or Robert J. Kasunic, Associate Register of Copyrights and Director of Registration Policy & Practice, or Erik Bertin, Deputy Director of Registration Policy and Practice, by email at *regans@copyright.gov, rkas@copyright.gov,* and *ebertin@copyright.gov,* or by telephone at (202) 707–8350.

SUPPLEMENTARY INFORMATION: When Congress enacted the Copyright Act of 1976 (the ''Act''), it authorized the Register of Copyrights to specify by regulation the administrative classes of works for the purpose of seeking a registration, and the nature of the deposits required for each such class. *See* 17 U.S.C. 408(c). In addition, Congress granted the Register the discretion to allow groups of related works to be registered with one application and one filing fee, a procedure known as ''group registration.'' *See* 17 U.S.C. 408(c)(1). Congress recognized that requiring applicants to submit separate applications for certain types of works may be so burdensome and expensive that authors and copyright owners may forgo registration altogether, since copyright registration is not a prerequisite to copyright protection. H.R. Rep. No. 94–1476, at 154 (1976); S. Rep. No. 94–473, at 136 (1975). Pursuant to the authority granted by Congress, the Register has issued regulations permitting the U.S. Copyright Office (the ''Office'') to issue a group registration for limited categories of works, including serials, provided that certain conditions have been met. *See generally* 37 CFR 202.3(b)(5), 202.4.

On November 30, 2018, the Office issued a final rule amending the regulation governing the group registration of serials (''GRSE''). 83 FR 61546 (Nov. 30, 2018). Among other changes, the 2018 final rule updated the application and deposit requirements by phasing out the paper form (known as Form SE/Group) and phasing out the submission of physical copies. Beginning December 31, 2019, applicants will be required to use the online application designated for group serials and to upload a digital copy of each issue.

Requiring applications and deposits to be submitted electronically increases the efficiency of the group registration process. Electronic submissions take less time to process and are easier to track and handle than paper applications and physical copies. They reduce the burden on applicants by eliminating the cost of mailing the deposit to the Office. And they improve the quality of the registration record, because it is easier to locate and retrieve a digital deposit if it is needed for litigation or other legitimate purposes. 83 FR 22896, 22900 (May 17, 2018).

The Office provided a one-year phase-out period to give publishers time to adjust to the new application and deposit requirements. To facilitate this transition, the Literary Division contacted every applicant that has submitted a group serial claim since December 31, 2018, to notify them of the upcoming changes.

Over the past three years, there has been a steady increase in electronic deposits for group serial claims. In 2017, electronic deposits accounted for 23% of these claims and physical deposits accounted for 76%. In 2018, electronic deposits increased to 34% while physical deposits dropped to 65%.[1] This trend accelerated once the 2018 final rule went into effect: Between December 31, 2018, and July 24, 2019, electronic deposit copies accounted for 59% of group serial claims, while physical deposits accounted for the remaining 41%.

The phase out period will expire at the end of this year. Therefore, the Office is amending the regulation to eliminate the reference to Form SE/Group and physical deposit copies. Beginning December 31, 2019, the Office will no longer accept paper applications or physical deposits for this group option.

The regulation does give the Office the discretion to waive the online application filing requirement and grant special relief from the digital deposit requirement in exceptional cases, subject to conditions imposed on the applicant by the Associate Register of Copyrights and Director of the Office of Registration Policy and Practice. 37 CFR 202.4(d)(4), 202.20(d)(1)(iii). Requests for special relief will be considered on a case-by-case basis. But the fact that a serial is published in a physical form does not necessarily mean that a request will be granted. The Office requires digital deposits for most group registration options as a quid pro quo for allowing multiple works to be registered with one application and one filing fee.[2] In the case of group serials, the Office delayed this requirement for one year to give publishers time to prepare for the new workflow. Serials are typically created using digital publishing software, even though the issue itself may be distributed in a physical form. In such cases, the electronic file that was used to create the physical copy may be used to satisfy the digital deposit requirement, as long as it contains a complete copy of the issue and satisfies the other legal and formal requirements for this group option.[3]

Because the updates are technical and non-substantive changes that do not ''alter the rights or interests of parties,'' they are not subject to the notice and comment requirements of the Administrative Procedure Act.[4] Furthermore, the Office finds good cause that providing notice and comment is ''unnecessary'' because the changed requirements and phase-out period were adopted in a previous public proceeding; this final rule merely removes related obsolete language.[5]

List of Subjects in 37 CFR Part 202

Copyright, Preregistration and registration of claims to copyright.

Final Regulations

For the reasons set forth in the preamble, the Copyright Office amends 37 CFR part 202 as follows:

PART 202—PREREGISTRATION AND REGISTRATION OF CLAIMS TO COPYRIGHT

■ 1. The authority citation for part 202 continues to read as follows:

Authority: 17 U.S.C. 408(f), 702.

■ 2. Amend § 202.4 by revising paragraphs (d)(2) and (3) to read as follows:

§ 202.4 Group registration.

* * * * *

(d) * * *

(2) *Application.* The applicant must complete and submit the online application designated for a group of serial issues. The application may be

[1] For the remainder of claims submitted in 2017 through July 24, 2019, applicants either submitted both an electronic and physical deposit for the same claim or did not submit any deposit at all.

[2] *See* 37 CFR 202.4(c)(9), (e)(6)(ii)(A), (f)(3), (g)(8), (h)(9), (i)(9).

[3] These requirements are currently set forth in 37 CFR 202.4(d)(3)(i).

[4] *See Nat'l Mining Ass'n* v. *McCarthy,* 758 F.3d 243, 250 (D.C. Cir. 2014); 5 U.S.C. 553(b) (notice and comment not required for ''interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice'').

[5] *See* 5 U.S.C. 553(b).

submitted by any of the parties listed in § 202.3(c)(1).

(3) *Deposit.* The applicant must submit one complete copy of each issue that is included in the group. Copies submitted under this paragraph (d)(3) will be considered solely for the purpose of registration under 17 U.S.C. 408, and will not satisfy the mandatory deposit requirement under 17 U.S.C. 407. The issues must be submitted in digital form, and each issue must be contained in a separate electronic file. The applicant must use the file-naming convention and submit digital files in accordance with instructions specified on the Copyright Office's website. The files must be submitted in Portable Document Format (PDF), they must be assembled in an orderly form, and they must be uploaded to the electronic registration system as individual electronic files (*i.e.,* not .zip files). The files must be viewable and searchable, contain embedded fonts, and be free from any access restrictions (such as those implemented through digital rights management) that prevent the viewing and examination of the work. The file size for each uploaded file must not exceed 500 megabytes, but files may be compressed to comply with the requirement in this paragraph (d)(3).

* * * * *

Dated: October 23, 2019.

Karyn A. Temple,

Register of Copyrights and Director of the U.S. Copyright Office.

Approved by:

Carla D. Hayden,

Librarian of Congress.

[FR Doc. 2019–24451 Filed 11–8–19; 8:45 am]

BILLING CODE 1410–30–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R9–OAR–2018–0821; FRL–10001–65–Region 9]

Determination of Attainment by the Attainment Date for the 2008 Ozone National Ambient Air Quality Standards; Phoenix-Mesa, Arizona

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to determine that the Phoenix-Mesa ozone nonattainment area (''Phoenix NAA''), which is classified as ''Moderate'' for the 2008 ozone National Ambient Air Quality Standards (NAAQS or ''standards''), attained the NAAQS by the Moderate area attainment date of July 20, 2018. This determination is based on complete, quality-assured, and certified data for 2015–2017. This final action is necessary to fulfill the EPA's statutory obligation to determine whether ozone nonattainment areas attained the NAAQS by the applicable attainment date.

DATES: This rule will be effective on December 12, 2019.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2018–0821. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *https://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Nancy Levin, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105. By phone: (415) 972–3848 or by email at *levin.nancy@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us,'' and ''our'' refer to the EPA.

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I. Proposed Action

On June 13, 2019 (84 FR 27566), the EPA proposed to determine that the Phoenix NAA attained the 2008 ozone standard [1] by the Moderate area attainment date of July 20, 2018, based on complete, quality-assured, and certified ambient air quality monitoring data for the 2015–2017 monitoring period. Based on our proposed finding of attainment by the applicable attainment date, we also proposed to determine that the CAA requirement for the State Implementation Plan (SIP) to provide for contingency measures to be implemented in the event the area fails to attain (''attainment contingency measures'') would no longer apply to the Phoenix NAA. Our proposed action contains more information on our determinations.

II. Public Comments and EPA Responses

The EPA's proposed action provided a 30-day public comment period. During this period, we received comments from five commenters. We summarize the comments and provide our responses below.

Commenter #1: Arizona Center for Law in the Public Interest

Comment: Arizona Center for Law in the Public Interest (ACLIPI) noted that monitoring data from 2018 and 2019 show multiple exceedances of the 2008 ozone standard and concluded that the Phoenix NAA does not ''actually'' comply with the standard. ACLIPI asserted that '' 'paper compliance' with the 2008 ozone standard does not solve Phoenix's ongoing ozone pollution problem'' and the ''EPA's proposed action allows the State to avoid or significantly delay taking meaningful action to protect public health [which] contravenes the express policy of the Clean Air Act that 'protection of public health is the highest priority.' ''

Response: CAA section 181(b)(2)(A) requires the EPA to determine whether an ozone nonattainment area (NAA) attained the standard by the applicable attainment date ''based on the area's design value (*as of the attainment date*).'' [2] The applicable attainment date for the Phoenix NAA for the 2008 ozone NAAQS is not later than July 20, 2018.[3] Because the design value for the 2008 ozone NAAQS is based on the three most recent, complete calendar years of data, attainment must be evaluated based on 2015–2017 data. Accordingly, we are not permitted to consider 2018 or 2019 data in evaluating whether the area attained by the applicable attainment date.

We note that the more recent monitoring data would be relevant if we were making a ''clean data determination'' and suspending attainment-related requirements for the Phoenix NAA under 40 CFR 51.1118. These data would also be relevant if we were redesignating the area to attainment under CAA section 107(d)(3). However, as explained in our proposal, we are not taking either of those actions at this time. Therefore, the designation and classification of the Phoenix NAA for the 2008 ozone NAAQS will remain Moderate

[1] Since the primary and secondary 2008 ozone standards are identical, we hereinafter refer to ''standards'' in the singular. 73 FR 16436.

[2] CAA section 181(b)(2)(A) (emphasis added).

[3] 40 CFR 51.1103; 81 FR 26697, 26698.

nonattainment until such time as the EPA determines that the area meets the CAA requirements for redesignation to attainment. In order to redesignate the area to attainment, the EPA will have to determine, among other things, that the Phoenix NAA has continued to attain the NAAQS at the time of final redesignation, that the air quality improvement is due to permanent and enforceable emission reductions, and that the State of Arizona's (''State's'') maintenance plan provides for maintenance of the NAAQS for at least ten years beyond redesignation.[4]

Finally, the commenter cited CAA section 319(b)(3)(A), which establishes five principles that the EPA must follow in developing implementing regulations for exceptional events, including that ''protection of public health is the highest priority.'' [5] The regulatory provisions implementing this principle are found in 40 CFR 51.930, which requires air agencies requesting data exclusion to take appropriate and reasonable actions to protect public health from exceedances or violations of the NAAQS.[6] Specifically, agencies must promptly notify the public when the air quality exceeds or is expected to exceed the NAAQS, educate the public regarding steps they can take to minimize exposure, and provide for the implementation of appropriate measures to protect public health from exceedances or violations of ambient air quality standards caused by exceptional events.[7] The commenter has not identified whether or how it believes the State has failed to meet these requirements. Accordingly, we do not agree that the determination of attainment by the attainment date contravenes the principle that protection of public health is the highest priority.

Comment: ACLIPI noted that, in the proposed determination of attainment, the EPA excluded exceedances of the 2008 ozone standard on June 20, 2015 and July 7, 2017, based on the EPA's concurrence with the State's request to find that these exceedances were due to ''exceptional events'' under the EPA's Exceptional Events Rule. The commenter claimed that the Arizona Department of Environmental Protection's (ADEQ's) documentation does not support treating the June 20, 2015 exceedances as exceptional events because the documentation ''does not convincingly establish any causal relationship between the Lake Fire and the June 2015 exceedances, much less a clear causal relationship.''

Response: As indicated by the commenter, one of the required elements of an exceptional events demonstration is a showing that ''there exists a clear causal relationship between the specific event and the monitored exceedance or violation.'' [8] This showing must be supported by analyses comparing the claimed event-influenced concentration(s) to concentrations at the same monitoring site at other times,[9] and may also be supported by other types of analyses.[10]

The EPA reviews the information and analyses in the air agency's demonstration package using a weight of evidence approach.[11] As explained in the preamble to revisions to the Exceptional Events Rule promulgated in 2016:

> . . . in applying a ''weight of evidence'' approach to reviewing individual exceptional events demonstrations, the EPA believes it is appropriate to consider all relevant evidence and qualitatively ''weigh'' this evidence based on its relevance to the Exceptional Events Rule criterion being addressed, the degree of certainty, its persuasiveness, and other considerations appropriate to the individual pollutant and the nature and type of event.

Therefore, the EPA considers a variety of evidence when evaluating whether there is a clear causal relationship between a specific event and the monitored exceedance or violation, and weighs the available evidence based on its relevance, degree of certainty, persuasiveness, and other appropriate considerations.

The EPA's ''Guidance on the Preparation of Exceptional Events Demonstrations for Wildfire Events that May Influence Ozone Concentrations'' (September 2016) (hereinafter ''Wildfire Ozone Guidance'' or ''Guidance'') recommends a tiered approach for addressing the clear causal relationship element:

> Tier 1 clear causal analyses should be used for wildfire events that cause clear O_3 impacts in areas or during times of year that typically experience lower O_3 concentrations, and are thus simpler and less resource intensive than analyses for other events. Tier 2 clear causal analyses are likely appropriate when the impacts of the wildfire on O_3 levels are less clear and require more supportive documentation than Tier 1 analyses. Tier 3 clear causal analyses should be used for events in which the relationship between the wildfire and the O_3 exceedance or violation is more complicated than the relationship in a Tier 2 analysis, and thus would require more supportive documentation than Tier 2 analyses.[12]

The Guidance describes the ''key factors'' and specific types of technical analyses that can be used to evaluate these factors in order to determine which tier a particular demonstration falls into and whether it meets the clear causal criterion.[13]

In this case, as part of the discussions between the EPA and ADEQ after the initial notification and during the air agency's demonstration development, the EPA found that the June 20, 2015 event did not meet all the key factors for a wildfire ozone Tier 1 or Tier 2 analysis. Therefore, the EPA and ADEQ agreed that additional evidence to support the clear causal demonstration (*i.e.,* a Tier 3 analysis) was appropriate.[14] In accordance with this finding, ADEQ's documentation for the June 20, 2015 exceedances included additional evidence to support that (1) wildfire emissions were transported from the wildfire to the monitors; (2) wildfire emissions affected the monitors; and (3) wildfire emissions caused the ozone exceedances.[15] As described in further detail below, the EPA evaluated the relevance, persuasiveness, and certainty of this evidence and found that the weight of

[4] CAA section 107(d)(3)(E) and 175A(a).

[5] CAA section 319(b)(3)(A)(i).

[6] 40 CFR 51.930. See also 81 FR 68216, 68270 (''the regulatory requirements implementing [319(b)(3)(A)](i) and (iv) are found in 40 CFR 51.930, Mitigation of Exceptional Events'').

[7] Id. and 40 CFR 50.14(c)(1).

[8] 40 CFR 50.14(c)(3)(iv)(B). See also CAA section 319(b)(3)(B)(ii)(''a clear causal relationship must exist between the measured exceedances of a national ambient air quality standard and the exceptional event'').

[9] 40 CFR 50.14(c)(3)(iv)(C).

[10] 81 FR 68241, Table 1—Example Clear Causal Relationship Evidence and Analyses.

[11] 81 FR 68242 (''. . . the EPA will use a weight of evidence approach in reviewing submitted demonstrations and will consider the 'clear causal relationship' information, including the comparison to historical concentrations showing, along with evidence supporting the other Exceptional Events Rule criteria.'') See also ''Technical Support Document for EPA Concurrence On O_3 Exceedances Measured In The Phoenix-Mesa 2008 8-Hour O_3 Nonattainment Area on June 20, 2015 as Exceptional Events,'' (hereinafter ''TSD''), 1.

[12] Guidance, 4. This guidance uses ''O_3'' to refer to ''ozone.''

[13] Id. at 9–20.

[14] TSD, 8.

[15] Id. ADEQ's documentation for the June 20, 2015 exceedances consisted of three separate submittals: ''State of Arizona Exceptional Event Documentation for Wildfire-Caused Ozone Exceedances on June 20, 2015 in the Maricopa Nonattainment Area,'' (September 2016) (''initial submittal''); ''Addendum to: State of Arizona Exceptional Event Documentation for Wildfire-Caused Exceedances on June 20, 2015 in the Maricopa Nonattainment Area—September 2016; Additional Evidence that Ozone and Ozone Precursor Emissions From the Lake Fire Reached and Affected Ozone Monitors Within the Maricopa Nonattainment Area'' (May 2018) (''first addendum''); and ''Addendum to: State of Arizona Exceptional Event Documentation for Wildfire-Caused Exceedances on June 20, 2015 in the Maricopa Nonattainment Area—September 2016; Expanded Conceptual Model Linking Ozone and Ozone Precursors From the Lake Fire with the Ozone Exceedances in the Maricopa Nonattainment Area,'' (March 2019) (''second addendum'').

the evidence established the existence of a clear causal relationship between the Lake Fire and the June 20, 2015 exceedances.

In order to demonstrate that wildfire emissions were transported to the monitor, ADEQ's initial submittal presented a trajectory analysis using the HYbrid Single-Particle Lagrangian Integrated Trajectory model (HYSPLIT) and satellite imagery of smoke and National Oceanic and Atmospheric Administration (NOAA) smoke contours for light, medium, and heavy smoke.[16] The EPA found that these initial analyses ''provided evidence that smoke was present over the nonattainment area on June 19, 2015, but did not provide evidence that the smoke was at ground level, nor that smoke was present over the nonattainment area on June 20, 2015.'' [17] However, the second addendum to the demonstration included additional analyses to clarify transport of wildfire emissions and mechanisms for mixing to ground level along ''upper-air'' and ''lower-air'' pathways, including updated HYSPLIT analyses, satellite imagery and data, water vapor and dew point analysis, and meteorological data regarding boundary layer depths in the nonattainment area on June 20, 2015.[18] The EPA evaluated these analyses and determined that, collectively, they adequately established that ''emissions from the Lake Fire in California were transported to the nonattainment area and the affected monitoring sites and reached ground level on June 20, 2015.'' [19]

In order to demonstrate that the wildfire emissions affected the monitors, the initial submittal provided maps of daily maximum 8-hour average ozone concentrations from June 17 through June 21, 2015.[20] These maps showed a regional rise in ozone concentrations across much of Arizona on June 19 and 20, 2015, suggesting that factors affecting elevated ozone concentrations within the nonattainment area were regional in nature. The initial submittal also provided ozone diurnal profiles of the exceeding monitors on June 20, 2015. The first addendum supplemented this analysis by providing an expanded analysis of ozone diurnal hourly concentrations at the exceeding monitors for June 19 through 21, 2015, along with comparisons to historical hourly concentrations, which showed that ozone concentrations were at or above the 95th percentile values for several hours on June 20, 2015.[21] The initial submittal also provided an analysis of diurnal nitrogen dioxide (NO_2) concentrations, which the first addendum supplemented with an expanded statistical analysis of NO_2 similar to the expanded ozone analysis. In addition, the initial submittal also evaluated particulate matter with an aerodynamic diameter less than or equal to a nominal 2.5 micrometers ($PM_{2.5}$), which is much more commonly associated with fire emissions than NO_2, but found that $PM_{2.5}$ was not elevated within the nonattainment area prior to or during the exceedance day. To address the lack of elevated $PM_{2.5}$ observed in the nonattainment area, the initial submittal and first addendum examined speciation data for elemental carbon (EC) and organic carbon (OC).[22] After examining these analyses, we concluded that:

> Overall, the lack of elevated $PM_{2.5}$ in the nonattainment area raises questions about the extent to which wildfire emissions reached the ground and affected the monitor. However, the supplemental analyses showing elevated OC and relatively low EC/OC concentrations, and unusually elevated NO_2 and O_3 concentrations observed on a Saturday, along with the robust analysis of transport and mixing mechanisms described earlier in this document, ultimately support the conclusion that wildfire emissions reached the ground and affected measurements at the exceeding monitors on June 20, 2015.[23]

The initial submittal and addenda also provided additional evidence to demonstrate that the wildfire emissions caused the ozone exceedances observed on June 20, 2015, including three ''matching day'' analyses that (1) compared days in 2010 through 2015 during the month of June with similar meteorological conditions to June 20, 2015; (2) compared the conditions of all exceedance days in 2010 through 2015 during the month of June in comparison to June 20, 2015; and (3) discussed the characteristics of June 20, 2015, as a rare Saturday exceedance.[24] We found that these analyses demonstrated the unusual nature of the June 20, 2015 event. We also found that, along with the previously described analyses, the matching day analyses sufficiently demonstrated a clear causal relationship between the emissions generated by the Lake Fire and the exceedances measured at the Phoenix area monitors.[25]

As explained in further detail in response to other comments elsewhere in this document, the commenter has not provided any evidence that undermines this finding that the weight of the evidence supports a clear causal relationship between the Lake Fire and the exceedances. Accordingly, we conclude that the weight of the evidence establishes that the clear causal criterion has been met for the June 20, 2015 event.

Comment: ACLIPI claimed that ''there is nothing 'exceptional' about exceedances of the 2008 ozone standard at the monitors at issue'' since ''these monitors routinely register some of the highest ozone concentrations in the Phoenix NAA.''

Response: The term ''exceptional'' in the context of exceptional events does not require that the concentrations be the highest observed at the monitoring sites. CAA section 319(b)(1)(A) defines an ''exceptional event'' as an event that:

> (i) affects air quality;
> (ii) is not reasonably controllable or preventable;
> (iii) is an event caused by human activity that is unlikely to recur at a particular location or a natural event; and
> (iv) is determined by the Administrator through the process established in the [Exceptional Events Rule] to be an exceptional event.[26]

A previous version of the Exceptional Events Rule required that, in addition to meeting these statutory elements criteria, states also submit evidence that the event was associated with a measured concentration in excess of normal historical fluctuations, including background.[27] However, in the 2016 revisions to the Rule, the EPA removed this requirement and replaced it with a requirement for states to provide analyses comparing the claimed event-influenced concentration(s) to concentrations at the same monitoring site at other times in support of the clear causal criterion.[28] The revised rule also provides that states are not required to prove a specific percentile point in the distribution of data.[29] In other words, ''[t]here is no pass or fail threshold for the historical concentrations data presentation.'' [30]

Nonetheless, to facilitate development and evaluation of demonstrations for

[16] Id.

[17] Id. at 9.

[18] Id.

[19] Id. at 11.

[20] Id.

[21] Id.

[22] $PM_{2.5}$ is made of many different chemical species, including EC and OC. Elevated OC concentrations and low EC/OC ratios are generally associated with biomass smoke and therefore indicate the presence of wildfire emissions. See first addendum, 10.

[23] Id. at 13.

[24] Id. at 13–14.

[25] Id. at 14–15.

[26] See also 40 CFR 50.1(j).

[27] 40 CFR 50.14(c)(3)(iv)(C) (2007 version).

[28] 40 CFR 50.14(c)(3)(iv)(C) (2017 version). See also 81 FR 68241–68245.

[29] 40 CFR 50.14(c)(3)(iv)(C).

[30] Wildfire Ozone Guidance, 10.

wildfire-influenced ozone exceedances, the EPA has suggested statistical benchmarks for comparing the event-related ozone concentration with non-event-related high ozone concentrations as part of ''Tier 2 key factor 2.'' [31] Specifically, for key factor 2, a state would show that the exceedance is either (1) in the 99th or higher percentile of the 5-year distribution of ozone monitoring data, or (2) one of the four highest ozone concentrations within 1 year (among those concentrations that have not already been excluded under the Exceptional Events Rule, if any).[32] If either of these two criteria is met, then the event-influenced data are generally considered to be high compared to other data at the monitoring site.[33]

In this case, as part of the Tier 2 key factor 2 analyses,[34] ADEQ demonstrated that five of the six monitors had daily maximum 8-hour average ozone concentrations during the event at or above the 99th percentile for the 5-year period, while one monitor (Pinnacle Peak) did not. However, the event ozone concentration at Pinnacle Peak was the third highest ozone concentration measured at the site in 2015.[35] Based on the concentrations observed at these monitors, the event exceedances meet Tier 2 key factor 2, and are therefore high relative to other data at the monitoring site.

Comment: The commenter asserted that the exceedances were caused by local conditions and that ''if a wildfire smoke plume had transported to the Phoenix NAA and uniformly influenced its monitors, it would have caused abnormally high concentrations across the nonattainment area, or at least an atypical pattern of such concentrations,'' but ''[i]nstead the monitors that recorded the highest ozone concentrations were predictably located in the upslope/northeastern upslope portion.''

Response: As noted in the Wildfire Ozone Guidance, ozone production is non-linear and therefore impacts of wildfire emissions on ozone can be difficult to predict. While an atypical pattern of exceedances could provide additional evidence to support that wildfire emissions affected ozone concentrations, the lack of such a pattern does not preclude a finding that wildfire emissions influenced a monitor. Similarly, an area-wide increase is not a necessary factor to demonstrate a clear causal relationship between the wildfire emissions and observed exceedances. The EPA evaluated other analyses and evidence provided in the demonstration and addenda and concluded that the weight of the evidence established a clear causal relationship between the Lake Fire and the June 20, 2015 exceedances.

Comment: The commenter claimed that ''[t]here is nothing unusual about the fact that the June 2015 exceedances occurred on a Saturday'' and that ''[n]either ADEQ nor EPA has presented any support for the notion that high ozone concentrations on the weekend must have been affected by wildfire emissions, and that EPA cannot simply assume this to be true.''

Response: ADEQ provided evidence that the characteristics of the June 20, 2015 Saturday exceedances were unique. ADEQ reviewed all Saturday exceedances at the six monitors during the month of June from 2010 to 2015 and found that there were only two other Saturdays where exceedances were measured. These two other Saturday exceedance days were preceded by higher exceedances on the day prior (Friday) as part of a multi-day event from the weekday. The June 20, 2015 exceedance, however, ''is not a part of a prior episode event, and shows an increase of ozone from a Friday to Saturday,'' and ''the event is unique when compared to the prior six years of exceedance data and strongly suggests that an outside source of ozone or ozone precursor emissions caused the exceedances.'' [36] The EPA agreed that the exceedances were unusual, which points to a unique emissions source contributing to the exceedances, but did not claim that the unusual nature of these Saturday exceedances alone specifically identified wildfire emissions as the cause. Rather, the EPA considered the information indicating that the exceedances were unusual as part of the weight of evidence approach.

Comment: The commenter claimed that while the ''EPA correctly found that $PM_{2.5}$ concentrations were not elevated in the nonattainment area and therefore did not demonstrate wildfire influence, [the] EPA erroneously concluded this could be overcome by speciated carbon concentration data obtained from the Phoenix JLG Supersite ('Supersite') monitor.'' The commenter noted that ''the Supersite [monitor] did not exceed the 2008 standard on June 20, 2015; showed no signs of being significantly influenced by wildfire smoke on that day; and is located a minimum of 15 miles away from the nearest 'exceptional events' monitor.''

Response: Speciated carbon concentration data (*i.e.,* EC and OC data) are relevant in evaluating the existence of clear causal relationship between fire emissions and ozone exceedances because elevated OC concentrations and low EC/OC ratios are generally associated with biomass smoke and therefore indicative of the presence of wildfire emissions.[37] In this case, the Supersite monitor is the only location within the Phoenix NAA that measures EC and OC and is therefore the appropriate source of such data.[38]

The speciated carbon analysis at Supersite indicated elevated OC concentrations and relatively low EC/OC ratios, suggesting that wildfire emissions were present in the area. The fact that the Supersite monitor did not exceed the ozone standard on June 20, 2015, does not undermine the relevance of these data. Ozone is a secondary pollutant formed through photochemical production in a non-linear fashion. While precursors to ozone may be present in one location, ozone formation may occur on different spatial and temporal scales. In this instance the Supersite monitor showed elevated OC concentrations, relatively low EC/OC ratios, and elevated levels of NO_2, an ozone precursor emitted by wildfires; these indicate the presence of wildfire emissions in the area. While the Supersite monitor did not itself experience exceedances of the ozone NAAQS during the event, other monitors in the vicinity did. In addition, two other monitors besides the Supersite monitor showed elevated levels of NO_2.[39] This pattern is

[31] Id. at 21.

[32] Id.

[33] Id.

[34] The June 20, 2015 event did not qualify for a Tier 2 analysis because it did not meet Tier 2 Factor 1. TSD, 8. However, the EPA recommends that, as part of a Tier 3 analysis, that states ''explain how the events, monitor and exceedance compare'' with the Tier 2 key factors. Guidance, 26.

[35] TSD, 8.

[36] First addendum, 24.

[37] See, *e.g.,* J.L. Hand, et al. ''Spatial and Temporal Trends in $PM_{2.5}$ Organic and Elemental Carbon across the United States,'' *Advances in Meteorology,* Article ID 367674 (2013); Dan Jaffe, et al. ''Interannual Variations in $PM_{2.5}$ due to Wildfires in the Western United States'' *Environmental Science and Technology,* 42, 2812–2818 (2008); Dominic Spracklen., et al. ''Wildfires drive interannual variability of organic carbon in the western U.S. in summer,'' *Geophysical Research Letters,* 34, L16816 (2007).

[38] See Wildfire Ozone Guidance, 22 (supporting analyses of pollutants associated with wildfire emissions can be ''co-located or nearby'' the exceeding monitoring site(s) and ''in the same airshed (or nonattainment/near nonattainment area).'').

[39] As noted in response to the next comment, these were the only two other sites with NO_2 data determined to be relevant for this analysis. In addition, none of the other sites in the Phoenix NAA measure EC and OC, so those sites may have also had elevated OC concentrations and low EC/OC ratios.

consistent with the presence of wildfire emissions in the area contributing to the formation of ozone at the affected monitoring sites and thus supports the existence of a clear causal relationship between the wildfire emissions and the exceedances on June 20, 2015.

Comment: The commenter claimed that ''ADEQ's reliance on NO_2 concentration data is . . . misplaced'' due to the EPA statement that ''NO_2 is a poor tracer for fire because it is not specific to fire emissions and is emitted in large amounts by several anthropogenic sources (*e.g.,* cars, power plants)'' and that the West Phoenix, Central Phoenix, and Supersite monitors ''did not record abnormally high ozone concentrations on June 20, 2015'' and ''they are too far away from the 'exceptional events' monitors to provide relevant data.'' The commenter also stated that ADEQ ''should include data for all monitors in the NAA and not cherry-pick the data that arguably support its conclusion.''

Response: The EPA agrees that NO_2 is a poor tracer for isolating wildfire emissions because NO_2 is emitted by both anthropogenic sources and wildfires. However, given that NO_2 is emitted by wildfires and is a precursor to ozone, evidence of the presence or absence of elevated NO_2 concentrations in the nonattainment area around the time of the exceedances is relevant to review as part of the weight of evidence for determining whether a clear causal relationship between the wildfire emissions and the exceedances exists. Accordingly, in reviewing ADEQ's demonstration, we found that evidence concerning elevated NO_2 concentrations provided some additional support to the conclusion that the wildfire emissions affected the monitors.[40] Specifically, ADEQ's analysis revealed that ''several of the recorded hourly NO_2 concentrations were at or above the 95th percentile on [Saturday] June 20, 2015'' at West Phoenix, Central Phoenix, and Supersite, whereas daily NO_2 concentrations are typically lowest on weekend days.[41] Accordingly, we agreed with ADEQ's conclusion that concentrations of NO_2 at these monitors were unusual. However, we did not claim that the elevated concentrations alone were sufficient to demonstrate a clear causal relationship between wildfire emissions and the monitored exceedances. Instead, the EPA considered the unusual NO_2 concentrations as one of several pieces of evidence that supported the existence of a clear causal relationship using the weight of evidence approach.

As for the monitors chosen for this analysis, we believe that ADEQ provided an adequate rationale for focusing on West Phoenix, Central Phoenix, and Supersite monitoring sites: NO_2 is only monitored at six sites in the area, and the remaining three that were not included in this analysis were either outside of the Phoenix NAA (Buckeye) or serve as mobile source-oriented near-road monitors (Diablo and Thirty-Third Avenue).

Comment: The commenter claimed that, while ''ADEQ argues based on regression analysis that it is unusual for ozone concentrations to be so high at exceeding monitors under prevailing weather conditions,'' this analysis ''mainly proved that the regression equation it used consistently failed to predict high real-world ozone concentrations unaffected by wildfire.''

Response: The EPA agrees that the regression analysis consistently underpredicted ozone at high concentrations, including for non-event exceedances. As noted in the Technical Support Document (TSD) for our concurrence on the June 20, 2015 event, the regression analysis also did not meet metrics described in the Wildfire Ozone Guidance.[42] In evaluating the weight of the evidence, the EPA did not rely on the regression analysis to support the clear causal determination.

Comment: The commenter stated that the ''matching day analysis did not bolster the case for an 'exceptional event' '' as ''[t]he most this analysis could show was that the meteorological conditions that existed on June 20, 2015, would not normally be enough to be the sole cause of an exceedance of the 2008 ozone standard at the monitors that recorded exceedances.''

Response: The EPA agrees that the matching day analysis does not specifically implicate wildfire emissions. The EPA considered the matching day analysis as one of several pieces of evidence that supported the existence of a clear causal relationship using the weight of evidence approach. As explained in the TSD and elsewhere in this document, other pieces of evidence provided by ADEQ do implicate wildfire emissions. The commenter has not suggested an alternative cause for the unusually elevated levels of ozone on June 20, 2015, other than wildfire emissions, and we are not aware of any such cause.

Comment: ACLIPI claimed that satellite images of smoke over the Phoenix NAA are inconsistent with such smoke originating from the Lake Fire due to the shape and location of the smoke, and the ''upper air'' and ''lower air'' pathways in the conceptual model are ''difficult to conceive.''

Response: We disagree with the commenter's assertions that the observed smoke is unlikely to be from the Lake Fire and that the transport pathways within the conceptual model are unlikely. The observed smoke covers a large area and is both visible in the satellite imagery and identified as smoke as part of the NOAA smoke maps discussed further in a subsequent response. The satellite imagery also shows the smoke only at a snapshot in time; the shape and location of the smoke at a single point in time is inadequate to judge whether the smoke was transported from the Lake Fire (as opposed to fires in Mexico). The HYSPLIT trajectory analyses presented in the demonstration and addenda are consistent with this smoke originating from the Lake Fire. The size of the Lake Fire, relative to the fires in Mexico, also supports that the smoke originated from the Lake Fire.

As for the ''upper air'' and ''lower air'' pathways, ADEQ clearly described these in the second addendum and supported them with evidence including multiple HYSPLIT trajectories from different locations and at different times, a multi-dimensional dew point and water vapor analysis, and meteorological data from within the Phoenix NAA regarding boundary layer depths. The EPA found that these technical analyses supported the pathways identified in the conceptual model. The commenters did not provide any technical evidence to contradict these analyses or support their claim that the pathways are questionable.

Comment: The commenter stated that ''[t]he NOAA smoke maps tend to show that any transported Lake Fire smoke (as opposed [to] smoke from other sources) bypassed the Phoenix NAA completely'' and ''are inconclusive at best.''

Response: We disagree with the commenter's claims that the NOAA smoke maps show that transported Lake Fire smoke bypassed the Phoenix NAA completely. Multiple NOAA smoke maps show light and moderate levels of smoke over the nonattainment area. As described in the response to a previous comment regarding satellite imagery of smoke, this smoke was consistent with HYSPLIT trajectories showing transport from the Lake Fire. Additionally, the maps show smoke at a single point in time (*i.e.,* when a satellite passes overhead); smoke that is near the Phoenix NAA at the time corresponding to the smoke map may pass through the

[40] TSD, 13.

[41] First Addendum, 17.

[42] TSD, 13.

Phoenix NAA at another time. The maps cannot be used to show that smoke ''bypassed the [area] completely'' since they do not represent all points in time.

Comment: The commenter claimed that the estimated emissions quantity over distance (Q/D) ratio of 54 tons per day/kilometers (tpd/km) is ''well below the value of 100 tpd/km that EPA recommends as indicating clear causality.''

Response: The commenter has mischaracterized the nature of the 100 Q/D threshold in the Wildfire Ozone Guidance. A Q/D value of 100 or more does not by itself indicate clear causality, nor does a Q/D value less than 100 indicate the absence of clear causality. Rather, the Q/D ratio is one of two factors that the EPA uses to evaluate whether a Tier 2 or Tier 3 clear causal analysis is appropriate for a particular exceptional events demonstration.[43] The Guidance explains that the EPA selected 100 tpd/km ''as a conservative indicator'' of ozone impacts.[44] The EPA has concurred on a number of fire-related exceptional events demonstrations with Q/D values well below 100 tpd/km.[45]

Because the ratio for the June 20, 2015 event did not meet the 100 Q/D threshold for a Tier 2 analysis, we determined that a Tier 3 analysis, involving additional supportive documentation, was appropriate for this event. As described elsewhere in this document, ADEQ provided such additional documentation in the form of several different technical analyses. Collectively, the weight of this evidence establishes a causal relationship between the Lake Fire and the June 20, 2015 exceedances for the June 20, 2015 event.

Comment: ACLIPI asserted that it is unclear whether ADEQ provided adequate notice regarding the opportunity to comment on its exceptional events documentation. Specifically, ACLIPI asserted that ''ADEQ maintains email lists of parties interested in air quality actions to which the agency regularly distributes notices regarding upcoming rulemakings. If ADEQ sent notice to any stakeholders concerning its proposed exceptional events demonstration, it should explain how and to whom it sent notice.''

Response: The Exceptional Events Rule requires that, as part of the submission of an exceptional events demonstration, a state must (1) document that it followed a public comment process, including a comment period of at least 30 days; (2) submit any public comments received; and (3) address any comments disputing or contradicting factual evidence provided in the demonstration.[46] Although emailing stakeholders is one means of providing public notice of draft exceptional events demonstration,[47] nothing in the Exceptional Events Rule or the Clean Air Act requires states to take this approach. Rather, ''[p]roviding sufficient opportunity for public comment for a demonstration is case-by-case and depends on the circumstances and intended audience.'' [48]

In this case, for each of the submissions, ADEQ provided public notice by posting the draft demonstration submissions on its website and publishing a notice in the Arizona Republic at the start of the 30-day public comment period.[49] The EPA considers this to be adequate public notice under 40 CFR 51.14(c)(3)(v). Therefore, ADEQ is not required to explain whether or not it sent notice to any stakeholders.

Comment: ACLIPI asserted that, for the reasons previously cited in its comment letter, the EPA's invitation to the State to withdraw its contingency measure is unwarranted and should be revoked.

Response: In conjunction with our proposed finding of attainment by the applicable attainment date, we also proposed to determine that the CAA requirement for the State to submit a SIP revision to provide for contingency measures to be implemented in the event the area fails to attain by its attainment date (''attainment contingency measures'') will no longer apply for the Phoenix NAA. The State has already submitted a SIP revision providing for attainment contingency measures, so we also noted that the State could elect to withdraw the attainment contingency measures to lift the obligation on the EPA under section 110(k) to act on these measures.

For the reasons described in our proposal and elsewhere in this document, we are finalizing our determination that the Phoenix NAA attained the 2008 ozone standard by its Moderate area attainment date of July 20, 2018, and our determination that there is no existing requirement for attainment contingency measures for the 2008 ozone NAAQS in the Phoenix NAA.

Comment: ACLIPI argued that the EPA was incorrect that its proposed rulemaking ''does not directly affect the level of protection provided for human health or the environment'' and ''does not concern an environmental health risk'' to children. The commenter asserted that, if the EPA makes a determination of attainment by the attainment date, the Phoenix NAA would not be reclassified (''bumped up'') to a ''Serious'' classification, and the State would be ''excused from having to adopt and implement additional or more effective control measures, at least until the Phoenix NAA is inevitably reclassified to ''[M]oderate'' for the 2015 ozone standard.'' The commenter concluded that this delay poses a significant risk to human health, particularly for children, the elderly, and people with preexisting lung and cardiovascular diseases.

Response: We disagree with this comment. As explained in a previous response, we are required to determine whether the Phoenix NAA attained the 2008 ozone NAAQS by its Moderate area date of July 20, 2018, based on 2015–2017 data, which show that the area attained the 2008 ozone NAAQS during that period. This determination does not in and of itself affect the level of protection provided for human health, children's health, or the environment.

As alluded to by the commenter, if we had determined the Phoenix NAA had not attained the 2008 NAAQS by the attainment date, we would have reclassified the area to Serious nonattainment, which would have triggered additional planning and implementation requirements. However, this would not have directly altered the level of protection for human health or the environment within the area since the area would ultimately have been obligated to meet the same NAAQS.

In addition, the Phoenix area is currently designated and classified as a ''Marginal'' nonattainment area for the

[43] Guidance, 16–22.

[44] Guidance, 17.

[45] See, *e.g.,* ''Technical Support Document for EPA Concurrence on Ozone Exceedances Measured in Connecticut on May 25 and 26, 2016 as Exceptional Events'' (attachment to letter dated July 31, 2017), 7; ''Technical Support Document for EPA Concurrence on Ozone Exceedances Measured in Massachusetts on May 25 and 26, 2016 as Exceptional Events'' (attachment to letter dated September 19, 2017), 7;''Technical Support Document for EPA Concurrence on Ozone Exceedances Measured in Rhode Island on May 25 and 26, 2016 as Exceptional Events'' (attachment to letter dated September 19, 2017), 7.

[46] 40 CFR 50.14(c)(3)(v).

[47] See ''2016 Revisions to the Exceptional Events Rule: Update to Frequently Asked Questions,'' July 2019, 26.

[48] Id. at 25.

[49] May 18, 2018 submittal Section I, 4 and Appendix D; letter dated July 17, 2018, from Timothy Franquist, ADEQ, to Michael Stoker, EPA Region 9,; Demonstration, 4, Appendix E; First addendum, 2, Appendix B; letter dated July 17, 2018, from Timothy Franquist, ADEQ, to Michael Stoker, EPA Region 9; Second addendum, 1, Appendix C; letter dated April 26, 2019, from Timothy Franquist, ADEQ, to Michael Stoker, EPA Region 9.

2015 ozone NAAQS.[50] The EPA will determine whether the area has met the August 3, 2020 Marginal attainment date for the 2015 standard based on 2017–2019 monitoring data. While the commenter appears to assume that the area will not attain by the Marginal attainment date, and will therefore be bumped up to Moderate, the data are not yet available to make this determination.

Commenter #2: Public Comment (No Name)

Comment: The commenter argued that the EPA cannot make a determination of attainment because the ozone data being used is old (2015–2017). The commenter suggested that the EPA must have 2018 data, but that it has not provided updated design values on our public website. The commenter further noted that ADEQ has made 2018 data publicly available, and that these data show more than 26 days in 2018 when the 2008 NAAQS was exceeded. The commenter asserted that, with this number of exceedances, the EPA cannot make a determination of attainment and has a statutory obligation to bump up the area and require the State to comply with Serious area requirements.

Response: As explained above in response to a similar comment from ACLIPI, we are not permitted to consider 2018 or 2019 data in evaluating whether the area attained by the applicable attainment date of July 20, 2018. Our statutory obligation under CAA section 181(b)(2)(A) is to determine whether the Phoenix NAA attained the standard by the applicable attainment date based on the design value as of the attainment date. We are fulfilling that obligation with today's final action.

We also note that agency air data submitted to the EPA's Air Quality System (AQS) database is considered preliminary until such data are certified. Agencies are required to certify the data annually by May 1 of the following year. For example, the deadline for agencies to certify data collected during calendar year 2018 was May 1, 2019. After the certification deadline, the design values are reviewed by EPA staff before they are posted to the EPA website, which generally occurs within a few months of the certification deadline. The 2018 design values were posted to the EPA's website on July 23, 2019. The EPA makes both preliminary data submitted to the AQS database and data submitted to AirNow for public notification purposes available on the EPA's Air Data web page prior to data certification.[51]

Commenter #3: Arizona Chamber of Commerce

Comment: The commenter expressed support for the proposed determination and argued that it is proper to exclude the ''Qualifying Exceptional Events.''

Response: The EPA acknowledges the commenter's support for this action.

Comment: The commenter stated that the main cause of ozone is emissions from road and non-road engines, additional restrictions on major sources will not have a measurable impact on ozone levels, the Phoenix NAA has high background ozone and transport, and that the most effective way to reduce emissions in the area is to reduce emissions from on road and non-road engines through an emissions reduction credit (ERC) program for non-traditional ERCs. The commenter urged the EPA to help ADEQ and Maricopa County to establish an ERC framework for nontraditional sources so that the area can reduce emissions from vehicle emissions for 2015 NAAQS.

Response: The EPA acknowledges the comment but notes that it is not relevant to this action.

Commenter #4: Maricopa County

Comment: The commenter expressed support for the proposed determination of attainment by the attainment date.

Response: The EPA acknowledges the commenter's support for this action.

Commenter #5: ADEQ

Comment: The commenter expressed support for the proposed determination of attainment by the attainment date.

Response: The EPA acknowledges the commenter's support for this action.

III. EPA Action

No comments were submitted that change our assessment of the determinations as described in our proposed action. Therefore, the EPA is finalizing our determination that the Phoenix NAA attained the 2008 ozone standard by the Moderate area attainment date of July 20, 2018. We are also finalizing our determination that attainment contingency measures for this NAAQS no longer apply to the Phoenix NAA.

This action does not suspend the attainment-related requirements for the Phoenix NAA under 40 CFR 51.1118. We also note that this determination that the Phoenix ozone NAA has attained the 2008 ozone NAAQS does not constitute a redesignation of the area to attainment for the 2008 ozone standard. Under CAA section 107(d)(3)(E), redesignations to attainment require states to meet additional statutory criteria, including the EPA's approval of a SIP revision demonstrating maintenance of the standard for 10 years after redesignation. The designation status of the Phoenix area will remain Moderate nonattainment for the 2008 ozone NAAQS until such time as the EPA determines that the area meets the CAA requirements for redesignation to attainment.

IV. Environmental Justice Considerations

The EPA believes that this action will not have disproportionately high or adverse human health or environmental effects on minority, low-income, or indigenous populations. The purpose of this rule is to determine whether the Phoenix NAA attained the 2008 ozone standard by the Moderate area attainment date, which is required under the CAA for purposes of implementing the 2008 ozone standard. As such, this action does not directly affect the level of protection provided for human health or the environment.

V. Statutory and Executive Order Reviews

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

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

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is not an Executive Order 13771 regulatory action because this action is not significant under Executive Order 12866.

C. Paperwork Reduction Act (PRA)

This rule does not impose any new information collection burden under the PRA not already approved by the OMB.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in

[50] 40 CFR 81.303.

[51] *https://www.epa.gov/outdoor-air-quality-data.*

UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. This action imposes no enforceable duty on any state, local or tribal governments, or the private sector.

F. Executive Order 13132: Federalism

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

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

This action has tribal implications. However, it will neither impose substantial direct compliance costs on federally recognized tribal governments, nor preempt tribal law. Four tribes have areas of Indian country within or directly adjacent to the Phoenix NAA: Fort McDowell Yavapai Nation, Gila River Indian Community, Salt River Pima-Maricopa Indian Community of the Salt River Reservation, and the Tohono O'odham Nation of Arizona. The EPA sent letters to potentially affected tribes located within or directly adjacent to the boundaries of the Phoenix NAA informing them of our proposed action and offering consultation.[52] We did not receive any requests for consultation.

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

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

I. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

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

[52] See letters from Elizabeth Adams, EPA Region IX Air and Radiation Division Director, to tribal officials, dated June 13, 2019.

J. National Technology Transfer Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

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

The EPA believes the human health or environmental risk addressed by this action will not have potential disproportionately high and adverse human health or environmental effects on minority, low-income, or indigenous populations. The results of this evaluation are contained in the section of the preamble titled ''Environmental Justice Considerations.''

L. Congressional Review Act (CRA)

The CRA, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this action 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 publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

M. Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 13, 2020. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

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

Dated: October 21, 2019.

Deborah Jordan,

Acting Regional Administrator, Region IX.

Part 52, Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for Part 52 continues to read as follows:

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

Subpart D—Arizona

■ 2. Add § 52.153 to read as follows:

§ 52.153 Control strategy and regulations: Ozone.

(a) *Determination of attainment by the attainment date.* Effective December 12, 2019 the EPA has determined that the Phoenix-Mesa Moderate nonattainment area in Arizona attained the 2008 8-hour ozone National Ambient Air Quality Standards (NAAQS) by the applicable attainment date of July 20, 2018, based upon complete, quality-assured, and certified data for the calendar years 2015–2017. The EPA has also determined that the requirement of section 172(c)(9) to provide for contingency measures to be implemented in the event the area fails to attain by its attainment date for the 2008 8-hour NAAQS does not apply to the area.

(b) [Reserved]

[FR Doc. 2019–23829 Filed 11–8–19; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[EPA–R04–OAR–2018–0552; FRL–10001–35–Region 4]

Air Plan Approval and Designation of Areas; FL; Redesignation of the Hillsborough County 2010 1-Hour Sulfur Dioxide Nonattainment Area to Attainment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: In a letter dated June 7, 2018, the State of Florida, through the Florida Department of Environmental Protection (FDEP), submitted a request for the Environmental Protection Agency (EPA) to redesignate the Hillsborough County sulfur dioxide (SO_2) nonattainment area (hereinafter referred to as the

''Hillsborough County Area'' or ''Area'') to attainment for the 2010 1-hour SO_2 primary national ambient air quality standard (NAAQS) and to approve an accompanying state implementation plan (SIP) revision containing a maintenance plan for the Area. Through a letter dated April 16, 2019, FDEP submitted a revision to the June 7, 2018, redesignation request and SIP revision asking EPA to incorporate certain conditions into the SIP from a recent permit revision applicable to the Tampa Electric Company—Big Bend Station (Big Bend) power plant. EPA is taking final action: To determine that the Hillsborough County Area attained the 2010 1-hour SO_2 NAAQS by its applicable attainment date of October 4, 2018; to approve the SIP revision containing the State's plan for maintaining attainment of the 2010 1-hour SO_2 standard and to incorporate the maintenance plan into the SIP; to redesignate the Hillsborough County Area to attainment for the 2010 1-hour SO_2 NAAQS; and to incorporate into the SIP certain permitting conditions applicable to Big Bend, including a condition that lowers the SO_2 emissions cap and a condition that restricts fuel use at two electric generating units to natural gas.

DATES: This rule will be effective December 12, 2019.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R04–OAR–2018–0552. All documents in the docket are listed on the *www.regulations.gov* website. Although listed in the index, some information may not be publicly available, *i.e.,* confidential business information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Madolyn Sanchez, Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. Ms. Sanchez may be reached by phone at (404) 562–9644 or via electronic mail at *sanchez.madolyn@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. What is the background for the actions?

On June 2, 2010, EPA revised the primary SO_2 NAAQS, establishing a new 1-hour SO_2 standard of 75 parts per billion (ppb). *See* 75 FR 35520 (June 22, 2010). Under EPA's regulations at 40 CFR part 50, the 2010 1-hour SO_2 NAAQS is met at a monitoring site when the 3-year average of the annual 99th percentile of daily maximum 1-hour average concentrations is less than or equal to 75 ppb (based on the rounding convention in 40 CFR part 50, appendix T). *See* 40 CFR 50.17. Ambient air quality monitoring data for the 3-year period must meet a data completeness requirement. A year meets data completeness requirements when all four quarters are complete, and a quarter is complete when at least 75 percent of the sampling days for each quarter have complete data. A sampling day has complete data if 75 percent of the hourly concentration values, including state-flagged data affected by exceptional events which have been approved for exclusion by the Administrator, are reported.[1]

Upon promulgation of a new or revised NAAQS, the Clean Air Act (CAA or Act) requires EPA to designate as nonattainment any area that does not meet (or that contributes to ambient air quality in a nearby area that does not meet) the NAAQS. EPA designated the Hillsborough County Area as nonattainment for the 2010 1-hour SO_2 NAAQS, effective on October 4, 2013, using 2009–2011 complete, quality assured, and certified ambient air quality data. *See* 78 FR 47191 (August 5, 2013). The Hillsborough County Area is comprised of the portion of Hillsborough County encompassed by the polygon with the vertices using Universal Traverse Mercator (UTM) coordinates in UTM zone 17 with datum NAD83 as follows: (1) Vertices-UTM Easting (m) 358581, UTM Northing 3076066; (2) vertices-UTM Easting (m) 355673, UTM Northing 3079275; (3) UTM Easting (m) 360300, UTM Northing 3086380; (4) vertices-UTM Easting (m) 366850, UTM Northing 3086692; (5) vertices-UTM Easting (m) 368364, UTM Northing 3083760; and (6) vertices-UTM Easting (m) 365708, UTM Northing 3079121. Under the CAA, nonattainment areas must attain the NAAQS as expeditiously as practicable but not later than five years after the October 4, 2013, effective date of the designation. *See* CAA section 192(a). Therefore, the Hillsborough County Area's applicable attainment date was no later than October 4, 2018.

EPA's 2010 SO_2 nonattainment designation for the Area triggered an obligation for Florida to develop a nonattainment SIP revision addressing certain requirements under title I, part D, subpart 1 (hereinafter ''Subpart 1''), and to submit that SIP revision to EPA in accordance with the deadlines in title I, part D, subpart 5 (hereinafter ''Subpart 5''). Subpart 1 contains the general requirements for nonattainment areas for criteria pollutants, including requirements to develop a SIP that provides for the implementation of reasonably available control measures (RACM), requires reasonable further progress (RFP), includes base-year and attainment-year emissions inventories, a SIP-approved nonattainment new source review (NNSR) permitting program that accounts for growth in the area, enforceable emission limitations and other such control measures, and provides for the implementation of contingency measures. This SIP revision was due within 18 months following the October 4, 2013, effective date of designation (*i.e.,* April 4, 2015). *See* CAA section 191(a). Florida submitted a nonattainment SIP revision to EPA on April 3, 2015.

On July 3, 2017 (82 FR 30749), EPA approved Florida's April 3, 2015, SO_2 nonattainment SIP revision. This SIP revision provided a modeled attainment demonstration and satisfied the required nonattainment planning requirements mentioned above for the Hillsborough County Area. The revision included a base year emissions inventory, a modeling demonstration of attainment for the 2010 SO_2 NAAQS, RACM/Reasonable Available Control Technology (RACT), an RFP plan, a NNSR permitting program, and contingency measures for the Hillsborough County Area.

As part of that action, EPA incorporated into the Florida SIP specified SO_2 emissions caps, compliance monitoring, and recordkeeping and reporting requirements for emission units at the Mosaic Fertilizer, LLC Riverview facility (Permit No. 0570008–080–AC, issued on January 15, 2015) and Big Bend (Permit No. 0570039–074–AC, issued on February 26, 2015). Florida based its modeled attainment demonstration, submitted with its April 3, 2015,

[1] *See* 40 CFR part 50, appendix T, section 3(b).

nonattainment SIP revision, on these conditions. Big Bend has four emission units (EUs 1 through 4), and Big Bend's permit placed an SO_2 emissions cap on all four units at 3,162 pounds per hour (lb/hr) on a 30-day boiler operating day average. To demonstrate compliance with the four-unit cap, Permit No. 0570039–074–AC required each unit to monitor SO_2 emissions with a continuous emission monitoring system (CEMS).

On December 14, 2018, Florida issued a final air construction permit to Big Bend (Permit No. 0570039–120–AC) that, among other things, lowers the four-unit emissions cap from 3,162 lb/hr to 2,156 lb/hr; restricts EUs 1 and 2 to only burn natural gas; and since the amount of sulfur in natural gas is negligible, authorizes the removal of the SO_2 CEMS for EUs 1 and 2 and requires monitoring for these two units in accordance with the calculation method allowed for gas-fired acid rain units in 40 CFR part 75 to demonstrate compliance with the lowered emissions cap.[2] EUs 1 and 2 share a stack and a flue gas desulfurization (FGD) system to control SO_2. Permit No. 0570039–074–AC required certified CEMS as the method of SO_2 emissions monitoring and compliance for EUs 1 and 2. However, with the restriction on EUs 1 and 2 to burn natural gas in the revised permit, the new method of monitoring and compliance for EUs 1 and 2 utilizes the protocol in 40 CFR part 75, Appendix D to determine the hourly SO_2 emission rate from each unit. EUs 3 and 4 continue to certify compliance with the emissions cap through use of CEMS. Therefore, Big Bend will demonstrate compliance of the lowered four-unit emissions cap through a combination of 40 CFR part 75, Appendix D (EUs 1 and 2) and SO_2 CEMS data (EUs 3 and 4). As required by 40 CFR part 75, Appendix D, section 2.1, Big Bend will measure and record the hourly flow rate of natural gas combusted by EUs 1 and 2 with an in-line fuel flowmeter. The pounds-per-hour SO_2 emission rates for each of these two units will then be calculated by using the equation provided in 40 CFR part 75, Appendix D, section 3.3.1, along with the measured hourly natural gas flow rate to each unit and the vendor certified sulfur content of the combusted natural gas.

On June 7, 2018,[3] Florida submitted a request to EPA to redesignate the Hillsborough County Area to attainment for the 2010 1-hour SO_2 NAAQS and a related SIP revision containing a maintenance plan for the Area. On April 16, 2019, FDEP submitted a revision to the June 7, 2018, redesignation request and SIP revision asking EPA to incorporate into the SIP certain permit conditions established in Permit No. 0570039–120–AC.[4] As noted below, some of these conditions replace conditions that EPA incorporated into the SIP from Permit No. 0570039–074–AC in the Agency's July 3, 2017 action approving the State's nonattainment SIP. The conditions identified for incorporation into the SIP from Permit No. 0570039–120–AC are: (1) Section 2, Condition 4 (new)—describing the 40 CFR part 75, Appendix D monitoring methodology and compliance requirements for EUs 1 and 2; (2) the ''SO_2 Emissions Cap'' provision from Section 3, Condition 4 (replacement)—setting a four-unit emissions cap of 2,156 lb/hr averaged over a 30-day boiler operating day, requiring that EUs 1 and 2 demonstrate compliance with the cap by monitoring natural gas fuel flow and following the procedures in Appendix D to 40 CFR 75 to determine SO_2 mass emissions, and requiring that EUs 3 and 4 demonstrate compliance with the cap through CEMS; (3) the ''SO_2 CEMS'' provision from Section 3, Condition 4 (replacement)—requiring EUs 3 and 4 to use CEMS to demonstrate compliance with the cap and to meet the quality assurance and quality control requirements outlined in the facility's title V permit; and (4) the ''Methods of Operation'' for Units 1 and 2 provision from Section 3, Condition 6 (new)—restricting EUs 1 and 2 to burning only natural gas from a federally regulated pipeline. In a notice of proposed rulemaking (NPRM) published on July 31, 2019 (84 FR 37173), EPA proposed to determine that the Area attained the 2010 1-hour SO_2 NAAQS by its attainment date of October 4, 2018; to approve the maintenance plan for the Area as meeting the maintenance plan requirements of CAA section 175A and to incorporate it into the SIP; to approve Florida's request for redesignation of the Area from nonattainment to attainment for the 2010 1-hour SO_2 NAAQS as meeting the redesignation requirements of CAA section 107(d)(3)(E); and to incorporate into the SIP the aforementioned permitting conditions applicable to Big Bend. No comments were received on the July 31, 2019, proposed rulemaking. The details of Florida's submittal and the rationale for EPA's actions are further explained in the NPRM, including the modeled attainment demonstration and consideration of SO_2 ambient air monitoring data trends in the area to determine attainment with the 2010 1-hour SO_2 NAAQS.

II. What are the effects of these actions?

Approval of the redesignation request changes the legal designation of the Hillsborough County Area, found at 40 CFR 81.310, from nonattainment to attainment for the 2010 1-hour SO_2 NAAQS. Approval of Florida's associated SIP revision also incorporates a plan into the SIP for maintaining the 2010 1-hour SO_2 NAAQS in the Hillsborough County Area as described in the NPRM. The CAA section 175A maintenance plan also establishes contingency measures to remedy any future violations of the 2010 1-hour SO_2 NAAQS and procedures for evaluation of potential violations. The Area is required to implement this maintenance plan and the prevention of significant deterioration program for the 2010 1-hour SO_2 NAAQS. The approved maintenance plan can only be revised if the revision meets the requirements of CAA section 110(l) and, if applicable, CAA section 193. Approval of the SIP revision also incorporates into the SIP certain permitting conditions applicable to Big Bend, making them permanent and federally enforceable.

III. Incorporation by Reference

In this rule, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference into Florida's SIP the following conditions from Air Permit No. 0570039–120–AC issued by FDEP to Big Bend with an effective date of December 14, 2018, related to an SO_2 emissions cap and fuel restriction at the facility and associated compliance monitoring, recordkeeping, and reporting requirements:[5] (1) Section 2, Condition 4; (2) the ''SO_2 Emissions Cap'' provision from Section 3, Condition 4;[6] (3) the ''SO_2 CEMS''

[2] Florida incorporated the conditions applicable to Big Bend from Permit No. 0570039–120–AC into the facility's Title V operating permit on February 8, 2019.

[3] The June 7, 2018, submission was received by EPA on June 12, 2018.

[4] The April 19. 2019, submission was received by EPA on April 25, 2019.

[5] For additional information regarding these permit conditions, see Section I, above, and Section V of the NPRM.

[6] In its April 16, 2019, submittal, Florida identifies this provision as ''Section 3, Subsection B, Specific Condition 2''; however, it is contained under the heading ''4. Permit Being Modified: Permit No. 0570039–096–AC'' in Section 3 of Permit No. 0570039–120–AC. See Section V of the NPRM for additional information.

provision from Section 3, Condition 4;[7] and (4) the ''Methods of Operation'' for Units 1 and 2 provision from Section 3, Condition 6.[8] Therefore, these material have been approved by EPA for inclusion in the state implementation plan, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.[9]

EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and at the EPA Region 4 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

IV. Final Action

EPA is taking final actions regarding Florida's request to redesignate the Hillsborough County Area to attainment for the 2010 1-hour SO_2 NAAQS and associated SIP revision. EPA is determining that the Hillsborough County Area attained the 2010 1-hour SO_2 NAAQS by its applicable attainment date of October 4, 2018. EPA is also approving the SIP revision containing the State's plan for maintaining attainment of the 2010 1-hour SO_2 standard and incorporating the maintenance plan into the SIP. EPA is approving Florida's redesignation request and redesignating the Hillsborough County Area to attainment for the 2010 1-hour SO_2 NAAQS. Finally, EPA is incorporating the aforementioned permit conditions for Big Bend into the SIP. As mentioned above, approval of the redesignation request changes the official designation of the Hillsborough County Area from nonattainment to attainment, as found in 40 CFR part 81.

IV. Statutory and Executive Order Reviews

Under the CAA, redesignation of an area to attainment and the accompanying approval of a maintenance plan under section 107(d)(3)(E) are actions that affect the status of a geographical area and do not impose any additional regulatory requirements on sources beyond those imposed by state law. A redesignation to attainment does not in and of itself create any new requirements, but rather results in the applicability of requirements contained in the CAA for areas that have been redesignated to attainment. Moreover, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. *See* 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, these actions merely approve state law as meeting Federal requirements and do not impose additional requirements beyond those imposed by state law. For this reason, these actions:

- Are not significant regulatory actions subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Are not Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory actions because redesignations and SIP approvals are exempted under Executive Order 12866;
- Do not impose information collection burdens under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Are certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Do not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Do not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Are not economically significant regulatory actions based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Are not significant regulatory actions subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Are not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Will not have disproportionate human health or environmental effects under Executive Order 12898 (59 FR 7629, February 16, 1994).

These actions are not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action 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 publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 13, 2020. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. *See* section 307(b)(2).

List of Subjects

40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Sulfur dioxide, Reporting and recordkeeping requirements.

40 CFR Part 81

Environmental protection, Air pollution control.

Dated: October 10, 2019.

Mary S. Walker,

Regional Administrator, Region 4.

40 CFR parts 52 and 81 are amended as follows:

[7] In its April 16, 2019, submittal, Florida identifies this provision as ''Section 3, Subsection B, Specific Condition 3; however, it is contained under the heading ''4. Permit Being Modified: Permit No. 0570039–096–AC'' in Section 3 of Permit No. 0570039–120–AC. See Section V of the NPRM for additional information.

[8] In its April 16, 2019, submittal, Florida identifies this provision as ''Section 3, Subsection A, Specific Condition 3a; however, it is contained under the heading ''6. Permits Being Modified: Permit Nos. 0570039–066–AC & 109–AC'' in Section 3 of Permit No. 0570039–120–AC. See Section V of the NPRM for additional information.

[9] *See* 62 FR 27968 (May 22, 1997).

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

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

Subpart K—Florida

■ 2. Section 52.520 is amended by:

■ a. In paragraph (d), revising the entry for ''Tampa Electric Company—Big Bend Station'' Air Permit No. 0570039–074–AC,

■ b. In paragraph (d), adding a new entry for ''Tampa Electric Company—Big Bend Station'' at the end of the table, and

■ c. In paragraph (e), adding a new entry for ''2010 1-hour SO_2 Maintenance Plan for the Hillsborough Area'' at the end of the table to read as follows.

§ 52.520 Identification of plan.

* * * * *

(d) * * *

EPA-APPROVED FLORIDA SOURCE-SPECIFIC REQUIREMENTS

Name of source	Permit No.	State effective date	EPA approval date	Explanation
*	*	*	*	*
Tampa Electric Company-Big Bend Station.	Air Permit No. 0570039–074–AC.	2/26/2015	7/3/2017, 82 FR 30749	Only Section 3, Subsection B, Condition 5.
*	*	*	*	*
Tampa Electric Company-Big Bend Station.	Air Permit No. 0570039–120–AC.	12/14/2018	11/12/2019 [Insert citation of publication].	Only Section 2, Condition 4; the ''SO_2 Emissions Cap'' provision from Section 3, Condition 4; the ''SO_2 CEMS'' provision from Section 3, Condition 4; and the ''Methods of Operation'' for Units 1 and 2 provision from Section 3, Condition 6.

(e) ''

EPA-APPROVED FLORIDA NON-REGULATORY PROVISIONS

Provision	State effective date	EPA approval date	**Federal Register**, notice	Explanation
*	*	*	*	*
2010 1-hour SO_2 Maintenance Plan for the Hillsborough Area.	6/7/2018	11/12/2019	[Insert citation of publication].	

PART 81—DESIGNATION OF AREAS FOR AIR QUALITY PLANNING PURPOSES

■ 3. The authority citation for part 81 continues to read as follows:

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

■ 4. In § 81.310, the table entitled ''Florida-2010 Sulfur Dioxide NAAQS (Primary)'' is amended by revising the entry for ''Hillsborough County, FL'' to read as follows:

§ 81.310 Florida.

* * * * *

FLORIDA-2010 SULFUR DIOXIDE NAAQS (PRIMARY)

Designated area	Designation	
	Date [1]	Type
Hillsborough County, FL [2]	12/12/2019	Attainment
Hillsborough County (part).		
That portion of Hillsborough County encompassed by the polygon with the vertices using Universal Traverse Mercator (UTM) coordinates in UTM zone 17 with datum NAD83 as follows: (1) Vertices-UTM Easting (m) 358581, UTM Northing 3076066; (2) vertices-UTM Easting (m) 355673, UTM Northing 3079275; (3) UTM Easting (m) 360300, UTM Northing 3086380; (4) vertices-UTM Easting (m) 366850, UTM Northing 3086692; (5) vertices-UTM Easting (m) 368364, UTM Northing 3083760; and (6) vertices-UTM Easting (m) 365708, UTM Northing 3079121.		
*	*	*

[1] This date is 4/9/2018, unless otherwise noted.
[2] Excludes Indian country located in each area, if any, unless otherwise specified.
[3] Includes any Indian country in each county or area, unless otherwise specified. The EPA is not determining the boundaries of any area of Indian country in this table, including any area of Indian country located in the larger designation area. The inclusion of any Indian country in the designation area is not a determination that the state has regulatory authority under the Clean Air Act for such Indian country.

* * * * *

[FR Doc. 2019–23375 Filed 11–8–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2018–0094; FRL–10001–27]

Tebuconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of tebuconazole in or on multiple commodities which are identified and discussed later in this document. In addition, this regulation removes certain established tebuconazole tolerances that are superseded by new tolerances established in this final rule. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective November 12, 2019. Objections and requests for hearings must be received on or before January 13, 2020, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2018–0094, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can i get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Publishing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can i file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2018–0094 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before January 13, 2020. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2018–0094, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

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

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of July 24, 2018 (83 FR 34968) (FRL–9980–31), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7E8648) by IR–4 Project Headquarters, Rutgers, The State University of New Jersey, 500 College Road, East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.474 be amended by establishing tolerances for residues of the fungicide tebuconazole, including its metabolites and degradates, determined by measuring only alpha-[2-(4-chlorophenyl)ethyl]-alpha-(1,1-dimethylethyl)-1*H*-1,2,4-triazole-1-ethanol, in or on *Brassica,* leafy greens, subgroup 4–16B, except watercress at 2.5 parts per million (ppm); Cottonseed, subgroup 20C at 2.0 ppm; Fruit, pome, group 11–10 at 1.0 ppm; Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 6.0 ppm; Fruit, stone, group 12–12, except cherry at 1.0 ppm; Nut, tree, group 14–12 at 0.05 ppm; Sunflower, subgroup 20B at 0.1 ppm; Tropical and subtropical, small fruit, inedible peel, subgroup 24A at 1.6 ppm; and Watercress at 9.0 ppm.

Upon establishment of the above tolerances, the petitioner requested that the following established tolerances be removed from 40 CFR 180.474: *Brassica,* leafy greens, subgroup 5B at 2.5 ppm; Cotton, undelinted seed at 2.0 ppm; Fruit, pome, group 11 at 0.05 ppm; Fruit, stone, group 12, except cherry at 1.0 ppm; Grape at 5.0 ppm; Lychee at 1.6 ppm; Nut, tree, group 14 at 0.05 ppm; Peach at 1.0 ppm; Pistachio at 0.05 ppm; Plum, pre- and post-harvest at 1.0 ppm; and Sunflower, seed at 0.05 ppm, as they are superseded by this regulation. That document referenced a summary of the petition prepared by Makhteshim Agan of North America (''ADAMA''), the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA is establishing tolerances that vary slightly from what was requested. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for tebuconazole including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with tebuconazole follows.

A. Toxicological Profile

EPA has evaluated the available toxicity database and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

A summary of the toxicological profile for tebuconazole can be found in the final rule published in the **Federal Register** on November 15, 2013 (78 FR 68741) (FRL–9392–1). Specific information on the studies received and the nature of the adverse effects caused by tebuconazole as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document, ''Tebuconazole: Human Health Aggregate Risk Assessment for Establishment of Registrations and a Permanent Tolerance for Residues in/on Watercress, Add Greenhouse Tomato to Label and Crop Group Conversions/Expansions to *Brassica* Leafy Greens, Subgroup 4–16B, Except Watercress; Cottonseed, Subgroup 20C; Pome Fruit, Group 11–10, Stone Fruit, Group 12–12, Except Cherry; Small Vine Climbing Fruit, Except Fuzzy Kiwifruit, Subgroup 13–07F; Tropical and Subtropical Small Fruit, Inedible Peel, Subgroup 24A, Tree Nut, Group 14–12 and Sunflower, Subgroup 20B'' at pages 45–48 in docket ID number EPA–HQ–OPP–2018–0094.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides.*

A summary of the toxicological endpoints for tebuconazole used for human risk assessment is discussed in Unit III of the final rule published in the **Federal Register** of November 15, 2013 (78 FR 68741) (FRL–9392–1).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to tebuconazole, EPA considered exposure under the petitioned-for tolerances as well as all existing tebuconazole tolerances in 40 CFR 180.474. EPA assessed dietary exposures from tebuconazole in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for tebuconazole. In estimating acute dietary exposure, EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM–FCID) Version 3.16. This software uses food consumption information from the United States Department of Agriculture (USDA) 2003–2008 National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, a partially refined acute probabilistic dietary exposure assessment was conducted for all existing and proposed uses of tebuconazole. For the acute assessment, anticipated residues for grapes, grape juice, tree nuts, pome fruits, fruiting vegetables, cucurbit vegetables, banana, plantain, asparagus, hops, bulb onion and green onion subgroups, lychee, *Brassica* leafy green subgroup, mango, livestock commodities, and stone fruit were used. Data for peach, grapes, and oranges were derived using the latest USDA Pesticide Data Program (PDP) monitoring data. Anticipated residues for all other registered and proposed food commodities were based on field trial data or feeding studies. Anticipated residues for all current uses were further refined using percent crop treated (PCT) data where available. Percentage of imported orange juice and oranges were also provided. DEEM 2018 default and some empirical processing factors were assumed.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used DEEM–FCID, Version 3.16, which uses the food consumption data from the USDA 2003–2008 NHANES/WWEIA. As to residue levels in food, estimates from PDP data (mean residue levels) and average residues from field trials were used. Mean residue levels from PDP were used for apple, arugula, asparagus, snap bean, black bean, broad been, cowpea, great northern bean, kidney bean, lima bean, mung bean, navy bean, pinto bean, cantaloupe, cherry, chickpea, chives, fresh leaves, crabapple, garden and upland cress, cucumber, garden beet roots, goji berry, grape, raisin, grape juice, guar seed,

honeydew melon, leeks, lentil seed, loquat, milk, nectarine, mustard greens, oats, oat bran, green onion, oranges, orange juice, orange peel, peach, peach baby food, canned peach, peanut, peanut butter, pear, bell peppers, non-bell peppers, plum, rape greens, shallot bulb, shallot fresh leaves, soybean, summer squash, winter squash, tomatillo, tomato, tree tomato, watermelon, wheat grain and flour. In some cases, data were translated from representative commodities of their crop group.

iii. *Cancer.* Based on the data cited in Unit III.A. of the previously referenced document, **Federal Register**, November 15, 2013 (78 FR 68741) (FRL–9392–1), EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to tebuconazole. The chronic risk assessment or RfD approach is considered to be protective of any cancer effects; therefore, a separate quantitative cancer risk assessment is not required.

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: Data are available on pesticide use and food consumption in a particular area, and the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

For the acute dietary risk assessment, the Agency used the maximum PCT estimates for the following crops that are currently registered for tebuconazole: almonds 15%; apples 2.5%; apricots 20%; asparagus 30%; barley 2.5%; beans, green 2.5%; cantaloupes 10%; cherries 45%; corn 2.5%; cotton 2.5%; cucumbers 2.5%; dry beans/peas 5%; garlic 95%; grapes 40%; nectarines 30%; oats 2.5%; onions 5%; peaches 25%; peanuts 65%; pears 5%; pecans 25%; pistachios 15%; plums/prunes 5%; pumpkins 10%; soybeans 2.5%; squash 5%; sweet corn 5%; walnut 5%, and wheat 20%.

In the chronic dietary risk assessment, EPA used the average percent crop treated estimates for the following crops that are currently registered for tebuconazole: almonds 5%; apples 2.5%; apricots 10%; asparagus 5%; barley 2.5%; beans, green 1%; cantaloupes 2.5%; cherries 25%; corn 1%; cotton 1%; cucumbers 1%; dry beans/peas 2.5%; garlic 65%; grapes 25%; nectarines 20%; oats 2.5%; onions 5%; peaches 10%; peanuts 45%; pears 5%; pecans 10%; pistachios 5%; plums/prunes 2.5%; pumpkins 2.5%; soybeans 1%; squash 2.5%; sweet corn 2.5%; walnuts 2.5%; watermelons 15%; and wheat 15%.

The following estimated percent import estimates for the import oranges were used: For acute risk, orange 16%; and orange juice 58%; and for chronic risk: orange 12%; orange juice 46%. For all other crops not listed above, EPA assumed 100 PCT.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and California Department of Pesticide Regulation (CalDPR) Pesticide Use Reporting (PUR) for the chemical/crop combination for the most recent 10 years. EPA uses an average PCT for chronic dietary risk analysis and a maximum PCT for acute dietary risk analysis. The average PCT figures for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding up to the nearest 5%, except for those situations in which the average PCT is less than 1% or less than 2.5%. In those cases, the Agency would use less than 1% or less than 2.5% as the average PCT value, respectively. The maximum PCT figure is the highest observed maximum value reported within the most recent 10 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%, except where the maximum PCT is less than 2.5%, in which case, the Agency uses less than 2.5% as the maximum PCT.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which tebuconazole may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for tebuconazole in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of tebuconazole. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.*

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI–GROW) models, the EDWCs of tebuconazole for acute exposures are estimated to be 87.7 parts per billion (ppb) for surface water and 1.56 ppb for ground water. For chronic exposures for non-cancer assessments are estimated to be 68.8 ppb for surface water and 1.56 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, a

distribution of 30-year daily surface water concentration was estimated for the EDWCs of tebuconazole. For chronic dietary risk assessment, the water concentration of value 68.8 ppb was used to assess the contribution to drinking water. The Agency is relying on the drinking water residues used in the dietary risk assessment previously provided, ''Drinking water and ecological risk for new use of tebuconazole/fluoxastrobin combination for turf and ornamental use'', which can be found at *http://regulations.gov,* under docket ID number EPA–HQ–OPP–2013–0653–0007.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Tebuconazole is currently registered for the following uses that could result in residential exposures: Golf course turf, flower gardens, trees and ornamentals, and pressure treated wood that were assessed previously. No new residential uses of tebuconazole are associated with this petition.

EPA assessed residential exposure using the following assumptions: For residential handlers, exposure is expected to be short-term. Intermediate-term exposures are not likely because of the intermittent nature of applications by homeowners. For post-application exposures, the Agency assessed residential dermal and incidental oral post-application exposure for adults and children golfing, working in gardens, and performing physical activities on pressure-treated wood after application of tebuconazole as scenarios where homeowners may receive exposure to tebuconazole residues. Post-application exposure is expected to be short-term in duration. For assessment of both handler and post-application exposures, dermal and inhalation exposures were combined since the same endpoint and point of departure (POD) are used for both routes of exposure.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticide science-and-assessing-pesticide-risks/ standard-operating-procedures residential-pesticide.*

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to tebuconazole and any other substances. Previously, HED concluded that there are no conclusive data that the conazoles share a common mechanism of toxicity; however, EPA is in the process of re-examining these data as part of registration review. Although the conazole fungicides (triazoles) produce 1,2,4 triazole and its acid-conjugated metabolites (triazolylalanine and triazolylacetic acid), 1,2,4 triazole and its acid-conjugated metabolites do not contribute to the toxicity of the parent conazole fungicides (triazoles). Tebuconazole does not appear to produce any other toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that tebuconazole has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.*

The Agency has assessed the aggregate risks from the 1,2,4 triazole and its acid-conjugated metabolites (triazolylalanine and triazolylacetic acid) separately. The most recent assessment is dated August 8, 2018, titled, ''Common Triazole Metabolites: Updated Aggregate Human Health Risk Assessment to Address New Section 3 Registrations for Use of Prothioconazole and Tebuconazole.'' EPA concluded that the current uses of tebuconazole do not significantly change the results of that aggregate human health risk assessment. Therefore, the aggregate exposure to the triazole metabolites remains below EPA's level of concern.

D. Safety Factor for Infants and Children

Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

EPA has determined that reliable data support reducing the FQPA SF to 3X, as that factor will be safe for infants and children. Detailed discussions of the Agency's FQPA SF rationale can be found in the final rule published in the **Federal Register** on May 16, 2018 (83 FR 22995) (FRL9976–62), which also established tolerances for tebuconazole in/on various food commodities, and in the risk assessment document for the subject rulemaking found in docket ID number EPA–HQ–OPP–2018–0094 at *http://www.regulations.gov,* ''Tebuconazole: Human Health Aggregate Risk Assessment for Establishment of Registrations and a Permanent Tolerance for Residues in/on Watercress, Add Greenhouse Tomato to Label and Crop Group Conversions/ Expansions to *Brassica* Leafy Greens, Subgroup 4–16B, Except Watercress; Cottonseed, Subgroup 20C; Pome Fruit, Group 11–10, Stone Fruit, Group 12–12, Except Cherry; Small Vine Climbing Fruit, Except Fuzzy Kiwifruit, Subgroup 13–07F; Tropical and Subtropical Small Fruit, Inedible Peel, Subgroup 24A, Tree Nut, Group 14–12 and Sunflower, Subgroup 20B''.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* The acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to tebuconazole will occupy 94% of the aPAD for children 1 to 2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* There are no residential use patterns that result in chronic residential exposure to residues of tebuconazole. Dietary (food and water) route of exposure alone is

relevant to chronic aggregate risk. The combined chronic dietary exposure from food and drinking water is estimated to be 5.7% of the cPAD for the general U.S. population and 14% of the cPAD for all infants, the population subgroup with the highest estimated chronic dietary exposure to tebuconazole.

3. *Short- and Intermediate-term risks.* Short- and intermediate-term aggregate exposure take into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). For short-term aggregate risk assessments, a deterministic approach was used in which point estimates of exposure from each source are added together; and each of the point estimates used are in turn deterministic. Dietary exposure estimates use point estimates for food and drinking water residues (anticipated residues based on PDP data, field trial data, tolerance level residues, and PCT) and the residential scenarios also employ point estimates (central to high-end values considered protective). Exposures are assumed to occur over the same time frame, and no use frequency data are considered. There is the potential for residential exposure to co-occur with background dietary exposure over the short-term (1–30 days), whereas co-occurring intermediate exposures (1–6 months) are less likely. However, since the POD employed for both durations are the same, the aggregate assessments address both exposure durations.

EPA reassessed residential post-application exposure from registered golf course use and the impact on aggregate risk using the TTR study. Using data from the TTR study for non-irrigated and irrigated plots, EPA calculated residential post-application exposure and risk estimates for population subgroups including; adults, youths 11 to <16 years old, and children 6 to <11 years old. For these age groups, the activity of golfing results in MOEs for irrigated turf ranging from 2,100 in youth 6 to less than 11 years old to 2,500 in adults. For non-irrigated turf, for the same population subgroups, MOEs range from 560 to 660. Under the golfing scenario for both irrigated and non-irrigated turf and for each population subgroup, resulting MOEs were all greater than the level of concern (LOC) of 300. Residential exposures and risk estimates from gardens, trees, ornamentals, and pressure treated wood were unchanged from the most recent previous assessments which reported MOEs greater than EPA's LOC of 300.

4. *Aggregate cancer risk for U.S. population.* Based on the Agency's determination that the chronic risk assessment will be protective of any cancer effects, a separate quantitative cancer risk assessment was not conducted. Because there is no chronic risk of concern from aggregate exposure to tebuconazole, the Agency concludes that aggregate exposure to tebuconazole will not result in cancer risks of concern.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to tebuconazole residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate gas chromatographic methods with nitrogen/phosphorus detection (GC/NPD) methods are available for enforcing tolerances in plant and livestock commodities. These methods have undergone an independent laboratory validation and a petition method validation (PMV). The methods are available in the residue analytical method index on EPA's website and may also be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. Tolerances established in this rulemaking are harmonized with established Codex MRLs, except for apricot. The Codex MRL for apricot is 2 ppm. EPA is establishing a tolerance of 1 ppm for plum subgroup 12–12C, which harmonizes with the Codex MRLs for eight commodities in that subgroup other than apricot.

C. Revisions to Petitioned-For Tolerances

Instead of establishing a tolerance for Fruit, stone, group 12–12, except cherry, EPA is establishing tolerances for the subgroups in group 12–12 to harmonize with the relevant Codex MRLs. The Codex MRLs for nectarine and peach are 2 ppm, so EPA is establishing a U.S. tolerance for peach, subgroup 12–12B at 2 ppm. EPA is establishing a U.S. tolerance of 1 ppm for plum, subgroup 12–12C, which is harmonized with the Codex MRLs for eight commodities in that subgroup. In addition, several tolerances are being established at different levels than requested to conform with EPA rounding class practice by removing the trailing zero.

V. Conclusion

Therefore, tolerances are established for residues of tebuconazole, including its metabolites and degradates, determined by measuring only alpha-[2-(4-chlorophenyl)ethyl]-alpha-(1,1-dimethylethyl)-1*H*-1,2,4-triazole-1-ethanol, in or on *Brassica,* leafy greens, subgroup 4–16B, except watercress at 2.5 ppm; Cottonseed, subgroup 20C at 2 ppm; Fruit, pome, group 11–10 at 1 ppm; Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 6 ppm; Nut, tree, group 14–12 at 0.05; Peach subgroup 12–12B at 2 ppm; Plum subgroup 12–12C at 1 ppm; Sunflower, subgroup 20B at 0.1 ppm; Tropical and subtropical, small fruit, inedible peel, subgroup 24A at 1.6 ppm; and Watercress at 9 ppm. In addition, EPA is removing the following tolerances from paragraph (a)(1) because they are superseded by the new tolerances being established in this rulemaking: *Brassica,* leafy greens, subgroup 5B at 2.5 ppm; Cotton, undelinted seed at 2.0 ppm; Fruit, pome, group 11 at 0.05 ppm; Fruit, stone, group 12, except cherry at 1.0 ppm; Grape at 5.0 ppm; Lychee at 1.6 ppm; Nut, tree, group 14 at 0.05 ppm; Peach at 1.0 ppm; Pistachio at 0.05 ppm; Plum, pre- and post-harvest at 1.0 ppm; and Sunflower, seed at 0.05 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory

Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), nor is it considered a regulatory action under Executive Order 13771, entitled ''Reducing Regulations and Controlling Regulatory Costs'' (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA 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 publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 25, 2019.

Daniel Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.474, amend the table in paragraph (a)(1) as follows:

■ a. Remove the entry for ''Brassica, leafy greens, subgroup 5B'';

■ b. Add alphabetically the entry for ''*Brassica,* leafy greens, subgroup 4–16B, except watercress'';

■ c. Remove the entry for ''Cotton, undelinted seed'';

■ d. Add alphabetically the entry for ''Cottonseed, subgroup 20C'';

■ e. Remove the entry for ''Fruit, pome, group 11'';

■ f. Add alphabetically the entries for ''Fruit, pome, group 11–10'' and ''Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F'';

■ g. Remove the entries for ''Fruit, stone, group 12, except cherry''; ''Grape''; ''Lychee''; and ''Nut, tree, group 14'';

■ h. Add alphabetically the entry for ''Nut, tree, group 14–12'';

■ i. Remove the entry for ''Peach'';

■ j. Add alphabetically the entry for ''Peach subgroup 12–12B'';

■ k. Remove the entries for ''Pistachio'' and ''Plum, pre- and post-harvest'';

■ l. Add alphabetically the entry for ''Plum subgroup 12–12C'';

■ m. Remove the entry for ''Sunflower, seed''; and

■ n. Add alphabetically the entries for ''Sunflower, subgroup 20B''; ''Tropical and subtropical, small fruit, inedible peel, subgroup 24A''; and ''Watercress''.

The additions read as follows:

§ 180.474 Tebuconazole; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * * * *	
Brassica, leafy greens, subgroup 4–16B, except watercress	2.5
* * * * *	
Cottonseed, subgroup 20C	2
Fruit, pome, group 11–10	1
Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F	6
* * * * *	
Nut, tree, group 14–12	0.05
* * * * *	
Peach subgroup 12–12B	2
* * * * *	
Plum subgroup 12–12C	1
* * * * *	
Sunflower, subgroup 20B	0.1
Tropical and subtropical, small fruit, inedible peel, subgroup 24A	1.6
* * * * *	
Watercress	9
* * * * *	

* * * * *

[FR Doc. 2019–24267 Filed 11–8–19; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2019–0283; FRL–10000–50]

Propyzamide; Pesticide Tolerance for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of propyzamide in or on cranberry. This action is in response to EPA's granting of an emergency exemption under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on cranberry. This regulation establishes a maximum permissible level for residues of propyzamide in or on this commodity. The time-limited tolerance expires on December 31, 2022.

DATES: This regulation is effective November 12, 2019. Objections and requests for hearings must be received on or before January 13, 2020 and must be filed in accordance with the

instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2019–0283, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Director, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Publishing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under section 408(g) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2019–0283 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before January 13, 2020. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2019–0283, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

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

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with FFDCA sections 408(e) and 408(l)(6) of, 21 U.S.C. 346a(e) and 346a(1)(6), is establishing a time-limited tolerance for residues of the herbicide propyzamide, including its metabolites and degradates in or on cranberry. Compliance with the tolerance level in or on cranberry at 1 part per million (ppm) is to be determined by measuring only those propyzamide residues convertible to methyl 3,5-dichlorobenzoate, expressed as the stoichiometric equivalent of propyzamide, 3,5-dichloro-N-(1,1-dimethyl-2-propynyl)benzamide. This time-limited tolerance expires on December 31, 2022.

Section 408(l)(6) of FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under FIFRA section 18. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on FIFRA section 18 related time-limited tolerances to set binding precedents for the application of FFDCA section 408 and the safety standard to other tolerances and exemptions. Section 408(e) of FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, *i.e.,* without having received any petition from an outside party.

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Propyzamide on Cranberry and FFDCA Tolerances

The Massachusetts Department of Food and Agriculture (MDAR) notified EPA that an emergency condition exists for cranberry growers due to the presence of dodder in newly planted and renovated cranberry fields in five

counties throughout the state. According to MDAR, dodder is a serious and devasting pest in commercial cranberry production. The state reported that an urgent and nonroutine situation exists because cranberry fields are heavily infested with dodder and that the available registered alternatives do not provide effective control. Significant economic losses were expected due to yield and quality decreases without a suitable pesticide tool to control dodder.

After having reviewed the submission, EPA determined that an emergency condition exists for this State, and that the criteria for approval of an emergency exemption are met. EPA has authorized a specific exemption under FIFRA section 18 for the use of propyzamide on cranberry for control of dodder in Massachusetts.

As part of its evaluation of the emergency exemption application, EPA assessed the potential risks presented by residues of propyzamide in or on cranberry. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in FFDCA section 408(l)(6). Although this time-limited tolerance expires on December 31, 2022, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on cranberry after that date will not be unlawful, provided the pesticide was applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this time-limited tolerance at the time of that application. EPA will take action to revoke this time-limited tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this time-limited tolerance is being approved under emergency conditions, EPA has not made any decisions about whether propyzamide meets FIFRA's registration requirements for use on cranberry or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this time-limited tolerance decision serves as a basis for registration of propyzamide by a State for special local needs under FIFRA section 24(c). Nor does this tolerance by itself serve as the authority for persons in any State other than Massachusetts to use this pesticide on the applicable crop under FIFRA section 18 absent the issuance of an emergency exemption applicable within that State. For additional information regarding the emergency exemption for propyzamide, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

Consistent with the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure expected as a result of this emergency exemption request and the time-limited tolerance for propyzamide on cranberry at 1 ppm. EPA's assessment of exposures and risks associated with establishing this time-limited tolerance follows.

A. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.* A summary of the toxicological endpoints for propyzamide used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR PROPYZAMIDE FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (Females 13 to 49 years of age).	An endpoint attributable to a single exposure was not available in the database including the developmental toxicity studies in rats and rabbits.		
Acute dietary (All Populations)	LOAEL = 40 mg/kg/day.	Acute RfD = 0.04 mg/kg/day.	Acute Neurotoxicity Rat Study.
	UF_A = 10x UF_H = 10x FQPA SF (UF_L) = 10x (LOAEL to NOAEL extrapolation).	aPAD = 0.04 mg/kg/day	NOAEL was not established; LOAEL = 40 mg/kg/day (the lowest dose tested) based on increased landing foot splay in females and decreased motor activity in both sexes on Day 1.
Chronic dietary (All populations)	LOAEL= 40 mg/kg/day.	Chronic RfD = 0.013 mg/kg/day.	The POD of 40 mg/kg/day based on a weight of evidence approach from the 4 rat studies listed below.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR PROPYZAMIDE FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
	UF_A = 10x UF_H = 10x FQPA SF (UF_L/UF_{DB}) = 30x (for lack of CTA study and LOAEL to NOAEL extrapolation).	cPAD = 0.013 mg/kg/day	*Subchronic neurotoxicity (SCN) (Fischer rat):* NOAEL of 2.38 mg/kg/day based on the significant decreases in body weight, body weight gain, and food consumption seen at 11.28 mg/kg/day (LOAEL) in males. *Acute neurotoxicity (ACN) (Fischer rat):* NOAEL was not established. The LOAEL is 40 mg/kg/day based on the increase in landing foot splay in female rats and the decrease in motor activity seen in both genders on Day 1. (A 10X LOAEL to NOAEL uncertainty factor (UF_L) yields a derived POD of 4 mg/kg/day (40÷10)). *Combined chronic toxicity/carcinogenicity (CD rats):* NOAEL of 8.46/10.69 mg/kg/day based on increased relative liver weight and histopathological lesions in the liver, thyroid, and ovaries at 42.59/55.09 mg/kg/day (LOAEL). *Male pubertal study (CD rats):* NOAEL of 2.5 mg/kg/day based on decreased serum T4 at 10 mg/kg/day (LOAEL).
Incidental oral short-term (1 to 30 days).	LOAEL= 40 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF (UF_L /UF_{DB}) = 30x (for lack of CTA study and LOAEL to NOAEL extrapolation).	Residential LOC for MOE = 3000.	Same as Chronic RfD.
Dermal short-term (1 to 30 days) and intermediate-term (1 to 6 months).	NOAEL = 100 mg/kg/day.	Residential LOC for MOE = 1000. UF_A = 10x UF_H = 10x FQPA SF (UF_{DB}) =10x (for lack of CTA study).	28-day dermal toxicity study in rat: LOAEL = 500 mg/kg/day based on decreases in body weight and food consumption in males.
Inhalation short-term (1 to 30 days) and Intermediate-term (1 to 6 months).	LOAEL= 40 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF (UF_L/UF_{DB}) = 30x (for lack of CTA study and LOAEL to NOAEL extrapolation).	Residential LOC for MOE = 3,000.	Same as Chronic RfD.
Cancer (Oral, dermal, inhalation).	Classification: ''Not Likely to be Carcinogenic to Humans'' at doses that do not result in induction of hepatic cell proliferation or metabolic enzymes leading to disruption of thyroid or gonadal endocrine axes.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF_A = extrapolation from animal to human (interspecies). UF_{DB} = to account for the absence of data or other data deficiency. UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment.

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to propyzamide, EPA considered exposure under the time-limited tolerance established by this action as well as all existing propyzamide tolerances in 40 CFR 180.317. EPA assessed dietary exposures from propyzamide in food as follows:

i. *Acute exposure.* Such effects were identified for propyzamide. In estimating acute dietary exposure, EPA used food consumption information from the Dietary Exposure Evaluation and Model-Food Commodity Intake

Database (DEEM–FCID). As to residue levels in food, EPA assumed that propyzamide residues were present at tolerance levels in all commodities for which tolerances have been established or proposed and that 100% of the crops were treated with propyzamide.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the Dietary Exposure Evaluation and Model-Food Commodity Intake Database (DEEM–FCID). As to residue levels in food, EPA assumed that propyzamide residues were present at tolerance levels in all commodities for which tolerances have been established or proposed and that 100% of the crops were treated with propyzamide.

iii. *Cancer.* Based on the data summarized in Unit IV.A., EPA has concluded that propyzamide does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for propyzamide. Tolerance level residues and 100% CT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used Tier II screening level water exposure models in the dietary exposure analysis and risk assessment for propyzamide in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of propyzamide. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.*

Based on the Tier II Surface Water Concentration Calculator (SWCC) and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of propyzamide for acute exposures are estimated to be 102 parts per billion (ppb) for surface water and 21 ppb for ground water; for chronic exposures for non-cancer assessments are estimated to be 47 ppb for surface water and 18.6 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 102 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value of 47 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Propyzamide is currently registered for use on golf courses that could result in post-application residential exposures to adults and children. EPA assessed residential post-application dermal exposures from golfing for adults, children 6 to <11 and children 11 to <16 and determined that there are no post-application risk estimates of concern since the dermal margin of exposures (MOEs) are >1,000. For the golf course post-application scenarios for adults and children identified above, MOEs ranged from 1,900 to 2,500.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at: *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide.*

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA has not found propyzamide to share a common mechanism of toxicity with any other substances, and propyzamide does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that propyzamide does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.*

C. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional SF when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There was no evidence of quantitative or qualitative increased susceptibility in developing fetuses or in offspring of rats or rabbits following prenatal and/or postnatal exposure to propyzamide. However, a comparative thyroid assay study is required to determine whether pregnant women or developing young are more or less susceptible, compared to adults, to thyroid toxicity.

3. *Conclusion.* EPA has determined that reliable data show that the safety of infants and children would be adequately protected if the FQPA SF were increased to 10X for both interspecies and intraspecies variation, and 30X for the lack of a NOAEL and lack of a comparative thyroid study. That decision is based on the following findings:

i. The toxicity database for propyzamide is incomplete. The required comparative thyroid assay and subchronic inhalation studies have not been received for propyzamide; therefore, uncertainty factors identified above have been applied to account for these deficiencies. In addition, the acute dietary endpoint for the general population (including infants and children) was chosen from an acute neurotoxicity study with a lowest observed adverse effect level of 40 mg/kg/day based on the increase in landing foot splay in female rats and the decrease in motor activity observed on Day 1. As such, the lack of an established NOAEL as well as uncertainties attributed to intraspecies variability and interspecies extrapolations contributed to an incomplete toxicity database for propyzamide.

ii. There is no indication that propyzamide is a neurotoxic chemical and there is no need for a developmental neurotoxicity study; however, there is need for additional UFs to account for the lack of a comparative thyroid study and the use of a LOAEL to extrapolate a NOAEL.

iii. There is no evidence that propyzamide results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% CT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to propyzamide in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by propyzamide.

D. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to propyzamide will occupy 46% of the aPAD for all infants <1 year old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic dietary exposure to propyzamide from food and water will utilize 33% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Propyzamide is currently registered for a use that could result in short-term residential exposure. The Agency has identified and assessed short-term residential dermal post-application exposures for the registered golf course use for propyzamide. There are no post-application risk estimates of concern (*i.e.,* dermal MOEs ≥1,000) for the golf course use. The short-term residential exposures from the golfing use pattern were not aggregated with dietary exposures since the risk assessment endpoints for dermal and oral toxicity were different. The acute and chronic aggregate risk estimates are equivalent to the dietary risk estimates and are not of concern.

4. *Intermediate-term risk.* Intermediate-term residential exposures are not anticipated from the registered propyzamide uses, therefore, an intermediate-term aggregate assessment was not conducted.

5. *Aggregate cancer risk for U.S. population.* In accordance with the Agency's 2005 Guidelines for Carcinogenic Risk Assessment, propyzamide is classified as ''Not likely to be Carcinogenic to Humans'' at doses that do not result in induction of hepatic cell proliferation or metabolic enzymes leading to disruption of thyroid or gonadal endocrine axes. Quantification of carcinogenic risk is not required.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to propyzamide residues.

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodologies are available to enforce the tolerance expression of residues in/or plant commodities (PAM II Method I, using gas-liquid chromatography with electron-capture detection (GLC/ECD)) and livestock commodities (Method GRM 02.21, using gas chromatography with negative-ion chemical ionization mass spectrometry detection (GC/MS)). These methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established any MRLs for propyzamide.

VI. Conclusion

Therefore, a time-limited tolerance is established for residues of the herbicide propyzamide, including its metabolites and degradates. Compliance with the tolerance level in or on cranberry at 1 ppm is to be determined by measuring only those propyzamide residues convertible to methyl 3,5-dichlorobenzoate expressed as the stoichiometric equivalent of propyzamide, 3,5-dichloro-N-(1,1-dimethyl-2propynyl)benzamide. This tolerance expires on December 31, 2022.

VII. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA sections 408(e) and 408(l)(6). The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), nor is it considered a regulatory action under Executive Order 13771, entitled ''Reducing Regulations and Controlling Regulatory Costs'' (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established in accordance with FFDCA sections 408(e) and 408(l)(6), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does

this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA 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 publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 16, 2019.

Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—AMENDED

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.317, revise paragraph (b) to read as follows:

§ 180.317 Propyzamide; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* The time-limited tolerance specified in the table in this paragraph (b) is established for residues of the herbicide propyzamide, including its metabolites and degradates, in or on the specified agricultural commodity in the table in this paragraph (b), resulting from use of the pesticide pursuant to FIFRA section 18 emergency exemptions. Compliance with the tolerance level specified in the table in this paragraph (b) is to be determined by measuring only those propyzamide residues convertible to methyl 3,5-dichlorobenzoate, expressed as the stoichiometric equivalent of propyzamide, 3,5-dichloro-N-(1,1-dimethyl-2-propynyl)benzamide in or on the commodity. The time-limited tolerance expires on the date specified in the table in this paragraph (b).

Commodity	Parts per million	Expiration date
Cranberry.	1	December 31, 2022.

* * * * *

[FR Doc. 2019–24295 Filed 11–8–19; 8:45 am]

BILLING CODE 6560–50–P

Proposed Rules

Federal Register
Vol. 84, No. 218
Tuesday, November 12, 2019

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.

FEDERAL RESERVE SYSTEM

12 CFR Part 246

[Regulation TT; Docket No. R–1683]

RIN 7100–AF 63

Supervision and Regulation Assessments of Fees for Bank Holding Companies and Savings and Loan Holding Companies With Total Consolidated Assets of $100 Billion or More

AGENCY: Board of Governors of the Federal Reserve System (Board).

ACTION: Notice of proposed rulemaking.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is inviting comment on a proposal to amend the Board's assessment rule (Regulation TT), pursuant to Dodd-Frank Wall Street Reform and Consumer Protection Act (the Dodd-Frank Act), to address amendments made by the Economic Growth, Regulatory Relief, and Consumer Protection Act (EGRRCPA). The proposed amendments to Regulation TT raise the minimum threshold for being considered an assessed company from $50 billion to $100 billion in total consolidated assets for bank holding companies and savings and loan holding companies and adjust the amount charged to assessed companies with total consolidated assets between $100 billion and $250 billion to reflect changes in supervisory and regulatory responsibilities resulting from EGRRCPA.

DATES: Comments must be received on or before January 9, 2019.

ADDRESSES: You may submit comments, identified by Docket No. 1683 and RIN 7100 AF–63, by any of the following methods:

- *Agency Website: http://www.federalreserve.gov.* Follow the instructions for submitting comments at *http://www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm.*
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: regs.comments@federalreserve.gov.* Include docket and RIN numbers in the subject line of the message.
- *Fax:* (202) 452–3819 or (202) 452–3102.
- *Mail:* Ann Misback, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.
- All public comments are available from the Board's website at *http://www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm* as submitted, unless modified for technical reasons or to remove sensitive personally identifiable information at the commenter's request. Public comments may also be viewed electronically or in paper form in Room 146, 1709 New York Avenue, Washington, DC 20006 between 9:00 a.m. and 5:00 p.m. on weekdays.

FOR FURTHER INFORMATION CONTACT: Anna Lee Hewko, Associate Director, (202) 530–6260, Teresa Scott, Manager, (202) 973–6114, Naima Jefferson, Lead Financial Institution Policy Analyst, (202) 912–4613, Mark Greiner, Lead Financial Institution Policy Analyst, (202) 452–5290, Kelsi Wilken, Lead Business Analyst, (202) 530–6287, Division of Supervision and Regulation; Laurie Schaffer, Associate General Counsel (202) 452–2272 or Daniel Hickman, Senior Counsel, (202) 973–7432, Legal Division, Board of Governors of the Federal Reserve System, 20th and C Streets NW, Washington, DC 20551. For the hearing impaired only, Telecommunication Device for the Deaf (TTD), (202) 263–4869.

SUPPLEMENTARY INFORMATION:

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I. Introduction

Section 318 of the Dodd-Frank Act,[1] as enacted, directed the Board to collect assessments, fees, or other charges (assessments), from bank holding companies and savings and loan holding companies with $50 billion or more in total consolidated assets, and nonbank financial companies designated by the Financial Stability Oversight Council (Council) for supervision by the Board (collectively, assessed companies), equal to the expenses the Board estimates are necessary or appropriate to carry out its supervision and regulation of those companies. The Board transfers the assessment proceeds to the U.S. Treasury's General Account.

The Economic Growth, Regulatory Relief, and Consumer Protection Act (EGRRCPA)[2] amended several provisions of the Dodd Frank Act, which resulted in various changes to the regulatory framework such as tailoring the application of certain prudential standards for large banking organizations,[3] tailoring and revising the Board's company-run and supervisory stress test requirements, amending resolution planning requirements, and modifying the assessment framework. Specifically, section 401 of EGRRCPA raised the minimum size threshold for bank holding companies and savings and loan holding companies to be considered assessed companies from $50 billion to $100 billion in total consolidated assets. In addition, section 401 directed the Board to adjust the amount charged to assessed companies with total consolidated assets between $100 billion and $250 billion to reflect any changes in supervisory and regulatory responsibilities resulting from EGRRCPA.[4]

[1] Public Law 111–203, 124 Stat. 1376 (2010), section 318, codified at section 11 of the Federal Reserve Act, 12 U.S.C. 248(s).

[2] Public Law 115–174, 132 Stat. 1296 (2018).

[3] EGRRCPA raised the $50 billion minimum asset threshold for general application of enhanced prudential standards to bank holding companies with $250 billion, and provided the Board with discretion to apply standards to bank holding companies with total consolidated assets of between $100 billion and $250 billion.

[4] In addition, EGRRCPA provided that any bank holding company, regardless of asset size, that has been identified as a global systemically important bank holding company under 12 CFR 217.402, shall be considered a bank holding company with total consolidated assets equal to or greater than $250

II. The Assessment Process

In August 2013, the Board adopted the final rule to implement section 318 of the Dodd Frank Act, Regulation TT,[5] which became effective on October 25, 2013. Regulation TT explains the Board's assessment framework and details how the Board: (a) Determines whether a company is an assessed company for each assessment period,[6] (b) estimates the total expenses that are necessary or appropriate to carry out the supervisory and regulatory responsibilities to be covered by the assessment, (c) determines the assessment amount for each assessed company, and (d) bills for and collects the assessment from the assessed companies. Since 2013, the Board has annually provided notice of the supervision and regulation assessment on the Board's public website.[7]

III. The Assessment Proposal

The proposed rule would revise the minimum threshold for assessed bank holding companies and savings and loan holding companies from $50 billion or more in total consolidated assets to $100 billion or more in total consolidated assets. The proposed rule also would adjust the amount charged to assessed companies with between $100 billion and $250 billion in total consolidated assets to reflect changes in supervisory and regulatory responsibilities resulting from EGRRCPA. The proposal would align the assessment framework with the Board's application of prudential standards based on banking organizations' risk profiles. The Board is inviting comments on all aspects of this proposed rulemaking.

A. Identification of Assessed Companies

EGRRCPA raised the asset threshold for bank holding companies and savings and loan holding companies to be considered assessed companies from $50 billion or more in total consolidated assets to $100 billion or more in total consolidated assets.[8] The proposed rule will revise the asset threshold for bank holding companies and savings and loan holding companies in the definition of an assessed company in Regulation TT to reflect this change. All nonbank financial companies designed by the Council for supervision by the Board would continue to be assessed companies. The Board would continue to make the determination of whether a company is an assessed company for each assessment period, based on information reported by the company on regulatory or other reports as determined by the Board.[9]

B. Apportioning the Assessment Basis to Assessed Companies

Section 401 of EGRRCPA directs the Board to adjust the amount charged to assessed companies with between $100 billion and $250 billion in total consolidated assets to reflect any changes in supervisory and regulatory responsibilities resulting from EGRRCPA. Consistent with section 401 of EGRRCPA, the Board has issued a final rule (the tailoring rule) that establishes four categories for the application of enhanced prudential standards based on certain indicators designed to measure the risk profile of a banking organization.[10] In addition, concurrently with the tailoring rule, the Board, with the Office of the Comptroller of the Currency (OCC) and the Federal Deposit Insurance Corporation (FDIC), separately finalized amendments to the capital and liquidity requirements of the agencies to introduce the same risk-based categories for tailoring standards.[11] The Board and the FDIC also finalized changes to the resolution planning requirements (the resolution planning rule) to align with the tailoring rule's risk-based categories, build on the Board's tailoring of its rules and experience implementing those rules, and account for changes to the enhanced prudential standards requirements made by EGRRCPA.[12] Collectively, these final rules will result in changes to the Board's supervisory and regulatory responsibilities with respect to certain companies, including modification of enhanced prudential standards relating to capital, stress testing, and resolution planning.

The Board is proposing to modify Regulation TT to incorporate the tailoring rule's risk-based categories for purposes of adjusting the amount charged to assessed companies with between $100 billion and $250 billion in total consolidated assets.[13] This would align the Board's assessment rule with its enhanced prudential standards framework for large banking organizations and EGRRCPA-related changes to the Board's supervision and regulation of those companies.

Because these categories are designed to tailor supervisory and regulatory requirements to the level of risk associated with specific firms, the categories provide a consistent basis for adjusting the assessments for assessed companies with between $100 billion and $250 billion in total consolidated assets.[14] The Board proposes that

billion for purposes of the assessments standards and requirements. Public Law 115–174, 132 Stat. 1296 (2018), section 401(f).

[5] 12 CFR part 246.

[6] Assessment period means January 1 through December 31 of each calendar year.

[7] *See, https://www.federalreserve.gov/supervisionreg/supervisory-assessment-fees.htm.*

[8] In accordance with EGRRCPA, bank holding companies and savings and loan holding companies with total consolidated assets between $50 billion and $100 billion were not assessed for the 2018 assessment period.

[9] All organizational structure and financial information that the Board would use for the purpose of determining whether a company is an assessed company, including information with respect to whether a company has control over a U.S. bank or savings association, must have been received by the Board on or before June 15 following that assessment period and must reflect events that were effective on or before December 31 of the assessment period.

[10] Prudential Standards for Large Bank Holding Companies and Savings and Loan Holding Companies (Final Rule) 84 FR 59032 (November 1, 2019); Prudential Standards for Large Bank Holding Companies and Savings and Loan Holding Companies (Proposed Rule), 83 FR 61408 (November 29, 2018); Prudential Standards for Large Foreign Banking Organizations; Revisions to Proposed Prudential Standards for Large Domestic Bank Holding Companies and Savings and Loan Holding Companies (Proposed Rule), 84 FR 21988 (May 15, 2019).

[11] *See* Changes to Applicability Thresholds for Regulatory Capital and Liquidity Requirements (Final Rule) 84 FR 59230 (November 1, 2019); Proposed Changes to Applicability Thresholds for Regulatory Capital and Liquidity Requirements (Proposed Rule), 83 FR 66024 (December 21, 2018).

[12] *See* Resolution Plans Required (Final Rule) 84 FR 59194 (November 1, 2019); Resolution Plans Required (Proposed Rule) 84 FR 21600 (May 14, 2019).

[13] *See* Prudential Standards for Large Bank Holding Companies and Savings and Loan Holding Companies (Final Rule) 84 FR 59032 (November 1, 2019). The tailoring rule establishes the following categories for the application of prudential standards:

- *Category I:* U.S. global systemically important banks;
- *Category II:* Domestic firms with $700 billion or more in total consolidated assets, or $100 billion or more in total consolidated assets and $75 billion or more in cross-jurisdictional activity; and foreign banking organizations with $700 billion or more in combined U.S. assets, or with $100 billion or more in combined U.S. assets and $75 billion or more in cross jurisdictional activity measured based on the firm's combined U.S. operations;
- *Category III:* Domestic firms that have (a) $250 billion or more in total consolidated assets or (b) $100 billion or more in total consolidated assets and $75 billion or more in any of the following risk-based indicators: Nonbank assets, weighted short-term wholesale funding, or off-balance-sheet exposure; and foreign banking organizations that have (a) $250 billion or more in combined U.S. assets or (b) $100 billion or more in combined U.S. assets and $75 billion or more in any of the following risk-based indicators: Nonbank assets, weighted short term wholesale funding or off-balance-sheet exposure measured based on the firm's combined U.S. operations; and,
- *Category IV:* Domestic firms that have total consolidated assets equal to or greater than $100 billion but less than $250 billion; and foreign banking organizations with at least $100 billion in combined U.S. assets.

[14] EGRRCPA acknowledges that eligibility for the adjustment can be effected by the risk-based category of supervision and regulation of an assessed company. Under section 401(f) of

Continued

assessed companies subject to Category IV standards pursuant to the tailoring rule (Category IV firms), would receive an adjusted assessment rate, to reflect this tailoring and other EGRRCPA-related changes to the supervision and regulation of these companies. In addition, the Board proposes that any assessed companies that are not subject to enhanced prudential standards outlined in Categories I through IV pursuant to the tailoring rule (''other'' firms) [15] would also receive the adjusted assessment rate because the Board does not incur the supervisory and regulatory costs associated with such standards for those firms. Under the proposal, and consistent with EGRRCPA and the requirements in the tailoring rule, firms with between $100 and $250 billion in total consolidated assets that are subject to Category I, II, or III standards would not be eligible for the adjusted assessment rate.

Consistent with Regulation TT's methodology for determining whether a company is an assessed company, the determination of whether a company is eligible for the adjusted assessment rate will be based on the company's status with respect to the four categories of prudential standards in the tailoring rule as of December 31 of the assessment period.

Question 1: What, if any, alternatives to the tailoring rule categories should the Board consider as a basis for adjusting the assessment charged to assessed companies from $100 billion to $250 billion in total consolidated assets?

Question 2: What, if any, challenges does the proposed December 31 ''as of'' date present for determining whether an assessed company is subject to Category I through IV standards for purposes of Regulation TT?

C. Assessment Rate

The tailoring rule and resolution planning rule will modify the application of certain enhanced prudential standards and supervisory and regulatory programs for Category IV firms relating to capital stress testing; risk management; liquidity risk management, stress testing, and buffer requirements; single-counterparty credit limits; and resolution planning programs.[16] In addition, the Board has indicated that it intends to issue a capital plan proposal that would align capital planning requirements with the two-year supervisory stress testing cycle and provide greater flexibility for Category IV firms.[17]

As a result of these changes, the Board expects the share of its expenses incurred in the supervision and regulation of Category IV and ''other'' firms to decline relative to the share of expenses incurred in the supervision and regulation of assessed companies subject to Categories I, II, and III standards (Category I, II, and III firms).[18] The expenses associated with these programs for Category IV and ''other'' firms were estimated to be approximately 10 percent of the Board's total estimated expenses for assessed companies in 2018.[19] Accordingly, the Board proposes to adjust the amount charged to assessed companies with total consolidated assets between $100 billion and $250 billion to reflect EGRRCPA-related changes by reducing Category IV and ''other'' firms' share of the net assessment basis [20] by 10 percent. The Board is providing this estimate of costs, based in part on potential modifications to the supervisory and regulatory framework for large banking organizations, in order for the issuance of the assessment proposal to coincide with the issuance of the tailoring rule and to provide sufficient opportunity for public comment. To the extent that the actual modifications of the relevant supervisory and regulatory programs differ from the basis for the underlying estimate of costs, the proposed rule may be revised to reflect these changes.

The assessment rate for Category IV and ''other'' firms would be determined according to the following formula, where the estimated share of total program costs attributable to EGRRCPA-related supervisory and regulatory changes for Category IV and ''other'' firms is represented by the variable *S:*

$$\text{Assessment rate for Category IV and ''other'' firms} = \frac{[(\text{Net assessment basis} \times \text{Category IV and ''other'' firms' share of the total assessable assets of all assessed companies}) \times (1 - S)]}{\text{Category IV firms and ''other'' firms' total assessable assets}}$$

The assessment rate for Category IV and ''other'' firms would be determined by multiplying the net assessment basis by these firms' share of the total assessable assets of all assessed companies multiplied by 0.9 (*i.e.,* $1 - S$, or $1 - 0.1$), the product of which is then divided by the total assessable assets of Category IV and ''other'' firms.

The assessment rate for Category I, II, and III firms would be determined according to the following formula:

$$\text{Assessment rate for Category I, II and III firms} = \frac{[(\text{Net assessment basis} \times \text{Category I, II, and III firms' share of the total assessable assets of all assessed companies}) + (\text{Net assessment basis} \times \text{Category IV and ''other'' firms' share of total assessable assets} \times S)]}{\text{Category I, II, and III firms' total assessable assets}}$$

The assessment rate for Category I, II, and III firms would be determined by multiplying the net assessment basis by these firms' share of the total assessable assets of all assessed companies, plus the sum of the net assessment basis multiplied by the Category IV and ''other'' firms share of the total assessable assets multiplied by 0.1 (*i.e., S*), the sum of which is then divided by the total assessable assets of Category I, II, and III firms.

The assessment formula, for calculating a specific assessed company's assessment amount, will remain a base amount of $50,000 plus the assessed company's total assessable assets multiplied by the assessed company's assessment rate:

$$\text{Assessment} = \$50{,}000 + (\text{Assessed company's total assessable assets} \times \text{Assessed company's assessment rate})$$

Assessment Calculation Example

For purposes of illustration, based on information from the 2018 assessment period, there were 56 assessed companies with aggregate total assessable assets of $18.6 trillion and an aggregate assessment basis of $585.9

EGRRCPA, all U.S. GSIBs (*i.e.,* companies subject to Category I standards), regardless of asset size, are considered to have total consolidated assets equal to or greater than $250,000,000,000 for purposes of the assessments standards and requirements. Public Law 115–174, 132 Stat. 1296 (2018), section 401(f).

[15] For example, insurance savings and loan holding companies and foreign banking organizations with small U.S. presences.

[16] *See* Prudential Standards for Large Bank Holding Companies and Savings and Loan Holding Companies (Final Rule) 84 FR 59032 (November 1, 2019); Changes to Applicability Thresholds for Regulatory Capital and Liquidity Requirements, 84 FR 59230 (November 1, 2019); Resolution Plans Required (Final Rule) 84 FR 59194 (November 1, 2019).

[17] *See* Prudential Standards for Large Bank Holding Companies and Savings and Loan Holding Companies (Proposed Rule) 83 FR 61408, 61421 (November 29, 2018); Prudential Standards for Large Foreign Banking Organizations; Revisions to Proposed Prudential Standards for Large Domestic Bank Holding Companies and Savings and Loan Holding Companies (Proposed Rule) 84 FR 21988, 22003 (May 15, 2019).

[18] Assessed companies subject to Category I, II, and III standards would continue to bear their share of costs for these programs.

[19] The Board and Reserve Banks generally do not account for expenses on a firm-by-firm or program-by-program basis; therefore, the share of EGRRCPA-related program costs represents an estimate based on analysis of system-wide accounting data and time surveys.

[20] The assessment basis is the average of the amount of total expenses the Board estimates is necessary or appropriate to carry out the supervisory and regulatory responsibilities for assessed companies. 12 CFR 246.4(d). The net assessment basis is the assessment basis net of the total $50,000 base amount charged to all assessed companies (*i.e.,* net assessment basis = assessment basis − (# of assessed companies × $50,000)).

million.[21] Using these figures, and the methodologies set forth in this proposal, a Category IV firm with total assessable assets of $100 billion would have been required to pay an assessment of approximately $2.9 million and a Category I firm with total assessable assets of $1 trillion would have been required to pay an assessment of approximately $32.9 million.

Question 3: What, if any, alternative methods for calculating adjusted assessment rates should the Board consider, and why?

Question 4: The Board currently averages the assessment basis over three years in order to reduce volatility in assessments. What, if any, alternative approaches to the three-year average should the Board consider and, why?

As described above, the EGRRCPA-related supervisory and regulatory changes that are the basis for the estimated reduction in program costs for Category IV and ''other'' firms are expected to occur beginning in 2020. Accordingly, the Board proposes that the revised assessment rates would apply beginning with the 2020 assessment period. Consistent with the existing assessment process, assessed companies would receive a notice of assessment for the 2020 assessment period, using the new assessment rates, no later than June 30, 2021. Assessed companies would continue to have 30 calendar days from June 30 to appeal the Board's determination (a) that the company is an assessed company or (b) of the company's total assessable assets.

Question 5: Does the proposed rule and proposed effective date present implementation challenges? What, if any, alternative approaches should the Board consider? Responses should address whether the Board should consider implementing transitional arrangements in the rule to address these challenges.

IV. Impact Analysis

Using data from the 2018 assessment period, the change in the minimum threshold of total consolidated assets from $50 billion to $100 billion decreased the number of assessed companies from 64 to 56. These companies would have been charged an aggregate amount of $10.1 million, or approximately 1.7 percent of the estimated assessment basis.

As of December 31, 2018, firms with between $100 billion and $250 billion in total consolidated assets accounted for 17 percent of total U.S. industry assets. In 2018, an assessed company subject to Category IV standards with $100 billion in total consolidated assets would have been charged $3.1 million. Under the proposed rule, an assessed company subject to Category IV standards with $100 billion in total consolidated assets would be charged $2.9 million.

Question 6: The Board invites comment on all aspects of the impact analysis associated with the proposal. What, if any, additional costs and benefits should be considered? Commenters are encouraged to submit data on potential impacts, as well as potential costs or benefits of the proposal that the Board may not have considered.

V. Administrative Law Matters

A. Paperwork Reduction Act Analysis

Regulation TT contains a ''collection of information'' within the meaning of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) that would be affected by the proposed rule. Specifically, under the proposal, bank holding companies and savings and loan holding companies with total consolidated assets of between $50 billion and $100 billion would no longer be assessed companies, and therefore would no longer be respondents for the reporting provision located at section 246.5(b) of Regulation TT, which permits assessed companies to submit a written statement to appeal the Board's determination that the company is an assessed company or its determination of the company's total assessable assets.

In accordance with the requirements of the PRA, the Board may not conduct or sponsor, and a respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. Under the authority delegated to the Board by OMB, the Board recently approved a revision to the collection of information pursuant to Regulation TT to account for the changes described above (OMB Control Number 7100–0369).[22]

B. Regulatory Flexibility Act Analysis

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), generally requires an agency, in connection with a proposed rule, to prepare and make available for public comment an initial regulatory flexibility analysis that describes the impact of a proposed rule on small entities. However, a regulatory flexibility analysis is not required if the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The Small Business Administration (SBA) has defined ''small entities'' to include banking organizations with total assets of less than or equal to $600 million.[23] The Board has considered the potential impact of the proposal on small entities in accordance with the RFA. The Board believes that the proposal will not have a significant economic impact on a substantial number of small entities.

This notice of proposed rulemaking is being issued because section 401 of EGRRCPA raised the minimum threshold for being considered an assessed bank holding company and savings and loan holding company from $50 billion to $100 billion in total consolidated assets and directed the Board to adjust the amount charged to assessed companies with between $100 billion and $250 billion in total consolidated assets. As discussed in the **SUPPLEMENTARY INFORMATION** section, the objective in proposing this rule is to update Regulation TT to reflect the new minimum threshold for being considered an assessed holding company and to revise the assessment rate calculation to account for EGRRCPA-related changes in the Board's supervisory and regulatory responsibilities. The Board is required by section 318 of the Dodd-Frank Act to collect assessments equal to the total expenses the Board estimates are necessary or appropriate to carry out supervisory and regulatory responsibilities with respect to assessed companies. Section 401 of EGRRCPA directs to Board to revise the assessment framework by raising the minimum threshold for being considered an assessed holding company to $100 billion in total consolidated assets and adjusting the amount charged to assessed companies with between $100 billion and $250 billion in total consolidated assets.

The proposal would apply to assessed companies, which includes bank holding companies and savings and loan holding companies with $100 billion or more in total consolidated assets, foreign banking organizations that are bank holding companies and savings and loan holding companies with $100 billion or more in total global consolidated assets, and nonbank financial companies that the Council has determined must be supervised by the Board. These companies are well above the $600 million asset threshold

[21] *See, https://www.federalreserve.gov/supervisionreg/supervision-regulation-assessment-2018.htm.*

[22] 84 FR 39847 (Aug. 12, 2019).

[23] *See* 13 CFR 121.201; 84 FR 34261 (July 18, 2019).

at which a banking organization is considered a ''small entity'' under SBA regulations.[24] Because the proposal is not likely to apply to any company with assets of $600 million or less if adopted in final form, the proposal is not expected to affect any small entity for purposes of the RFA.

Bank holding companies and savings and loan holding companies with between $50 billion and $100 billion in total consolidated assets will no longer be subject to Regulation TT. Bank holding companies and savings and loan holding companies with $100 billion or more in total consolidated assets will continue to be assessed companies subject to Regulation TT. The Board's proposed rule is unlikely to impose any new recordkeeping, reporting, or compliance requirements. The Board does not believe that the proposal duplicates, overlaps, or conflicts with any other Federal rules. The Board believes that no alternatives to the proposed rule are available for consideration. In light of the foregoing, the Board does not believe that the proposal, if adopted in final form, would have a significant economic impact on a substantial number of small entities. Nonetheless, the Board seeks comment on whether the proposal would impose undue burdens on, or have unintended consequences for, small banking organizations, and whether there are ways such potential burdens or consequences could be minimized in a manner consistent with the purpose of the proposal.

C. Solicitation of Comments and Use of Plain Language

Section 722 of the Gramm-Leach-Bliley Act (Pub. L. 106–102, 113 Stat. 1338, 1471, 12 U.S.C. 4809) requires the Federal banking agencies to use plain language in all proposed and final rules published after January 1, 2000. The Board has sought to present the proposed rule in a simple and straightforward manner and invites comment on the use of plain language. For example:

- *Is the material organized to suit your needs? If not, how could the Board present the proposed rule more clearly?*
- *Are the requirements in the proposed rule clearly stated? If not, how could the proposed rule be more clearly stated?*
- *Does the proposal contain technical language or jargon that is not clear? If so, which language requires clarification?*
- *Would a different format (grouping and order of sections, use of headings, paragraphing) make the proposed rule easier to understand? If so, what changes would achieve that?*
- *Is this section format adequate? If not, which of the sections should be changed and how?*
- *What other changes can the Board incorporate to make the proposed rule easier to understand?*

List of Subjects in 12 CFR 246

Administrative practice and procedure, Banks, banking, Holding companies, Reporting and recordkeeping requirements, Savings associations.

Authority and Issuance

For the reasons set forth in the **SUPPLEMENTARY INFORMATION**, the Board proposes to amend 12 CFR part 246 as follows:

PART 246—SUPERVISION AND REGULATION ASSESSMENTS OF FEES (REGULATION TT)

■ 1. The authority citation for Part 246 is revised to read as follows:

Authority: Pub. L. 111–203, 124 Stat. 1376, 1526 (2010), Pub. L. 115–174, 132 Stat. 1296 (2018), and section 11(s) of the Federal Reserve Act (12 U.S.C. 248(s)).

■ 2. Amend § 246.1 by revising paragraphs (a) through (c) to read as follows:

§ 246.1 Authority, purpose and scope.

(a) *Authority.* This part (Regulation TT) is issued by the Board of Governors of the Federal Reserve System (Board) under section 318 of Title III of the Dodd-Frank Wall Street Reform and Consumer Protection Act (the Dodd-Frank Act) (Pub. L. 111–203, 124 Stat. 1376, 142332, 12 U.S.C. 5365 and 5366), section 401 of the Economic Growth, Regulatory Relief, and Consumer Protection Act (EGRRCPA) (Pub. L. 115–174, 132 Stat. 1296), and section 11(s) of the Federal Reserve Act (12 U.S.C. 248(s)).

(b) *Scope.* This part applies to:

(1) Any bank holding company having total consolidated assets of $100 billion or more, as defined below;

(2) Any savings and loan holding company having total consolidated assets of $100 billion or more, as defined below; and

(3) Any nonbank financial company supervised by the Board, as defined below.

(c) *Purpose.* This part implements provisions of section 318 of the Dodd-Frank Act and section 401 of EGRRCPA that direct the Board to collect assessments, fees, or other charges from companies identified in paragraph (b) of this section that are equal to the total expenses the Board estimates are necessary or appropriate to carry out the supervisory and regulatory responsibilities of the Board with respect to these assessed companies and to adjust the amount charged to assessed companies with total consolidated assets between $100 billion and $250 billion to reflect any changes in supervisory and regulatory responsibilities resulting from EGRRCPA.

* * * * *

■ 3. Amend § 246.2 by adding paragraphs (n) through (p) to read as follows:

§ 246.2 Definitions.

* * * * *

(n) Category I, II, and III firms are assessed companies subject to Category I, II, or III standards, as defined under 12 CFR parts 238 and 252, as of December 31 of the assessment period.

(o) Category IV firms are assessed companies subject to Category IV standards, as defined under 12 CFR parts 238 and 252, as of December 31 of the assessment period.

(p) ''Other'' firms are assessed companies not subject to the Category I, II, III, or IV standards, as defined under 12 CFR parts 238 and 252, as of December 31 of the assessment period.

■ 4. Section 246.3 is revised to read as follows:

§ 246.3 Assessed companies.

An assessed company is any company that:

(a) Is a top-tier company that, on December 31 of the assessment period:

(1) Is a bank holding company, other than a foreign bank holding company, with $100 billion or more in total consolidated assets, as determined based on the average of the bank holding company's total consolidated assets reported for the assessment period on the Federal Reserve's Form FR Y–9C (''FR Y–9C''),

(2)(i) Is a savings and loan holding company, other than a foreign savings and loan holding company, with $100 billion or more in total consolidated assets, as determined, except as provided in paragraph (a)(2)(ii) of this section, based on the average of the savings and loan holding company's total consolidated assets as reported for the assessment period on the FR Y–9C or on the Quarterly Savings and Loan

[24] While nonbank financial companies designated by the Council are considered assessed companies, it is unlikely that these companies would have less than $600 million in consolidated assets, because material financial distress at such firms, or the nature, scope, size, scale, concentration, interconnectedness, or mix of activities at such firms, are likely to pose a threat to the financial stability of the United States.

Holding Company Report (FR 2320), as applicable.

(ii) If a company does not calculate its total consolidated assets under GAAP for any regulatory purpose (including compliance with applicable securities laws), the company may request that the Board permit the company to file a quarterly estimate of its total consolidated assets. The Board may, in its discretion and subject to Board review and adjustment, permit the company to provide estimated total consolidated assets on a quarterly basis. For purposes of this part, the company's total consolidated assets will be the average of the estimated total consolidated assets provided for the assessment period.

(b) Is a top-tier foreign bank holding company on December 31 of the assessment period, with $100 billion or more in total consolidated assets, as determined based on the average of the foreign bank holding company's total consolidated assets reported for the assessment period on the Federal Reserve's Form FR Y–7Q (''FR Y–7Q''), provided, however, that if any such company has filed only one FR Y–7Q during the assessment period, the Board shall use an average of the foreign bank holding company's total consolidated assets reported on that FR Y–7Q and on the FR Y–7Q for the corresponding period in the year prior to the assessment period.

(c) Is a top-tier foreign savings and loan holding company on December 31 of the assessment period, with $100 billion or more in total consolidated assets, as determined based on the average of the foreign savings and loan holding company's total consolidated assets reported for the assessment period on the reporting forms applicable during the assessment period, provided, however, that if any such company has filed only one reporting form during the assessment period, the Board shall use an average of the foreign savings and loan holding company's total consolidated assets reported on that reporting form and on the reporting form for the corresponding period in the year prior to the assessment period, or

(d) Is a nonbank financial company supervised by the Board.

■ 5. Section 246.4, is amended by revising paragraph (c)(1) and adding paragraphs (d)(3) and (4) to read as follows:

§ 246.4 Assessments.

* * * * *

(c) *Assessment rates.* Assessment rates means, with regard to a given assessment period, the two rates published by the Board for the calculation of assessments for Category IV and ''other'' firms and for Category I, II, and III firms.

(1)(i) The assessment rate for Category IV and ''other'' firms will be calculated according to this formula:

$$\frac{[(\text{Net Assessment Basis} \times \text{Category IV and ''other'' firms' share of total assessable Assessment rate assets of all assessed companies}) \times (1 - S)]}{\text{Category IV and ''other'' firms' total assessable assets}}$$

(ii) The assessment rate for Category I, II, and III firms will be calculated according to this formula:

$$\text{Assessment rate} = \frac{[(\text{Net Assessment Basis} \times \text{Category I, II, and III firms' share of total assessable assets of all assessed companies}) + (\text{Net Assessment Basis} \times \text{Category IV and ''other'' firms' share of total assessable assets} \times S)]}{\text{Category I, II, and III firms' total assessable assets}}$$

* * * * *

(d) * * *

(3) Net Assessment Basis is the assessment basis, as defined by paragraph (d)(2), net of the total $50,000 base amount charged to all assessed companies. *Net Assessment Basis* = assessment basis − (number of assessed companies × $50,000).

(4) The variable *S* represents the estimated share of total costs attributable to changes in supervisory and regulatory responsibilities resulting from EGRRCPA for Category IV and ''other'' firms. *S* = 0.1 (10 percent).

* * * * *

By order of the Board of Governors of the Federal Reserve System, November 5, 2019.

Ann Misback,

Secretary of the Board.

[FR Doc. 2019–24491 Filed 11–8–19; 8:45 am]

BILLING CODE 6210–01–P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1112, 1130, and 1236

[CPSC Docket No. 2017–0020]

Safety Standard for Infant Sleep Products

AGENCY: Consumer Product Safety Commission.

ACTION: Supplemental notice of proposed rulemaking.

SUMMARY: In the **Federal Register** of April 7, 2017, the Consumer Product Safety Commission (CPSC) published a notice of proposed rulemaking (2017 NPR) pursuant to the Danny Keysar Child Product Safety Notification Act, section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), to promulgate a consumer product safety standard for infant inclined sleep products (inclined sleep products). The 2017 NPR allowed an incline between 10 and 30 degrees for the seat back angle of an inclined sleep product. The 2017 NPR proposed to adopt a voluntary standard for inclined sleep products developed by ASTM International, with a modification to the standard's definition of ''accessory.'' Based on subsequent information and events, the Commission is now issuing a supplemental proposed rule (Supplemental NPR), proposing to adopt the current ASTM standard for inclined sleep products, with modifications that would make the mandatory standard more stringent than the voluntary standard. The proposed changes include limiting the seat back angle for sleep to 10 degrees or less. CPSC's proposed standard would cover products intended for infant sleep that are not already addressed by another standard. Additionally, the Commission proposes to include the mandatory standard for infant sleep products in the Commission's list of notices of requirements (NORs). The Commission also proposes to amend the consumer registration rule to identify explicitly infant sleep products as a durable infant or toddler product subject to CPSC's consumer registration requirements.

DATES: Submit comments by January 27, 2020.

ADDRESSES: Comments related to the Paperwork Reduction Act aspects of the marking, labeling, and instructional literature requirements of the proposed mandatory standard for infant sleep products should be directed to the Office of Information and Regulatory Affairs, the Office of Management and Budget, Attn: CPSC Desk Officer, FAX: 202–395–6974, or emailed to *oira_submission@omb.eop.gov.*

Other comments, identified by Docket No. CPSC–2017–0020, may be submitted electronically or in writing:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: *http://www.regulations.gov.* Follow the instructions for submitting comments. CPSC does not accept comments submitted by electronic mail (email), except through *www.regulations.gov.* CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Written Submissions: Submit written submissions in the following way: Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions) to: Division of the Secretariat, Consumer Product

Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504–7923.

Instructions: All submissions received must include the agency name and docket number for this proposed rulemaking. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to: *http://www.regulations.gov.* Do not submit electronically any confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If you wish to provide such information, please submit it in writing.

Docket: For access to the docket to read background documents or comments received, go to: *http://www.regulations.gov,* and insert the docket number, CPSC–2017–0020, into the ''Search'' box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Celestine T. Kish, Project Manager, Directorate for Engineering, U.S. Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone: (301) 987–2547; email: *ckish@cpsc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background and Statutory Authority

A. Statutory Authority

Section 104(b) of the CPSIA, 15 U.S.C. 2056a(b), requires the Commission to: (1) Examine and assess the effectiveness of voluntary consumer product safety standards for durable infant or toddler products, in consultation with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts; and (2) promulgate consumer product safety standards for durable infant or toddler products. Standards issued under section 104 are to be ''substantially the same as'' the applicable voluntary standards, or more stringent than the voluntary standard if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product. 15 U.S.C. 2056a(b)(1)(B).

Section 104 of the CPSIA requires the Commission to consult with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts to examine and assess the effectiveness of the relevant voluntary standards. CPSC staff regularly participates in the juvenile products subcommittee meetings of ASTM International (ASTM). ASTM subcommittees consist of members who represent producers, users, consumers, government, and academia.[1] The consultation process for the inclined sleep products rulemaking commenced in 2011, and CPSC staff has been actively participating in the development of the new standard since that time.

A ''durable infant or toddler product'' is a ''durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years.'' *Id.* 2056a(f)(1). The CPSIA includes a non-exhaustive list of categories of products that are durable infant or toddler products, such as cribs, toddler beds, and bassinets and cradles. *Id.* 2056a(f)(2). As discussed in section I.B of this preamble, in the 2017 NPR CPSC proposed to categorize infant inclined sleep products as a ''durable infant or toddler product'' under section 104 of the CPSIA, as a subset of the bassinet and cradle category. In this Supplemental NPR, CPSC proposes to identify ''infant sleep products'' as a category of durable infant or toddler products under section 104(f) of the CPSIA. CPSC proposes to define ''infant sleep products'' as products that provide sleeping accommodations for infants and are not currently covered by bassinets/cradles, cribs (full-size and non-full size), play yards, and bedside sleepers, as a durable infant or toddler product under section 104(f) of the CPSIA. Section 104(d) of the CPSIA requires durable infant or toddler products to establish product registration programs and comply with CPSC's implementing rule, 16 CFR part 1130. Under section 14 of the CPSA, children's products (such as durable infant or toddler products) must comply with testing and certification requirements that are implemented through 16 CFR parts 1107 and 1109.

B. 2017 NPR

When staff began work on the bassinet and cradle standard, staff considered infant inclined sleep products to fall within the scope of the bassinet/cradle standard. However, because the bassinet/cradle standard did not address products on the market that had a sleep incline greater than 10 degrees, the Commission directed staff to initiate a separate rulemaking effort for infant inclined sleep products. Accordingly, the infant inclined sleep products safety standard was an outgrowth of the bassinet/cradle safety standard, intended to address products with an incline greater than 10 degrees from horizontal.

In 2011, at the time CPSC separated infant inclined sleep products from the bassinet/cradle standard, ASTM simultaneously began work on developing a voluntary standard for infant inclined sleep products. ASTM published the resulting infant inclined sleep products standard in May 2015, and updated the standard twice in 2016 and twice in 2017. ASTM's latest standard for this product category is designated, ASTM F3118–17a, *Standard Consumer Safety Specification for Infant Inclined Sleep Products* (ASTM F3118–17a).

Pursuant to the procedure described in section 104 of the CPSIA, the 2017 NPR proposed a mandatory standard for infant inclined sleep products, incorporating by reference the then-current voluntary standard, ASTM F3118–17, with a modification to the standard's definition of ''accessory.'' 82 FR 16964 (April 7, 2017). At the time of the 2017 NPR for infant inclined sleep products, which included hammocks, the Commission was aware of 14 fatal incidents related to infant inclined sleep products, which were reported to have occurred between January 1, 2005 and September 30, 2016. Staff determined that 8 of the 14 infant deaths involved freestanding, framed inclined sleep products, and that 3 infant deaths involved an unrestrained infant who was found to have rolled over into a facedown position. Staff found that in two additional deaths, the infant reportedly rolled over into a facedown position, but the reports did not include any information about use of a restraint. CPSC staff had little information about the cause or manner of the three remaining infant deaths. *Id.* at 16965–66. Staff's incident data analysis in the 2017 NPR considered that these 14 fatalities and other reported incidents could be addressed by the requirements in the voluntary standard, ASTM F3118–17. *Id.* at 16967–68.

The 2017 NPR indicated that ASTM F3118–17 addressed the primary hazard patterns CPSC identified in the 657 incidents (including 14 deaths), except for the definition of ''accessory.'' Specifically, the 2017 NPR proposed that CPSC's standard would not include the term ''rigid frame'' in the definition of ''accessory inclined sleep product'' in section 3.1.1 of ASTM F3118–17, broadening the definition to encompass a new product that did not have a rigid frame. *Id.* at 16968–69, and 16975. The Commission concluded that these more stringent requirements were necessary to further reduce the risk of injury associated with infant inclined sleep products relating to the use of an

[1] ASTM International website: *www.astm.org,* About ASTM International.

inclined sleep product accessory. *Id.* at 16967.

As the 2017 NPR explained, durable infant or toddler products are children's products that must be certified as complying with all applicable CPSC-enforced requirements. 15 U.S.C. 2063(a); 82 FR at 16969. Certification must be based on testing conducted by a CPSC-accepted third party conformity assessment body (test laboratory). 15 U.S.C. 20163(a)(2). CPSC must publish a NOR for the accreditation of test laboratories to assess a product's conformity with a children's product safety rule, such as the proposed rule on infant inclined sleep products. Accordingly, the 2017 NPR proposed that if issued as a final rule, the new *Standard Consumer Safety Specification for Infant Inclined Sleep Products,* to be codified at 16 CFR part 1236, would be added to the list of NORs for children's product safety rules in 16 CFR part 1112, so that test laboratories applying for CPSC-acceptance could seek accreditation to test inclined infant sleep products. 82 FR at 16969.

Finally, the 2017 NPR proposed to amend 16 CFR part 1130, the Commission's requirements for consumer registration for durable infant or toddler products. *Id.* at 16969–70. The Commission proposed to amend the definition of ''durable infant or toddler product'' to clarify that infant inclined sleep products fall within the term, and are subject to the product registration card requirements in part 1130. *Id.*

On June 12, 2019, CPSC staff submitted a briefing package and a draft **Federal Register** notice to the Commission recommending that the Commission terminate the 2017 NPR. Staff recommended terminating the 2017 NPR because, by that time, CPSC had received reports of 42 additional fatalities since issuing the 2017 NPR, which were associated with rocker-like inclined sleep products, and because the Commission had issued additional safety alerts and recalls involving infant inclined sleep products. On October 16, 2019, staff provided the Commission with a briefing package recommending that the Commission instead issue this Supplemental NPR.[2]

C. 2019 Supplemental NPR—Overview

In this Supplemental NPR, the Commission proposes to issue a standard for infant sleep products, *i.e.,* products that (1) Provide sleeping accommodations for infants and (2) are not currently covered by bassinets/cradles, cribs (full-size and non-full size), play yards, and bedside sleepers. The Supplemental NPR proposes to incorporate by reference ASTM F 3118–17a with modifications to require that: (1) The seat back angle intended for sleep must be equal to or less than 10° and (2) the infant sleep product must meet the requirements for a bassinet/cradle in the standard at 16 CFR part 1218. The Commission also proposes to amend the consumer registration rule to identify ''infant sleep products'' as a category of durable infant or toddler products under section 104(f) of the CPSIA. Additionally, the Commission proposes to amend its regulation at 16 CFR part 1112 to add infant sleep products to the list of products that require third party testing.

II. Product Description

A. Scope of Products Within the Supplemental NPR

The scope of products covered by the 2017 NPR tracked the scope of ASTM F3118–17, covering ''a free standing product with an inclined sleep surface primarily intended and marketed to provide sleeping accommodations for an infant up to 5 months old or when the infant begins to roll over or pull up on sides, whichever comes first.'' The Supplemental NPR proposes to incorporate ASTM F3118–17a with substantial modifications, including revisions in the scope of the standard, section 1.3, to remove the term ''inclined,'' and to include any infant sleep product not currently covered by another mandatory rule for infant sleep products: Bassinets/cradles, cribs (full-size and non-full-size), play yards, and bedside sleepers. Accordingly, the scope of the Supplemental NPR includes all of the products in the 2017 NPR, plus additional infant sleep products not covered by any other infant sleep product standard. The following types of infant sleep products fall within the scope of the Supplemental NPR:

- *Frame-Type Inclined Sleep Products*—Frame-type inclined sleep products are elevated, intended to be placed on the floor, and are self-supporting. Typically, this design uses a metal frame covered by a fabric insert that contains the occupant. Some frame-type products have a rigid plastic insert under the sleeping surface, and/or extra padding with head positioning cushions. The base may be stationary or allow side-to-side/head-to-toe rocking. This type of product could have a fixed incline or be adjustable. Frame-type products can be intended for use by newborns or infants, or both, depending on the size of the product.
- *Hammocks*—Hammocks are typically constructed of fabric and suspended from one or two points, either above or on either side. Hammock products are constructed of various materials and generally conform to the shape of the child when placed in the product. However, some hammock designs use a mat, mattress, or other type of pad to provide a semi-rigid sleeping surface that maintains the product's form. Hammocks are intended to be suspended and can be supported by a frame or other structure, such as a ceiling.
- *Compact Inclined Sleep Products*—Compact inclined sleep products are freestanding, with the bottom of the seat a maximum of 6 inches (152 mm) above the floor. These products tend to be constructed of foam and are intended to be used on the floor.
- *Accessory Inclined Sleep Products*—An accessory inclined sleep product is intended to provide sleeping accommodations for infants or newborns and are attached to, or supported in some way, by another product. These products can be fixed or adjustable. An inclined sleep accessory is typically a rigid-frame product that has a stationary or fixed base and, in some cases, inclined sleep product accessories may be removed and used independently.

B. Market Description

The Supplemental NPR proposes to cover any infant product ''primarily intended and marketed[3] to provide sleeping accommodations'' that is designed for infants five months old or younger and that is not covered by another standard.[4] In general, the Supplemental NPR does not propose to cover products with adjustable seat back positions that are covered by other mandatory or voluntary standards in inclined position(s), such as bouncers, rockers, hand-held carriers, or infant swings, unless they have a seat back angle that is specifically marketed for sleep for children 5 months or younger.

[2] The October 16, 2019, Staff Briefing Package: Draft Supplemental Notice of Proposed Rulemaking for Infant Sleep Products under the Danny Keysar Child Product Safety Notification Act (Staff Supplemental Briefing Package) is available at: *https://www.cpsc.gov/s3fs-public/SupplementalNoticeofProposedRulemakingforInfantSleepProducts_10_16_2019.pdf?TPVAJZEQcz9x9sKeEGltm4LskkonxUWv.*

[3] This would include marketing information (such as on websites or in ad campaigns), product and retail package labeling, as well as supplier statements about the product.

[4] These include: Safety Standard for Full-Size Baby Cribs (16 CFR 1219); Safety Standard for Non-Full-Size Baby Cribs and Ply Yards (16 CFR 1220 and 1221); Safety Standard for Bedside Sleepers (16 CFR 1222); and Safety Standard for Bassinets and Cradles (16 CFR 1218).

To date, CPSC staff has found one bouncer on the market with an inclined position marketed for sleep for children in this age range.

Inclined infant sleep products sell on the U.S. market for approximately $65 for a frame-style inclined sleeper, $110 for a compact sleeper, $165 for an infant hammock,[5] and $236 for a play yard with an inclined sleeper accessory.[6] A hammock-style crib accessory that would be covered by the Supplemental NPR (but does not currently fall under the voluntary inclined sleeper standard or another sleep standard) sells for approximately $50.

Several product categories would not fall under the scope of the Supplemental NPR: (1) Sleep positioners; (2) sleep wedges, many of which are marketed as medical devices, putting them under the jurisdiction of the Food and Drug Administration; and (3) miniature infant hammocks marketed exclusively for use as photographic props (*i.e.,* photos of newborn babies).

III. Incident Data and Hazard Patterns

At the time of the 2017 NPR, the Commission was aware of 14 fatal incidents related to infant inclined sleep products, which were reported to have occurred between January 1, 2005 and September 30, 2016. Eight of the 14 deaths involved rocker-like inclined sleep products; in three cases, the unstrapped decedent was found to have rolled over into a facedown position. Two additional cases also reported a rollover into a facedown position, but the reports did not include any information about use of a restraint. CPSC had little information about the cause or manner of the three remaining deaths. The NPR recognized that reporting was ongoing and the number of reported fatalities could change. This Supplemental NPR updates fatal and nonfatal incident reports associated with the use of an infant inclined sleep product.

CPSC is aware of 451 incidents (59 fatal and 392 nonfatal) related to infant inclined sleep products that occurred from January 1, 2005 through June 30, 2019 and reported between October 1, 2016 and June 30, 2019. This count includes incidents reported after the reporting end date stated in the 2017 NPR. Forty-three percent of the incident reports (196 out of 451) are based solely on information from manufacturers/retailers. Various sources, such as hotlines, internet reports, newspaper clippings, medical examiners, and other state/local authorities provided the remaining incident reports to CPSC. Reporting is ongoing, and therefore, the number of reported fatalities, nonfatal injuries, and non-injury incidents may change in the future. Tab A of the Staff Supplemental Briefing Package describes the incident data and the hazard patterns associated infant inclined sleep products.

A. Fatalities

Since the 2017 NPR, through June 30, 2019, CPSC received reports of 59 deaths. One fatality involved a foam-based infant reclined sleeper; two fatalities occurred in napper attachments of play yards; and the remaining fatalities occurred in freestanding framed inclined sleep products. CPSC staff reviewed and categorized incident reports associated with the fatalities:

- Twenty-eight of the 59 reports contain unclear, conflicting, and/or inconsistent information. For example, in this category medical examiners often conclude the cause of death to be Sudden Infant Death Syndrome (SIDS) or Sudden Unexpected Infant Death (SUID) along with a co-contributing condition such as unsafe sleep environment (*e.g.,* soft bedding, inclined sleep surface) or other pre-existing medical condition. Considering all factors in each report confounds staff's ability to determine the pre-dominant factor causing a fatality. Occasionally, wording on the documents cite ''several possibilities'' and the cause of death is coded as Undetermined. Lack of clarity in these reports make it difficult for CPSC staff to consistently classify the 28 deaths.
- Eighteen reports describe infants placed in the product supine but who ended up in a compromised position in the product, resulting in suffocations or positional asphyxiations. In 11 of the 18 cases, no restraints were used; another six infants were placed in a supine position, but the use of restraints is unknown; and in one case, the infant was left restrained and supine, but found supine, slumped in a chin-to-chest position. One additional unrestrained infant fell out of the product and became wedged in a confined space.
- Eight reports provide very little information on the incidents. Lack of any information on the circumstances leading up to the death does not allow staff to classify these deaths.
- Four reports describe infant placement issues; three of the four decedents were reportedly placed prone on soft bedding in the product; and another decedent suffocated when a young sibling climbed into the sleep product on top of her.

CPSC does not know the age for 10 deceased infants. Staff concludes that for the remaining deaths, 39 infants were 5 months or less in age, while six infants were between 6- and 8-months of age. One decedent was 9-months old.

B. Nonfatal Incidents

Reports indicate that 96 of the 451 inclined sleep product-related nonfatal incidents involved an injury to the infant during product use. The severity of the injury types among the 96 reported injuries are as follows:

- Seven infants required hospital admission. Six of the seven infants suffered episodes of respiratory distress due to rolling over in the product; mold in the product; or undetermined reasons. One of the seven infants had to be hospitalized for *scoliosis* (curvature) of the back attributed to product use.
- Sixteen infants were treated and released from emergency departments (EDs). Eleven of these infants were treated for head injuries and contusions/bruises resulting from falls; three infants were treated for unexplained respiratory distress. Mold growth on the product was associated with respiratory distress in one additional infant and seizure symptoms in another.
- Seventy-three infants received some professional medical care, first-aid treatment, or the level of care received was not reported. Among them, 32 infants suffered from plagiocephaly (flat head syndrome), torticollis (twisted neck syndrome), or both conditions, associated with the use of the inclined sleep product; 27 infants suffered mostly respiratory and some skin problems associated with mold on the product; infants sustained the remaining injuries due to a fall from the product or a minor electric shock, or their injuries are unspecified.

The remaining 296 incident reports indicate that no injury occurred to the infant or provided no information about an injury. However, many of the descriptions indicate the potential for a serious injury, or even death, similar to those reported in the incident data.

C. Hazard Pattern Identification

The 2017 NPR identified nine hazard patterns among the 657 reported incidents. These hazard patterns included: Design issues, lack of

[5] The average price for an infant hammock supplied by a home-based manufacturer is approximately $200.

[6] Staff averaged prices across all models found for a particular type. Staff ignored as unknown shipping costs for a few hammock models delivered from overseas suppliers, which means that the average cost for an infant hammock may be a low estimate, depending upon how many hammocks are entering the U.S. via these overseas suppliers.

structural integrity, inadequate restraints, electrical issues, non-product-related or unknown issues, difficulty with correct positioning, miscellaneous product-related issues, unspecified falls, and consumer comments. Although the distribution of the data in this Supplemental NPR update varied somewhat, CPSC finds that the broader hazard categories are very similar. Within the broader hazard category of design, the Supplemental NPR identifies one new hazard pattern, as described below.

CPSC staff considered all 451 reported incidents (59 fatal and 392 nonfatal) to identify hazard patterns associated with infant inclined sleep products. The infant inclined sleep products category includes a variety of products. Some products, like hammocks, are suspended in air, while other seat-like products are meant to be placed on a floor level (yet incident reports indicate these products often were not placed on floor level). Other products sit on top of larger nursery products as attachments. CPSC staff identified hazard patterns that are quite different depending on which product is involved and how the product is being used. In order of frequency of incident reports, CPSC staff grouped the hazard patterns into the following categories:

1. *Design* of the infant inclined sleep product: One hundred and thirty-eight of the 451 reported incidents (31 percent) are in this category. Staff identified three major issues:

a. Fifty-nine reported incidents (43 percent) involved infants who developed respiratory and/or skin ailments due to the growth of mold on the product;

b. Forty-six reported incidents (33 percent) involved infants that rolled over—fully or partially—from their original supine position. Reports describe infants as young as 1- or 2-months of age as having rolled over; parents/caregivers, who witnessed and reported some of the nonfatal incidents, were able to rescue distressed infants quickly. Eighteen infants died due to suffocation or asphyxiation. Although a few of the infants were strapped into the product, a majority of the infants were either not restrained or the use of restraint is unreported.

c. Thirty-three reported incidents (24 percent) involved infants that developed physical deformations from extended product use, such as *plagiocephaly* (flat head syndrome), *scoliosis* (curvature) of the back, and/or *torticollis* (twisted neck syndrome).

The design category includes 19 deaths, 5 hospitalizations, and 4 emergency department (ED) visits. All but two of the deaths resulted from infants rolling over into a prone or semi-prone position, one decedent was found still supine and restrains, but slumped in a chin-to-chest position. The other infant rolled out of the product and wedged into a confined space. Infants unrestrained in the product caused two ED-treated falls. An additional 62 non-hospitalized, non-ED injuries are reported in this category.

2. *Electrical issues:* One hundred and twenty-seven of the 451 incident reports (28 percent) report battery leakage, electric shock, and/or overheating/melting of components, such as the vibrating unit, battery cover, switch, plug, or motor. Reports include two injuries in this category due to electric shock.

3. *Consumer comments:* Ninety of the 451 reports (20 percent) fall into this category. The reports consist of consumer comments/observations of perceived safety hazards, complaints about unauthorized sale of infant inclined sleep products, or inquiries regarding safety recall on inclined sleep products. One complaint describes misinformation in the instruction material. None of these reports indicate that an incident actually occurred.

4. *Undetermined due to confounding information:* Thirty-four of the 451 reports (8 percent) provide unclear, conflicting, and/or inconsistent information. Among the 28 deaths reported in this category, for example, medical examiners often concluded the cause of death to be SIDS or SUID, along with a co-contributing condition such as an unsafe sleep environment (*e.g.,* soft bedding, inclined sleep surface) or pre-existing medical condition. Staff is unable to determine the role of the product when documents describe multiple potentially contributing factors. Occasionally, the wording on the documents cite ''several possibilities,'' and the cause of death is coded as Undetermined. For the 6 nonfatal injuries, including the 2 hospitalized and 2 ED-treated injuries, the report described respiratory distress due to temporary cessation of breathing; however, these reports contain no official diagnosis for these episodes.

5. Lack of *structural integrity:* Twenty-eight of the 451 incidents (6 percent) report some sort of breakage of the product or its components. These reports include complaints of buckle/straps breaking, components such as hub, rail, or leg detaching/disengaging, hardware coming loose, and other unspecified components breaking. This category includes two ED-treated injuries, both due to falls.

6. *Other product-related issues:* Thirteen of the 451 incidents (3 percent) report other product-related issues, such as instability (product tipping over), inadequacy of restraint (infants falling out in spite of being restrained), or product assembly/installation difficulties. This category contains seven fall-related injuries, including two injuries that were treated and released from a hospital ED.

7. *Infant placement* issues: Four of the 451 incidents reports (1 percent) indicate that infant placement contributed to the incident. Of the four fatalities, reports describe three infants placed in a prone position on soft bedding; and another infant being crushed by a young sibling who climbed on top of her.

8. *Insufficient information:* For 17 of the 451 incidents (4 percent), reports contain insufficient information for staff to categorize them accurately. Staff has no information available on the circumstances of 8 deaths in this category. Reports for six injuries in this category describe unspecified falls treated in hospital EDs, with no information was on restraint usage.

D. Product Recalls and Safety Alerts

From May 10, 2000 to August 20, 2019, CPSC conducted 13 consumer-level recalls involving infant inclined sleep products. The recalls were conducted in response to hazards involving strangulation, suffocation, fall, structural stability, entrapment, exposure to mold, and death. Six recalls involved infant hammocks, six recalls involved infant inclined sleep products, and one recall involved an infant inclined sleep accessory included with a play yard. Tab G in the Staff Supplemental Briefing Package contains a detailed chart outlining recalls involving infant inclined sleep products.

The six infant hammocks were recalled for hazards including: Strangulation, suffocation, fall, structural stability, and entrapment. Recalls affected approximately 25,400 units of infant hammocks.

The six infant inclined sleep products and one infant inclined sleep accessory included with a play yard were recalled due to hazards including: entrapment, suffocation, fall, exposure to mold, and death after infants rolled from their back to their stomach or side while unrestrained in the products. Recalls affected approximately 6.4 million units of infant inclined sleep products. One recall for exposure to mold affected 800,000 units, and two recalls for entrapment and suffocation affected 195,000 units.

In 2019, two recalls occurred due to reports of infant deaths while using infant inclined sleep products, after the infants rolled from their back to their stomach or side while unrestrained, or under other circumstances. In response to the reported deaths in those products, CPSC conducted two additional recalls due to safety concerns with infant inclined sleep products, one with an infant inclined sleep product, and one with an infant inclined sleep accessory included with a play yard. Recalls involving infant inclined sleep products affected approximately 5.4 million units and the recall involving the infant inclined sleep accessory affected approximately 71,000 units.

The Commission also has issued two safety alerts involving infant inclined sleep products. A May 31, 2018 safety alert [7] advised of infant rollover deaths in inclined sleep products, and reminded caregivers to always use restraints and to stop using the product as soon as an infant can roll over. An April 5, 2019 safety alert [8] advised consumers to stop use of the inclined sleep product when an infant reaches three months of age, or as soon as an infant exhibits rollover capabilities.

IV. Mannen Study

During the development of this Supplemental NPR briefing package, staff received reports of 451 new incidents, 59 of which were deaths that occurred while in infant inclined sleep products. Accordingly, Commission staff contracted with Dr. Erin Mannen, Ph.D., a mechanical engineer with a biomechanics specialization, to conduct infant testing to evaluate the design of inclined sleep products. Tab B of the Staff Supplemental Briefing Package contains Dr. Mannen's study, *Biomechanical Analysis of Inclined Sleep* (Mannen Study).

The Mannen Study examined how 10 infants move and use their muscles on flat, inclined surfaces, and in selected inclined sleep products, and whether such product designs directly impact safety or present a risk factor that could contribute to the suffocation of an infant. Testing compared infants' muscle movement and oxygen saturation on a flat crib mattress at 0°, 10°, and 20° versus seven different inclined sleep products. Researchers recorded infant muscle activity using surface electromyography (EMG), and recorded oxygen saturation using a medical grade pulse oximeter. Researchers placed infants in a random order in each of the 10 testing conditions, in both the supine and prone positions, for at least 60 seconds (unless the oximeter data fell below 95%, in which case they were removed early to ensure safety).

Following are key findings of the Mannen Study:

- Inclined surfaces and incline sleep products resulted in significantly higher muscle activity of the turn core muscle (abdominals), which may lead to quicker fatigue and suffocation if an infant finds themselves prone in an incline sleep product.
- Muscle synergies (*i.e.,* how muscles work together) are significantly different in inclined sleep products. If an infant rolls from supine to prone in an inclined sleep product, it is likely the first time the baby has experienced the position and the demands the position requires of the muscles.
- Some inclined sleep products require greater neck and trunk adjustments during prone positioning, indicating that infants may struggle to adjust their posture to enable breathing and attempt to self-correct if a roll from supine to prone occurs.
- Prone lying in the incline sleep products puts infant at higher risk of suffocation as evidenced by oxygen saturation results.
- Some evidence was found that supports the idea that the inclined sleep products make the babies roll more easily from supine to prone. The flexed trunk and ease of head lifting during supine lying in an inclined sleep product may indicate that supine to prone rolling is achieved more easily.
- If babies roll from supine to prone in an inclined sleep product, then, due to the high musculoskeletal demands necessary to maintain safe posture to prevent suffocation, babies would fatigue faster than they would on a stable, flat surface.
- None of the inclined sleep products that were tested and evaluated as a part of this study are safe for infant sleep.

Additionally, the Mannen Study concludes:

- *20-Degree Incline Puts Infants at Risk for Muscle Fatigue and Suffocation:* Based on the results of the biomechanical study, the 20-degree incline resulted in significantly different muscle activity for the infants compared to the zero-degree incline surface. The increased demand on the abdominal muscles could lead to increased fatigue and suffocation if an infant is unable to reposition themselves after an accidental roll from supine to prone occurs.
- *10-Degree Incline Does Not Significantly Impact Infant Motion or Muscle Activity:* Based on the results of the biomechanical study, fewer differences in muscle activity or lying posture were revealed at a 10-degree mattress incline compared to the zero-degree incline surface. Ten degrees is a safe incline for sleep on a crib mattress surface.
- *Inclines Between 10 and 20 Degrees Should Be More Thoroughly Studied:* The experimental design of this study did not examine the angles between 10 and 20 degrees, so future work should focus on understanding which, if any, angles between 10 and 20 degrees may be safe for infant sleep.

The Mannen Study further states: ''It is likely that in incidents where babies were found deceased in the prone position, that an accidental roll occurred, and after some amount of struggling, the baby was fatigued and could no longer move into a position to prevent suffocation.'' Dr. Mannen concludes that an incline of 20 degrees or more puts an infant at risk compared to a 0–10 degree incline. Although her study did not test infants on inclines between 10–20 degrees, and thus did not offer conclusions for these angles, CPSC staff advises that additional testing on inclines between 10–20 degrees is unnecessary, because staff concludes that a flat surface that does not exceed 10 degrees offers the safest sleep environment for infants. This conclusion comports with staff's recommendations to remove the term ''inclined'' from the proposed mandatory standard, and to require that all sleep products not otherwise specified as cribs (full-size or non-full-size), play yards, or bedside sleepers meet the requirements in 16 CFR 1218 Safety Standard for Bassinets and Cradles, which, among other requirements, mandates that the seat back surface angle intended for sleep be 10 degrees or less.

V. International Standards for Inclined Sleep Products

The 2017 NPR described international standards that include infant inclined sleep products within their scope, noting that these standards are intended primarily to address hazards associated with products having flat sleeping surfaces, such as bassinets and cradles. These standards include:

- *The Cribs, Cradles, and Bassinets regulation included in the Canada Consumer Product Safety Act:* The Canadian regulation has similar requirements to ASTM F3118, such as

[7] *https://www.cpsc.gov/content/cpsc-consumer-alert-caregivers-urged-to-use-restraints-with-inclined-sleep-products.*

[8] *https://www.cpsc.gov/Newsroom/News-Releases/2019/CPSC–ALERT–CPSC-and-Fisher-Price-Warn-Consumers-About-Fisher-Price-Rock-N-Play-Due-to-Reports-of-Death-When-Infants-Roll-Over-in-the-Product.*

warnings, labels, and general performance requirements (*e.g.* lead content, small parts, openings). The Canadian regulation has additional requirements for slat strength, mesh material, structural integrity, and mattress supports. CPSC staff determined that the Canadian regulation provides similar performance requirements as ASTM F3118, but contains a more stringent requirement limiting the sleep seat back angle to 7° or less. However, the Canadian regulation allows a product to be marketed as a ''napper,'' which the Supplemental NPR proposes not to allow.

▪ *The European standard (SS–EN 1130: Furniture, Cribs, and Cradles Safety Requirements):* EN 1130 covers only inclined sleep products with a body and frame. The European standard would not include hammocks or similar products that are suspended from ceilings or other structures. EN 1130 includes requirements for construction and materials similar to the general ASTM F3118 requirements. Additional requirements include labeling, use instructions, packaging, and stability. EN 1130 is intended primarily to address hazards associated with bassinets and cradles and not the unique hazards associated with inclined sleep products. CPSC staff believes the ASTM standard is more inclusive because it includes all hammock styles. Additionally, EN 1130 does not address the hazards identified in the Mannen Study.

▪ *The Australian standard (AS/NZS 4385 Infants' rocking cradles—Safety requirements):* AS/NZS 4385 is intended for rocking cradles that swing, rock, or tilt, but specifically excludes hammocks that do not have this feature. Staff is unclear whether tilt means incline, thereby including in the Australian standard inclined sleep products as defined in ASTM F3118. AS/NZS 4385 contains requirements for construction, toxicology, and flammability, as well as general provisions, such as those for included toys. AS/NZS 4385 has some similar performance requirements as ASTM F3118, but is not as comprehensive. Additionally, the AS/NZS 4385 does not address the hazards identified in the Mannen Study.

VI. Voluntary Standard—ASTM F3118

A. History of ASTM F3118

Section 104(b)(1)(A) of the CPSIA requires the Commission to consult representatives of ''consumer groups, juvenile product manufacturers, and independent child product engineers and experts'' to ''examine and assess the effectiveness of any voluntary consumer product safety standards for durable infant or toddler products.'' As a result of incidents arising from inclined sleep products, the Commission directed CPSC staff to work with ASTM to develop voluntary requirements to address the hazard patterns related to the use of inclined sleep products. ASTM first approved ASTM F3118 on April 1, 2015, and published it in May 2015. Through the ASTM process, CPSC staff consulted with manufacturers, retailers, trade organizations, laboratories, consumer advocacy groups, consultants, and members of the public. The current standard, ASTM F3118–17a, was approved on September 1, 2017, and published in October of 2017. This is the fourth revision to the standard since it was first published in May 2015. ASTM F3118–17a is intended to address the following hazards: *(1)* Falls, *(2)* positional asphyxiation, and *(3)* obstruction of nose and mouth by bedding.

B. Description of the Current Voluntary Standard—ASTM F3118–17a

The 2017 NPR described the key provisions of ASTM F3118–17, including: scope, terminology, general requirements, performance requirements, test methods, marking and labeling, and instructional literature. 82 FR at 16967. The Supplemental NPR proposes to incorporate by reference the most recent version of the voluntary standard, ASTM F3118–17a, which is substantially the same as ASTM F3118–17, except that the accessory definition was updated to match the modification recommended in the 2017 NPR. Like the previous version, ASTM F3118–17a describes the scope of the voluntary standard, defines terms for various types of inclined sleep products, and sets out requirements for performance (such as for structural integrity and stability) and for warnings and instructions. As discussed elsewhere in this preamble, CPSC's proposed standard would make substantial modifications to ASTM F3118–17a.

VII. Assessment of the Voluntary Standard ASTM F3118–17a

In the 2017 NPR, CPSC proposed that incorporating by reference ASTM F3118–17, with a modification to the definition of ''accessory,'' would address the primary hazard patterns identified in the incident data. 82 FR at 16967–68. However, since the 2017 NPR, CPSC has become aware of additional fatalities and contracted the Mannen Study. The Mannen Study and more recent incident data indicate that ASTM F3118–17a is not adequate to address the risk of injury associated with infant inclined sleep products because the standard allows for products with a seat back angle greater than 10 degrees. The Commission finds that more stringent requirements than those found in ASTM F3118–17a are necessary in a mandatory rule to further reduce the risk of injury associated with infant inclined sleep products.

Following is an explanation of how the Supplemental NPR would address the product-related hazard patterns identified in section III.C of this preamble, discussing the proposed more stringent requirements where appropriate.

A. Design Problems

1. Suffocation Hazard

The Mannen Study results reveal that a 20° incline results in significantly different muscle activity for the infants compared to a 0° incline surface. The increased demand on infant abdominal muscles could lead to increased fatigue and suffocation if an infant is unable to reposition themselves after a roll from supine to prone occurs. At a 10° incline, fewer differences in muscle activity or lying posture were revealed compared to the 0° incline surface. According to Dr. Mannen's report, ''ten degrees is likely a safe incline for sleep on a crib mattress surface.'' Accordingly, the Commission proposes modifications to the introduction, scope, definitions, and performance requirements in ASTM F3118–17a, as described in section VIII of this preamble, to address the potential hazards of an infant sleeping on an inclined surface. Although her study did not test infants on inclines between 10°–20°, and thus did not offer conclusions for these angles, CPSC staff advises that additional testing on inclines between 10°–20° is unnecessary, concluding that a flat surface that does not exceed 10° offers the safest sleep environment for infants and would further reduce the risk of injury associated with inclined sleep products.

2. Additional Design Issues

CPSC staff identified two additional design issues: (1) Infant respiratory and/or skin ailments due to mold growth on the product, and (2) infant physical deformations such as *plagiocephaly* (flat head syndrome) and/or *torticollis* (twisted neck syndrome) from extended product use. In the reported cases of mold that resulted in respiratory problems for infants using the product, all cases were related to one particular

manufacturer's inclined sleep product. CPSC conducted a recall of that product in 2013. Infants who use an inclined sleep product that is known to develop visible mold can be at risk of developing health effects such as allergies, asthma, mycosis, and effects of mycotoxins. However, because the mold growth was restricted to one manufacturer's product and that product was recalled, the Commission is not proposing any modifications to address potential hazards associated with mold.

Plagiocephaly, cranial deformity or asymmetry (commonly known as flat head) is a condition that may exist at birth due to mechanical constraint of fetal head movement in the womb, birth-related injuries during assisted delivery, or as a result of increased likelihood of skull deformity as a consequence of premature birth. Muscular torticollis (twisted neck) is a known risk factor associated with plagiocephaly caused by constraint of head and neck movement. Although incident data indicate that consumers believe use of an inclined sleep product is the cause for their child's plagiocephaly/torticollis, no evidence supports this belief. Increase in the number of children with plagiocephaly may actually be attributed to the American Academy of Pediatrics' (AAP) recommendation to place infants to sleep on their backs to decrease the risk of sudden infant death syndrome (SIDS). Because the development of plagiocephaly and torticollis is not exclusively attributable to the use of infant inclined sleep products, the conditions are not addressable with performance standards. The Commission is not proposing any modifications to the voluntary standard to address these issues. Tab E of the Staff Supplemental Briefing Package provides the Directorate for Health Science's analysis of plagiocephaly and torticollis related to infant sleep products.

B. Electrical Issues

Staff determined that 127 of the 451 new incidents are related to electrical issues. The electrical-related issues included battery leakage, electric shock, and overheating of components. Some inclined sleep products have accessories that provide music, rocking motion, or vibration, which are either battery- or a/c-powered; however, F3118–17a does not include any performance requirements for electrical components. Other juvenile products that have similar features include performance requirements that could apply for infant sleep products. CPSC staff has raised this issue and is working with the ASTM Ad Hoc task group to develop performance requirements to address electrical hazards across juvenile products. Performance requirements would apply to other children's product standards, such as bouncers, swings, and bassinets. Because these requirements are currently under development, the Commission is not proposing electrical requirements in this Supplemental NPR, and instead expects staff to continue working with applicable ASTM subcommittees to develop electrical requirements for all applicable durable infant or toddler products with electrical components.

C. Structural Integrity and Other Product Related Issues

Structural integrity and other product related issues identified in this Supplemental NPR are similar to issues previously found in bassinet/cradle incidents. Accordingly, performance and testing requirements in the bassinet/cradle standard will likely address these incidents for infant sleep products.

D. Infant Placement Issues

Infants placed prone on soft bedding in inclined sleep products are at great risk for suffocation because of the incline and the soft bedding. Although requiring infant sleep products to comply with the bassinet/cradle standard will reduce the incline angle, and will provide warnings about not using soft bedding, parents may still place infants prone in the product. Staff will continue to work with ASTM and other organizations with information and education campaigns to prevent infants' deaths due to unsafe sleep practices.

VIII. Proposed Standard for Infant Sleep Products

This Supplemental NPR proposes to establish a children's product safety standard for infant sleep products as a type of durable infant or toddler product under section 104 of the CPSIA. The Mannen Study findings and incident reports indicate that neither ASTM F3118–17, nor ASTM F3118–17a, are adequate to address the risk of injury associated with infant inclined sleep products, because these voluntary standards allow for infant inclined sleep products with a seat back angle greater than 10 degrees. More stringent requirements are necessary in the mandatory standard to further reduce the risk of injury associated with infant inclined sleep products. Accordingly, the Supplemental NPR proposes to incorporate by reference ASTM F3118–17a as the mandatory standard for infant sleep products, with the following modifications:

a. Modify the introduction and scope of the standard to state the purpose of the standard is to address all infant sleep products not already covered by traditional sleep product standards.

b. Modify the definitions of accessory, compact, infant inclined sleep products, and newborn inclined sleep products to remove the term ''inclined.''

c. Modify seat back angle so the maximum allowable seat back angle must be equal to or less than 10° in all positions recommended for sleep.

d. Add new requirement—infant sleep products must meet 16 CFR 1218 Safety Standard for Bassinets and Cradles.

e. Remove all the performance requirements except for the above new or modified requirements.

f. Remove all test methods except for maximum seat back angle.

The Supplemental NPR proposes that infant sleep products meet 16 CFR 1218 Safety Standard for Bassinets and Cradles because this standard is an established standard for products that provide sleep accommodations for infants, and the standard addresses the hazard associated with inclined sleep by limiting the seat back angle to 10 degrees or less. Additionally, the name of CPSC's standard would not include the term ''inclined,'' and would be codified as 16 CFR part 1236, Safety Standard for Infant Sleep Products. A redline of these proposed changes is included at Tab C of the Staff Supplemental Briefing Package.

The Supplemental NPR proposes that infant sleep products meet the warning requirements in the bassinet and cradle standard, instead of those stated in ASTM F3118–17a. For this proposed modification, the Supplemental NPR relies on focus groups with parents and grandparents of infants less than 1 year of age. Participants provided information on caregivers' perceptions and reactions to safety messaging, indicating that participants were aware of warning labels on infant sleep products. Additionally, participants reported that the label shown during the focus group looked similar and contained comparable information to labels that they find on products they own. Some participants reported that they tend to gloss over warning labels, as they believe the language to be the same on every label. Some participants reported that they thought the main message on a warning label was to be careful and keep an eye on their infant. In contrast, a few participants believed that manufacturers use warning labels to protect themselves from liability or litigation. Participants'

recommendations to improve warning labels included making the labels more concise and making the labels ''stand out.'' CPSC staff is working with a contractor to develop new safe sleep warnings and messaging, potentially across all sleep products. In the future, staff could recommend changes in warnings based on this work.

IX. Proposed Amendment to 16 CFR Part 1112 To Include NOR for Infant Sleep Products

The CPSA establishes certain requirements for product certification and testing. Products subject to a consumer product safety rule under the CPSA, or to a similar rule, ban, standard or regulation under any other act enforced by the Commission, must be certified as complying with all applicable CPSC-enforced requirements. 15 U.S.C. 2063(a). Certification of children's products subject to a children's product safety rule must be based on testing conducted by a CPSC-accepted third party conformity assessment body. *Id.* 2063(a)(2). The Commission must publish an NOR for the accreditation of third party conformity assessment bodies to assess conformity with a children's product safety rule to which a children's product is subject. *Id.* 2063(a)(3). Thus, the proposed rule for 16 CFR part 1236, *Standard Consumer Safety Specification for Infant Sleep Products,* if issued as a final rule, would be a children's product safety rule that requires the issuance of an NOR.

The Commission published a final rule, *Requirements Pertaining to Third Party Conformity Assessment Bodies,* 78 FR 15836 (March 12, 2013), codified at 16 CFR part 1112 (''part 1112'') and effective on June 10, 2013, which establishes requirements for accreditation of third party conformity assessment bodies to test for conformity with a children's product safety rule in accordance with section 14(a)(2) of the CPSA. Part 1112 also codifies all of the NORs issued previously by the Commission.

All new NORs for new children's product safety rules, such as the inclined sleep products standard, require an amendment to part 1112. To meet the requirement that the Commission issue an NOR for the inclined sleep products standard, as part of this NPR, the Commission proposes to amend the existing rule that codifies the list of all NORs issued by the Commission to add inclined sleep products to the list of children's product safety rules for which the CPSC has issued an NOR.

Test laboratories applying for acceptance as a CPSC-accepted third party conformity assessment body to test to the new standard for inclined sleep products would be required to meet the third party conformity assessment body accreditation requirements in part 1112. When a laboratory meets the requirements as a CPSC-accepted third party conformity assessment body, the laboratory can apply to the CPSC to have 16 CFR part 1236, *Standard Consumer Safety Specification for Infant Sleep Products,* included in the laboratory's scope of accreditation of CPSC safety rules listed for the laboratory on the CPSC website at: *www.cpsc.gov/labsearch.*

X. Proposed Amendment to Definitions in Consumer Registration Rule

The statutory definition of ''durable infant or toddler product'' in section 104(f) applies to all of section 104 of the CPSIA. In addition to requiring the Commission to issue safety standards for durable infant or toddler products, section 104 of the CPSIA also directed the Commission to issue a rule requiring that manufacturers of durable infant or toddler products establish a program for consumer registration of those products. Public Law 110–314, section 104(d).

Section 104(f) of the CPSIA defines the term ''durable infant or toddler product'' and lists examples of such products, including several types of infant sleep products, such as cribs and bassinets and cradles. Section 104(f)(2)(A) & (L). As discussed previously, the infant sleep products safety standard is an outgrowth of the bassinet safety standard. The Supplemental NPR proposes that any infant sleep product that is not already subject to a mandatory consumer product safety rule for infant sleep, be subject to proposed part 1236, which would limit the seat back incline angle to 10 degrees or less. Like bassinets, such sleep products are durable products within the meaning of section 104 of the CPSIA.

Because this infant sleep product standard is an outgrowth of the bassinet standard, infant sleep products may be considered a sub-category of bassinets. To provide greater clarity that inclined sleep products are durable infant or toddler products, the Commission proposes to amend the Commission's consumer registration rule to explicitly include infant sleep products.

In 2009, the Commission issued a rule implementing the consumer registration requirement. 16 CFR part 1130. As the CPSIA directs, the consumer registration rule requires each manufacturer of a durable infant or toddler product to: provide a postage-paid consumer registration form with each product; keep records of consumers who register their products with the manufacturer; and permanently place the manufacturer's name and certain other identifying information on the product. When the Commission issued the consumer registration rule, the Commission identified six additional products as ''durable infant or toddler products'':

- Children's folding chairs
- changing tables;
- infant bouncers;
- infant bathtubs;
- bed rails; and
- infant slings.

16 CFR 1130.2. The Commission stated that the specified statutory categories were not exclusive, but that the Commission should explicitly identify the product categories that are covered. The preamble to the 2009 final consumer registration rule states: ''Because the statute has a broad definition of a durable infant or toddler product but also includes 12 specific product categories, additional items can and should be included in the definition, but should also be specifically listed in the rule.'' 74 FR 68668, 68669 (Dec. 29, 2009).

In this Supplemental NPR, the Commission proposes to amend the definition of ''durable infant or toddler product'' in the consumer registration rule to clarify that infant sleep products fall within the term ''durable infant or toddler product'' as a subset of bassinets and cradles, and must comply with the product registration card rule and section 104 of the CPSIA.

XI. Incorporation by Reference

The Commission proposes to incorporate by reference ASTM F3118–17a, with substantial modifications to further reduce the risk of injury. The Office of the Federal Register (OFR) has regulations concerning incorporation by reference. 1 CFR part 51. For a proposed rule, agencies must discuss in the preamble of the NPR ways that the materials the agency proposes to incorporate by reference are reasonably available to interested persons or how the agency worked to make the materials reasonably available. In addition, the preamble of the proposed rule must summarize the material. 1 CFR 51.5(a).

In accordance with the OFR's requirements, section VIII of this preamble summarizes the provisions of ASTM F3118–17a that the Commission proposes to incorporate by reference. ASTM F3118–17a is copyrighted. By permission of ASTM, the standard can

be viewed as a read-only document during the comment period on this NPR, at: *http://www.astm.org/cpsc.htm.* Interested persons may also purchase a copy of ASTM F3118–17 from ASTM International, 100 Bar Harbor Drive, P.O. Box 0700, West Conshohocken, PA 19428; *http://www.astm.org/cpsc.htm.* One may also inspect a copy at CPSC's Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone 301–504–7923.

XII. Effective Date

The Administrative Procedure Act (APA) generally requires that the effective date of a rule be at least 30 days after publication of the final rule. 5 U.S.C. 553(d). ASTM F3118–17a is a relatively new voluntary standard that covers a variety of products whose manufacturers may not be aware that their product must comply. The Commission is proposing to incorporate by reference ASTM F3118–17a, with substantial modifications to further reduce the risk of injury associated with infant inclined sleep products. To allow time for infant sleep product manufacturers to bring their products into compliance after a final rule is issued, the Commission proposes a 12-month effective date after publication of a final rule, for products manufactured or imported on or after that date. Because of the number of proposed modifications to ASTM F3118–17a, compliance with the mandatory standard may require time beyond the typical 6-month effective date for a section 104 rule. The Commission expects that most firms should be able to comply within the 12-month timeframe. Alternatively, given the hazards involved with infant inclined sleep products, the Commission could issue a final rule with a shorter effective date so that safer products would be available sooner. The Commission requests comments on whether either a longer or shorter effective date would be appropriate.

XIII. Regulatory Flexibility Act

A. Introduction

The Regulatory Flexibility Act (RFA) requires that agencies review a proposed rule for the rule's potential economic impact on small entities, including small businesses. Section 603 of the RFA generally requires that agencies prepare an initial regulatory flexibility analysis (IRFA) and make the analysis available to the public for comment when the agency publishes an NPR. 5 U.S.C. 603. Section 605 of the RFA provides that an IRFA is not required if the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. The IRFA must describe the impact of the proposed rule on small entities and identify significant alternatives that accomplish the statutory objectives and minimize any significant economic impact of the proposed rule on small entities. Specifically, the IRFA must contain:

- A description of the reasons why action by the agency is being considered;
- a succinct statement of the objectives of, and legal basis for, the proposed rule;
- a description of, and where feasible, an estimate of the number of small entities to which the proposed rule will apply;
- a description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities subject to the requirements and the type of professional skills necessary for the preparation of reports or records; and
- identification, to the extent possible, of all relevant federal rules that may duplicate, overlap, or conflict with the proposed rule; and

Additionally, the IRFA must describe any significant alternatives to the proposed rule that accomplish the stated objectives of applicable statutes and minimize any significant economic impact of the proposed rule on small entities.

CPSC staff prepared an IRFA for this rulemaking which appears at Tab F of the Staff Supplemental Briefing Package. We provide a summary of the IRFA below.

B. Reasons for Agency Action and Legal Basis for Supplemental NPR

As explained elsewhere in this preamble, section 104 of the CPSIA authorizes the Commission to issue standards for durable infant or toddler products and requires that such products comply with product registration requirements. The Commission is issuing this Supplemental NPR in response to reports of deaths involving inclined sleep products.

C. Supplemental NPR Requirements

The Supplemental NPR would incorporate by reference the voluntary standard for inclined sleep products (ASTM F3118–17a) with substantial modifications described in section VIII of this preamble. Products subject to the proposed standard would need to have a sleep surface angle no greater than 10° and would need to meet the requirements of the CPSC standard for bassinets and cradles. If the Commission issues a final rule, the proposed rule would become a mandatory standard, and firms with a sleep product that is subject to the rule would need to evaluate their product, determine what changes would be required to meet the standard, and modify the product so that it complies with the standard or cease supplying the product to the U.S. market. The manufacture or importation of noncompliant products would be prohibited after the effective date of the standard. Additionally, manufacturers and importers must certify that their products comply with applicable children's products safety standards, and this certification must be based on testing by a third party. 16 CFR part 1107.

D. Small Entities Supplying Infant Sleep Products and the Supplemental NPR's Impact on Small Businesses

Since the Commission issued the 2017 NPR, the U.S. inclined sleep product market has changed substantially. Manufacturers and importers have largely stopped producing for sale most frame-style inclined sleep products from the market, including some that were not subject to recalls, although one or two types of products remain.[9] Additionally, a significant decline in the infant hammock market has occurred, both among larger-scale suppliers and home-based manufacturers.

As part of the current market evaluation, staff identified 18 firms still supplying sleep products to the U.S. market with sleep surface angles greater than 10 degrees, but less than or equal to 30 degrees. Staff identified an additional firm supplying a sleep product with an incline of 10 degrees or less that is not being tested for compliance with either the bassinet standard or another sleep product standard (and thus, likely would be subject to the Supplemental NPR). Of these 19 total firms, six appear to be very small, home-based manufacturers of infant hammocks (two operating domestically and four overseas).[10] The RFA covers only domestic suppliers. Seven of the 19 firms are not as small as the home-based infant hammock

[9] Some units may still be available for sale even for products that are no longer being produced (this does *not* include recalled models).

[10] These suppliers were identified online, and staff believes that there may be additional home-based manufacturers supplying infant hammocks on a very small scale (possibly including some without an on-line presence).

manufacturers, but would meet the definition of ''small'' domestic entities based on U.S. Small Business Administration (SBA) guidelines for their North American Industry Classification System (NAICS) codes. These seven firms typically have only one inclined sleep model in their product lines.

In summary, CPSC staff is aware of nine small domestic firms currently marketing products that would be impacted by the Supplemental NPR in the United States (two home-based domestic hammock manufacturers, four small domestic manufacturers of inclined sleep products, and three small importers of inclined sleep products). Staff cannot definitively determine the impact of the Supplemental NPR because the impact would depend on several unknown factors including:

- How firms respond to the rule (*e.g.,* they would redesign, remarket, or drop products subject to the Supplemental NPR);
- The costs associated with redesigning, remarketing, or replacing an inclined sleep product;
- The change, if any, on demand for that product.

Staff estimates that third party testing costs could be $30 to $100 per sample for the maximum incline test alone, and testing to the bassinet standard could add costs up to another $1,000. Reliance on third party tests obtained by suppliers as allowed by the component part testing rule (16 CFR part 1109) could reduce testing costs to some extent. Staff found that third party costs are likely to be significant for the two very small home-based manufacturers of infant hammocks *if they choose to redesign;* and costs could be significant for an additional two small manufacturers, if they chose to redesign their products and testing as few as four units per model were required to provide a ''high degree of assurance.''

E. Alternatives

At least two alternatives are available that could minimize the economic impact on small entities while also meeting the statutory objectives: [11] (1) Eliminate the requirement that products must meet the bassinet standard if they do not already fall into another sleep product standard; or (2) allow a later effective date. However, under the first alternative, the cost of redesign would still likely be significant. Moreover, the Supplemental NPR is intended to ensure that all products providing sleep accommodations for infants meet a base set of safety requirements. This alternative would not accomplish this goal.

Second, the Commission could also reduce the Supplemental NPR's impact on small businesses by setting a later effective date than the proposed 12 months. A later effective date would reduce the economic impact on firms redesigning their existing products in two ways. Firms would be less likely to experience a lapse in production/importation, which could result if they are unable to bring their products into compliance and certify compliance based on third party tests within the required timeframe. Also, firms could spread the costs of developing compliant products over a longer time period, thereby reducing their annual costs, as well as the present value of their total costs (*i.e.,* they could time their spending to better accommodate their individual circumstances). The Commission requests comments on the 12-months effective date, which was set to help reduce the impact on affected firms, as well as feedback on how firms would likely respond to the Supplemental NPR.

F. Small Business Impacts of the Accreditation Requirements for Testing Laboratories

In accordance with section 14 of the CPSA, all children's products that are subject to a children's product safety rule must be tested by a CPSC-accepted third party conformity assessment body (*i.e.,* testing laboratory) for compliance with applicable children's product safety rules. Testing laboratories that want to conduct this testing must meet the NOR pertaining to third party conformity testing. NORs have been codified for existing rules at 16 CFR part 1112. Consequently, the Commission proposes to amend 16 CFR part 1112 to establish the NOR for those testing laboratories that want to test for compliance with the infant sleep products final rule (in essence, test for maximum seat back angle). This section assesses the impact of the amendment on small laboratories.

A final regulatory flexibility analysis (FRFA) was conducted as part of the promulgation of the original 1112 rule (78 FR 15836, 15855–58), as required by the RFA. Briefly, the FRFA concluded that the accreditation requirements would not have a significant adverse impact on a substantial number of small laboratories because no requirements were imposed on laboratories that did not intend to provide third party testing services. The only laboratories that were expected to provide such services were those that anticipated receiving sufficient revenue from the mandated testing to justify accepting the requirements as a business decision.

Based on similar reasoning, amending the rule to include the NOR for the infant sleep product standard will not have a significant adverse impact on small laboratories. Moreover, based upon the number of laboratories in the United States that have applied for CPSC acceptance of the accreditation to test for conformance to other juvenile product standards, we expect that only a few laboratories will seek CPSC acceptance of their accreditation to test for conformance with the infant sleep product standard. Most of these laboratories will have already been accredited to test for conformance to other juvenile product standards, and the only costs to them would be the cost of adding the infant sleep product standard to their scope of accreditation, a cost that test laboratories have indicated is extremely low when they are already accredited for other section 104 rules. Consequently, the Commission certifies that the NOR for the infant sleep product standard will not have a significant impact on a substantial number of small entities.

XIV. Environmental Considerations

The Commission's regulations address whether the agency is required to prepare an environmental assessment or an environmental impact statement. Under these regulations, certain categories of CPSC actions normally have ''little or no potential for affecting the human environment,'' and therefore do not require an environmental assessment or an environmental impact statement. Safety standards providing requirements for products come under this categorical exclusion. 16 CFR 1021.5(c)(1). The Supplemental NPR falls within the categorical exclusion.

XV. Paperwork Reduction Act

This proposed rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). In this document, pursuant to 44 U.S.C. 3507(a)(1)(D), we set forth:

- A title for the collection of information;
- a summary of the collection of information;
- a brief description of the need for the information and the proposed use of the information;

[11] Staff considered whether adopting the voluntary inclined sleeper standard with no modifications might also be an alternative, but ruled it out because it would not address the injuries and deaths that led to the recent inclined sleeper recalls.

- a description of the likely respondents and proposed frequency of response to the collection of information;
- an estimate of the burden that shall result from the collection of information; and
- notice that comments may be submitted to the OMB.

Title: Safety Standard for Infant Sleep Products.

Description: The Supplemental NPR would incorporate by reference ASTM F3118–17a, *Standard Consumer Safety Specification for Infant Inclined Sleep Products,* but with modifications, including to sections 8 and 9 which contain requirements for marking, labeling, and instructional literature. The Supplemental NPR would exclude from the rule infant sleep products covered by another mandatory standard for sleep products (Section 1.3). However, the Supplemental NPR would modify section 5.2 of ASTM F3118–17a to require that accessory, compact, infant sleep products, and newborn sleep products meet the requirements of the Safety Standard for Bassinets and Cradles (16 CFR 1218), including the marking, labeling, and instructional requirements. These marking, labeling, and instructional requirements fall within the definition of ''collection of information,'' as defined in 44 U.S.C. 3502(3).

Description of Respondents: Persons who manufacture or import infant sleep products.

Estimated Burden: We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

Burden type	Type of supplier	Number of respondents	Frequency of responses	Total annual responses	Hours per response	Total burden hours
Labeling	Home-based manufacturers	6	1	6	7	42
	Other Suppliers	13	1	13	1	13
Labeling Total						55
Instructional literature	Home-based manufacturers	6	1	50	300	300
Total Burden						355

Our estimate is based on the following:

Two groups of quantifiable entities supply infant sleep products to the U.S. market that will likely need to make some modifications to their existing warning labels to meet the requirements for bassinet and cradle warnings. The first group consists of very small home-based manufacturers, which may not currently have warning labels on their infant sleep products. Similar rulemakings (such as that for sling carriers) assumed that it would take home-based manufacturers approximately 15 hours to develop a new label. Given that some home-based manufacturers supply infant sleep products with warning labels already, we have estimated approximately 7 hours per response for this group of suppliers. Therefore, the total burden hours for very small home-based manufacturers is 7 hours per model × 6 entities × 1 models per entity = 42 hours.

The second group of quantifiable entities supplying infant sleep products to the U.S. market that will need to make some modifications to their existing warning labels are non-home-based manufacturers and importers. These firms do not operate at the low production volume of the home-based firms. All of the firms in this second group have existing warning labels on their products, but not for bassinets and cradles and would therefore, have to make label modifications. Given that these firms are used to working with warning labels, we estimate that the time required to make any modifications now or in the future would be about 1 hour per model. Based on an evaluation of supplier product lines, each entity supplies an average of 1 model of infant sleeper; therefore, the estimated burden associated with labels for this second group is 1 hours per model × 13 entities × 1 models per entity = 13 hours.

The total burden hours attributable to warning labels is the sum of the burden hours for both entity groups: Very small home-based manufacturers (42 burden hours) + non-home-based manufacturers and importers (13 burden hours) = 55 burden hours. We estimate the hourly compensation for the time required to create and update labels is $34.61 (U.S. Bureau of Labor Statistics, ''Employer Costs for Employee Compensation,'' March 2019, total compensation for all sales and office workers in goods-producing private industries, series id CMU201G000200000D: *http://www.bls.gov/ncs/*). Therefore, the estimated annual cost to industry associated with the labeling requirements is $1,904 ($34.61 per hour × 55 hours = $1,904). No operating, maintenance, or capital costs are associated with the collection.

The Standard for Bassinets and Cradles (section 9) requires instructions to be supplied with the product. As already noted, the proposed Safety Standard for Infant Sleep Products requires accessory, compact, infant sleep products, and newborn sleep products to meet these requirements. Under the OMB's regulations (5 CFR 1320.3(b)(2)), the time, effort, and financial resources necessary to comply with a collection of information that would be incurred by persons in the ''normal course of their activities'' are excluded from a burden estimate, where an agency demonstrates that the disclosure activities required to comply are ''usual and customary.''

We are unaware of infant sleep products that generally require use instructions but lack such instructions. However, it is possible that the six home-based manufacturers of infant hammocks may not supply instruction manuals as part of their ''normal course of activities.'' Based on information collected for the infant slings rulemaking, staff tentatively estimates that each small entity supplying homemade infant hammocks might require 50 hours to develop an instruction manual to accompany their products. These firms typically supply only one infant hammock model. Therefore, the costs of designing an instruction manual for these firms could be as high as $10,383 (50 hours per model × 6 entities × 1 models per entity = 300 hours × $34.61 per hour = $10,383). Not all firms would incur these costs every year, but new firms that enter the market would incur these costs, and this is a highly fluctuating market. Other firms are estimated to have no burden hours associated with section 9 of the Standard for Bassinets and Cradles because any burden associated with supplying instructions with infant sleep products would be ''usual and customary'' and not within

the definition of ''burden'' under the OMB's regulations.

Based on this analysis, CPSC staff estimates that the Supplemental NPR for infant sleep products would impose a burden to industry of 355 hours at a cost of $12,287 annually.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), we have submitted the information collection requirements of this rule to the OMB for review. Interested persons are requested to submit comments regarding information collection by December 12, 2019, to the Office of Information and Regulatory Affairs, OMB (see the **ADDRESSES** section at the beginning of this notice).

Pursuant to 44 U.S.C. 3506(c)(2)(A), we invite comments on:

- Whether the collection of information is necessary for the proper performance of the CPSC's functions, including whether the information will have practical utility;
- the accuracy of the CPSC's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- ways to enhance the quality, utility, and clarity of the information to be collected;
- ways to reduce the burden of the collection of information on respondents, including the use of automated collection techniques, when appropriate, and other forms of information technology;
- the estimated burden hours required for home-based manufacturers to modify warning labels;
- the estimated burden hours associated with label modification for non-home-based suppliers, including any alternative estimates;
- the estimated burden hours required for home-based manufacturers to modify (or, in some cases, create) instruction manuals.

XVI. Preemption

Section 26(a) of the CPSA, 15 U.S.C. 2075(a), provides that when a consumer product safety standard is in effect and applies to a product, no state or political subdivision of a state may either establish or continue in effect a standard or regulation that prescribes requirements for the performance, composition, contents, design, finish, construction, packaging, or labeling of such product dealing with the same risk of injury unless the state requirement is identical to the federal standard. Section 26(c) of the CPSA also provides that states or political subdivisions of states may apply to the Commission for an exemption from this preemption under certain circumstances. Section 104(b) of the CPSIA refers to the rules to be issued under that section as ''consumer product safety rules.'' Therefore, the preemption provision of section 26(a) of the CPSA would apply to a rule issued under section 104.

XVII. Request for Comments

This Supplemental NPR proposes a rule under section 104(b) of the CPSIA to issue a consumer product safety standard for infant sleep products, to amend part 1112 to add infant sleep products to the list of children's product safety rules for which the CPSC has issued an NOR, and to amend part 1130 to identify infant sleep products as a durable infant or toddler product subject to CPSC consumer registration requirements. The Commission requests comments on the standard's scope language; the proposed effective date; the costs of compliance with, and testing to, the proposed Safety Standard for Infant Sleep Products; and any aspect of this proposal. During the comment period, the ASTM F3118–17a Standard Consumer Safety Specification for Infant Inclined Sleep Products, is available as a read-only document at: *http://www.astm.org/cpsc.htm.*

The Commission requests comments on the following specific issues:

- Products likely to be impacted by the Supplemental NPR, including the product categories discussed in the preamble and any additional types of products that commenters believe may be impacted by the Supplemental NPR.
- How firms with inclined sleep surfaces will likely respond to the Supplemental NPR, including suppliers of products with inclines above 10 degrees and products with inclines less than or equal to 10 degrees that do not already comply with the bassinet standard. We would also appreciate any information on the possible responses of consumers to changes in marketing. Additionally, any information on the approximate percentage of revenue attributable to these types of products would be valuable. The Commission also requests any information regarding the safety of sleep angles in excess of 10 degrees but less than 20 degrees.
- The impact that promulgating the Supplemental NPR would have on the cost of testing and certifying products, particularly on small manufacturers and importers. Any information on the number of samples that must be tested would be especially helpful. The Commission also requests comments on the third party testing costs of the maximum incline test in the Supplemental NPR.
- The cost of redesign, the time required for redesign, the likely response of manufacturers to the Supplemental NPR's requirements (*i.e.,* redesign, remarket, or drop), the possible change in demand due to remarketing or changing the sleep surface's degree of incline, the cost of (and time required for) remarketing, and (for firms supplying comments) the relative significance of inclined sleepers to their total revenue. The Commission also requests comments on testing costs, including the number of inclined sleeper units that typically need to be tested to provide a ''high degree of assurance'' of compliance.
- The age and developmental milestones referenced in the scope and definitions of the various infant inclined sleep products covered by ASTM F3118–17a. Because this Supplemental NPR proposes to address ''infant sleep products'' not already covered by traditional sleep products, the Commission is considering removing the upper age limit from the scope of the mandatory standard, to accommodate a broad scope of infant sleep products within the standard. The Commission's consideration is based on the fact that when staff knew the age of an infant, twenty percent of the fatalities and injuries involved infants 6 months and older.
- The APA generally requires that the effective date of a rule be at least 30 days after publication of the final rule. 5 U.S.C. 553(d). Section XII of this preamble proposes a 12-month effective date after publication of a final rule, for products manufactured or imported on or after that date, stating that a longer effective date than the typical 6 months for a section 104 rule may be necessary because of the number of proposed modifications to ASTM F3118–17a. Given the hazards involved with infant inclined sleep products, the Commission could issue a final rule with a shorter effective date so that safer products would be available sooner. The Commission requests comments on whether either a longer or shorter effective date would be appropriate.

Comments should be submitted in accordance with the instructions in the **ADDRESSES** section at the beginning of this notice.

List of Subjects

16 CFR Part 1112

Administrative practice and procedure, Audit, Consumer protection, Reporting and recordkeeping requirements, Third party conformity assessment body.

16 CFR Part 1130

Administrative practice and procedure, Business and industry, Consumer protection, Reporting and recordkeeping requirements.

16 CFR Part 1236

Consumer protection, Imports, Incorporation by reference, Infants and children, Labeling, Law enforcement, and Toys.

For the reasons discussed in the preamble, the Commission proposes to amend Title 16 of the Code of Federal Regulations as follows:

PART 1112—REQUIREMENTS PERTAINING TO THIRD PARTY CONFORMITY ASSESSMENT BODIES

■ 1. The authority citation for part 1112 continues to read as follows:

Authority: Pub. L. 110–314, section 3, 122 Stat. 3016, 3017 (2008); 15 U.S.C. 2063.

■ 2. Amend § 1112.15 by adding paragraph (b)(46) to read as follows:

§ 1112.15 When can a third party conformity assessment body apply for CPSC acceptance for a particular CPSC rule or test method?

* * * * *

(b) * * *

(46) 16 CFR part 1236, Safety Standard for Infant Sleep Products.

* * * * *

PART 1130—REQUIREMENTS FOR CONSUMER REGISTRATION OF DURABLE INFANT OR TODDLER PRODUCTS

■ 3. The authority citation for part 1130 continues to read as follows:

Authority: 15 U.S.C. 2056a, 2065(b).

■ 4. Amend § 1130.2 by revising paragraph (a)(12) to read as follows:

§ 1130.2 Definitions.

* * * * *

(a) * * *

(12) Bassinets and cradles, including bedside sleepers and infant sleep products;

* * * * *

■ 5. Add part 1236 to read as follows:

PART 1236—SAFETY STANDARD FOR INFANT SLEEP PRODUCTS

Sec.

1236.1 Scope.
1236.2 Requirements for infant sleep products.

Authority: Sec. 104, Pub. L. 110–314, 122 Stat. 3016 (15 U.S.C. 2056a); Sec. 3, Pub. L. 112–28, 125 Stat. 273.

§ 1236.1 Scope.

This part establishes a consumer product safety standard for infant sleep products, including: Frame-type, hammock, compact, and accessory. This consumer product safety standard covers all infant sleep products that are not covered by another consumer product safety standard, including:

(a) 16 CFR part 1218 Safety Standard for Bassinets and Cradles;

(b) 16 CFR part 1219 Safety Standard for Full-Size Baby Cribs;

(c) 16 CFR part 1220 Safety Standard for Non-Full-Size Baby Cribs;

(d) 16 CFR part 1221 Safety Standard for Play Yards; and

(e) 16 CFR part 1222 Safety Standard for Bedside Sleepers.

§ 1236.2 Requirements for infant sleep products.

(a) Except as provided in paragraph (b) of this section, each infant sleep product must comply with all applicable provisions of ASTM F3118–17a, Standard Consumer Safety Specification for Infant Inclined Sleep Products (approved on September 1, 2017). The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from ASTM International, 100 Bar Harbor Drive, P.O. Box 0700, West Conshohocken, PA 19428; *http://www.astm.org/cpsc.htm.* You may inspect a copy at the Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone 301–504–7923, or 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: *www.archives.gov/federal-register/cfr/ibr-locations.*

(b) Comply with ASTM F3118–17a with the following additions or exclusions:

(1) Instead of complying with Introduction of ASTM F3118–17a, comply with the following:

(i) *Introduction.* (A) This consumer safety specification addresses incidents associated with infant inclined sleep products identified by the U.S. Consumer Product Safety Commission (CPSC).

(B) In response to incident data compiled by the CPSC, this consumer safety specification attempts to minimize the following: Fall hazards, positional asphyxiation, and obstruction of nose and mouth by bedding. The purpose of the standard is to address infant sleep products not already covered by traditional sleep product standards and to prevent deaths due to the use of Infant Sleep Products with a seat back angle greater than 10° from the horizontal.

(C) This consumer safety specification is written within the current state-of-the-art of infant sleep product technology and will be updated whenever substantive information becomes available that necessitates additional requirements or justifies the revision of existing requirements.

(ii) [Reserved].

(2) In section 1.1 of ASTM F3118–17a, replace the term ''infant inclined sleep products'' with ''infant sleep products.''

(3) In section 1.2 of ASTM F3118–17a, replace the term ''infant inclined sleep products'' with ''infant sleep products.''

(4) Instead of complying with section 1.3 of ASTM F3118–17a, comply with the following:

(i) 1.3 This consumer safety performance specification covers products that are not covered by other ASTM standards such as:

(A) ASTM F1169 Standard Consumer Safety Specification for Full-Size Baby Cribs;

(B) ASTM F406 Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards;

(C) ASTM F2194 Standard Consumer Safety Specification for Bassinets and Cradles; and

(D) ASTM F2906 Standard Consumer Safety Specification for Bedside Sleepers. This consumer safety performance specification covers free standing products with an infant sleep surface primarily intended and marketed to provide sleeping accommodations for an infant up to 5 months old or when the infant begins to roll over or pull up on sides, whichever comes first. It also covers smaller products intended for newborns up to 3 months old or when a newborn begins to wiggle out of position or turn over in the product or weighs more than 15 lb (6.8 kg), whichever comes first. It also covers infant and newborn sleep product accessories, which are attached to or supported by, another product with the same age or abilities, or both, as the free standing products. If the infant sleep product can be converted into a product for which another ASTM standard consumer safety specification exists, the product shall meet the applicable requirements of that standard.

(ii) [Reserved].

(5) In section 1.4 of ASTM F3118–17a, replace the term ''infant inclined sleep product'' with ''infant sleep product.''

(6) Instead of complying with section 2 of ASTM F3118–17a, comply with the following:

(i) 2. Referenced Documents.

(ii) 2.1 ASTM Standards.[12] (A) F406 Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards;

(B) F1169 Standard Consumer Safety Specification for Full-Size Baby Cribs;

(C) F2194 Consumer Safety Specification for Bassinets and Cradles;

(D) F2906 Standard Consumer Safety Specification for Bedside Sleepers.

(iii) 2.2 Federal Standards.[13]

(A) 16 CFR part 1218—Safety Standard for Bassinets and Cradles;

(B) 16 CFR part 1219—Safety Standard for Full-Size Baby Cribs;

(C) 16 CFR part 1220—Safety Standard for Non-Full-Size Baby Cribs;

(D) 16 CFR part 1221—Safety Standard for Play Yards; and

(E) 16 CFR part 1222—Safety Standard for Bedside Sleepers.

(7) Do not comply with sections 2.3 and 2.4 of ASTM F3118–17a, including Figures 1 and 2.

(8) In section 3.1.1 of ASTM F3118–17a, replace the following terms:

(i) Replace the term ''accessory inclined sleep product'' with ''accessory infant sleep product.''

(ii) Replace the term ''inclined sleep product'' with ''infant sleep product.''

(9) In section 3.1.2 of ASTM F3118–17a, replace the following terms:

(i) Replace the term ''compact inclined sleep product'' with ''compact infant sleep product.''

(ii) Replace the term ''newborn inclined sleep product'' with ''newborn infant sleep product.''

(10) Do not comply with sections 3.1.3 through 3.1.6 of ASTM F3118–17a.

(11) Instead of complying with section 3.1.7 of ASTM F3118–17a, comply with the following:

(i) 3.1.7 *infant sleep product, n*—a freestanding product, intended to provide a sleeping accommodation for an infant up to approximately 5 months of age, that is generally supported by a stationary or rocker base and that is not subject to any of the following standards:

(A) 16 CFR part 1218—Safety Standard for Bassinets and Cradles;

(B) 16 CFR part 1219—Safety Standard for Full-Size Baby Cribs;

(C) 16 CFR parts 1220 and 1221—Safety Standard for Non-Full-Size Baby Cribs and Play Yards; and

(D) 16 CFR part 1222—Safety Standard for Bedside Sleepers.

(ii) [Reserved].

(12) Do not comply with sections 3.1.7.1 through 3.1.9 of ASTM F3118–17a.

(13) Instead of complying with section 3.1.10 of ASTM F3118–17a, comply with the following:

(i) 3.1.10 *newborn sleep product, n*—a free standing product, intended to provide sleeping accommodations for a newborn up to approximately 3 months of age, that is supported by a stationary or rocker base and whose seat back length, measured from the bight, is not greater than 17 in. (432 mm) and that is not subject to any of the following standards:

(A) 16 CFR part 1218—Safety Standard for Bassinets and Cradles;

(B) 16 CFR part 1219—Safety Standard for Full-Size Baby Cribs;

(C) 16 CFR parts 1220 and 1221—Safety Standard for Non-Full-Size Baby Cribs and Play Yards; and

(D) 16 CFR part 1222—Safety Standard for Bedside Sleepers.

(ii) [Reserved].

(14) Do not comply with sections 3.1.11 through 3.1.13 of ASTM F3118–17a.

(15) Do not comply with section 5 of ASTM F3118–17a.

(16) Do not comply with sections 6.1 through 6.8 of ASTM F3118–17a.

(17) Instead of complying with section 6.9 of ASTM F3118–17a, comply with the following:

(i) *6.9 Maximum Seat Back Angle.*

(ii) *6.9.1 Accessory, Compact, and Infant Sleep Product*—The angle of the seat back surface intended for sleep along the occupant's head to toe axis relative to the horizontal shall not exceed 10° when tested in accordance with 7.11.2.

(iii) *6.9.2 Accessory, Compact, and Newborn Sleep Product*—The angle of the seat back surface intended for sleep along the occupant's head to toe axis relative to the horizontal shall not exceed 10° when tested in accordance with 7.11.3.

(iv) 6.9.3 *Accessory, Compact, Infant Sleep Products, and Newborn Sleep Products*—shall meet requirements of 16 CFR part 1218 Safety Standard for Bassinets and Cradles.

(18) Do not comply with sections 6.10 through 7.10 of ASTM F3118–17a.

(19) In section 7.11.2.1 of ASTM F3118–17a, replace ''*Infant Inclined Sleep Product and Infant Inclined Sleep Product Accessory*'' with ''*Accessory, Compact, Infant Sleep Products, and Newborn Sleep Products.*''

(20) In section 7.11.2.1 of ASTM F3118–17a, replace ''If applicable, place the product in the manufacturer's recommended highest incline angle position.'' with ''If applicable, place the product in the manufacturer's recommended highest seat back angle position intended for sleep.''

(21) In section 7.11.3 of ASTM F3118–17a, replace ''*Newborn Inclined Sleep Product and Newborn Inclined Sleep Product Accessory*'' with ''*Accessory, Compact, Infant Sleep Products, and Newborn Sleep Products.*''

(22) Do not comply with sections 7.12 through 9, or the Appendix, of ASTM F3118–17a.

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2019–23724 Filed 11–8–19; 8:45 am]

BILLING CODE 6355–01–P

[12] For referenced ASTM standard, visit the ASTM website, *www.astm.org,* or contact ASTM Customer Service at *service@astm.org.* For Annual Book of ASTM Standards volume information, refer to the standard's Document Summary page on the ASTM website.

[13] Available from U.S. Government Printing Office Superintendent of Documents, 732 N. Capitol St. NW, Mail Stop: SDE, Washington, DC 20401, *http://www.access.gpo.gov.*

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 160

RIN 3038–AE91

Privacy of Consumer Financial Information

AGENCY: Commodity Futures Trading Commission.

ACTION: Proposed rule.

SUMMARY: The Commodity Futures Trading Commission (''CFTC'' or ''Commission'') is proposing to make a correction to one of the Commission's regulations to restore text that was inadvertently deleted in a 2011 amendment to that regulation.

DATES: Comments must be received on or before December 12, 2019.

ADDRESSES: You may submit comments, identified by RIN 3038–AE91, by any of the following methods:

- *CFTC Comments Portal: https://comments.cftc.gov.* Select the ''Submit Comments'' link for this rulemaking and follow the instructions on the Public Comment Form.
- *Mail:* Send to Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Center, 1155 21st Street NW, Washington, DC 20581.
- *Hand Delivery/Courier:* Follow the same instructions as for Mail, above.

Please submit your comments using only one of these methods. Submissions through the CFTC Comments Portal are encouraged.

All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be

posted as received to *https://comments.cftc.gov.* You should submit 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 (''FOIA''), 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://comments.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 rulemaking 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 FOIA.

FOR FURTHER INFORMATION CONTACT: Joshua Sterling, Director, (202) 418–6056, *jsterling@cftc.gov;* Frank Fisanich, Chief Counsel, (202) 418–5949, *ffisanich@cftc.gov;* or Jacob Chachkin, Special Counsel, (202) 418–5496, *jchachkin@cftc.gov,* Division of Swap Dealer and Intermediary Oversight, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.

SUPPLEMENTARY INFORMATION:

I. Background

Section 501 of Title V of the Gramm-Leach-Bliley Act (''Title V'') mandates that certain agencies covered by Title V establish appropriate safeguards for the financial institutions subject to their jurisdiction relating to administrative, technical and physical safeguards—(1) to insure the security and confidentiality of customer records and information; (2) to protect against any anticipated threats or hazards to the security or integrity of such records; and (3) to protect against unauthorized access to or use of such records or information which could result in substantial harm or inconvenience to any customer.[2] The Commission and entities subject to its jurisdiction were originally excluded from Title V's coverage.[3] However, section 124 of the Commodity Futures Modernization Act of 2000[4] amended the Commodity Exchange Act (''CEA'') to add section 5g,[5] providing that futures commission merchants (''FCMs''), commodity trading advisors (''CTAs''), commodity pool operators (''CPOs''), and introducing brokers (''IBs'')[6] fall under the requirements of Title V and requiring the Commission to prescribe regulations in furtherance of Title V. Thus, in 2001, the Commission promulgated part 160 of its regulations to establish standards relating to Title V, and, specifically, § 160.30 in relation to section 501's mandate.[7]

Commission regulation 160.30 implements this mandate by requiring every FCM, RFED, CTA, CPO, IB, MSP, or SD that is subject to the jurisdiction of the Commission (''Covered Persons'')[8] to adopt policies and procedures to address administrative, technical and physical safeguards for the protection of customer records and information (the ''General Requirement'').[9] In addition, mirroring section 501 of the GLB Act, the 2001 Rulemaking further required (the ''Detailed Requirements'') that the policies and procedures be reasonably designed to: (i) Insure the security and confidentiality of customer records and information; (ii) protect against any anticipated threats or hazards to the security or integrity of customer records and information; and (iii) protect against unauthorized access to or use of customer records or information that could result in substantial harm or inconvenience to any customer.[10] However, when the 2011 Amendment revised § 160.30 to add SDs and MSPs to the list of entities in § 160.30's introductory sentence (and, thus, subject to it), the Detailed Requirements were inadvertently deleted.[11]

II. Proposal

The Commission is now proposing (the ''Proposal'') to restore the inadvertently deleted Detailed Requirements in § 160.30 as shown in the proposed amended rule text in this release. As discussed above, the Detailed Requirements mirror the requirements of section 501 of the GLB Act, pursuant to which part 160 of the Commission's regulations was adopted.

III. Related Matters

A. Regulatory Flexibility Act

The Regulatory Flexibility Act[12] (''RFA'') requires federal agencies to consider whether the rules they propose will have a significant economic impact on a substantial number of small entities and, if so, to provide a regulatory flexibility analysis regarding the economic impact on those entities. The Proposal would restore the inadvertently deleted Detailed Requirements in § 160.30. To the extent that the Proposal would impact Covered Persons that may be small entities for purposes of the RFA,[13] the Commission considered whether the Proposal would have a significant economic impact on such Covered Persons.

In restoring the inadvertently deleted Detailed Requirements the Proposal would simply set forth, consistent with

[1] 17 CFR 145.9. Commission regulations referred to herein are found at 17 CFR chapter I.

[2] Section 501, Subtitle A, Title V, Public Law 106–102, 113 Stat. 1338 (1999), as codified at 15 U.S.C. 6801.

[3] 15 U.S.C. 6809(3)(B).

[4] Section 124, Appendix E of Public Law 106–554, 114 Stat. 2763 (2000).

[5] 7 U.S.C. 7b–2.

[6] For the definitions of these intermediary categories, *see* section 1a of the CEA and § 1.3 of the Commission's regulations. 7 U.S.C. 1a and 17 CFR 1.3.

[7] Privacy of Customer Information, 66 FR 21235 (April 27, 2001) (''2001 Rulemaking''). The Commission later modified its part 160 regulations to apply them to retail foreign exchange dealers (''RFEDs''), swap dealers (''SDs''), and major swap participants (''MSPs''). Regulation of Off-Exchange Retail Foreign Exchange Transactions and Intermediaries, 75 FR 55409 (Sept. 10, 2010) for RFEDs, and Privacy of Consumer Financial Information; Conforming Amendments Under Dodd-Frank Act, 76 FR 43874 (July 22, 2011) for SDs and MSPs (''2011 Amendment''). For the definition of RFED, *see* § 5.1(h). 17 CFR 5.1(h). For the definitions of SD and MSP, *see* section 1a of the CEA and § 1.3 of the Commission's regulations. 7 U.S.C. 1a and 17 CFR 1.3.

[8] 17 CFR 160.30. Part 160 does not apply to foreign (non-resident) FCMs, RFEDs, CTAs, CPOs, IBs, MSPs, and SDs that are not registered with the Commission. 17 CFR 160.1. Therefore, they are not ''Covered Persons'' as defined in this release.

[9] 17 CFR 160.30.

[10] *See* 2001 Rulemaking at 21250.

[11] *See* 2011 Amendment at 43879. With respect to § 160.30, the preamble to the 2011 Amendment only discusses amending the introductory sentence of § 160.30 to add SDs and MSPs to the list of CFTC registrants that must comply with that regulation. *See id.* at 43876. Further, the Commission notes that the Detailed Requirements continued to be included in Commission staff guidance on compliance with § 160.30 after the 2011 Amendment. *See* CFTC Staff Advisory No. 14–21 (Feb. 26, 2014) (''§ 160.30 Guidance''). In addition, the Commission notes that restoring the Detailed Requirements will make § 160.30 more consistent with similar rules adopted by the Securities and Exchange Commission (''SEC'') and the Federal Trade Commission (''FTC'') under the GLB Act. *See* 17 CFR 248.30 and 16 CFR 314.3, respectively.

[12] 5 U.S.C. 601 *et seq.*

[13] The Commission has previously determined that certain entities are not ''small entities'' for purposes of the RFA. *See, e.g.,* 47 FR 18618, 18619 (Apr. 30, 1982) (registered FCMs); 75 FR 55410, 55416 (Sept. 10, 2010) (RFEDs); 77 FR 2613, 2620 (Jan. 19, 2012) (SDs and MSPs). However, the Commission has determined that CPOs exempt pursuant to 17 CFR 4.13(a) are small entities. *See* 46 FR 26004 (May 8, 1981); 47 FR at 18619. The definitions of IB and CTA are also broad enough to potentially encompass ''small entities.'' *See* 48 FR 35248, 35276 (Aug. 3, 1983) (recognizing that the IB definition ''undoubtedly encompasses many business enterprises of variable size''); 47 FR at 18620 (the category of CTAs is ''too broad'' for a general determination regarding their small entity status).

the § 160.30 Guidance and the GLB Act, what is necessary to satisfy the General Requirement that already applies to Covered Persons. Therefore, the Commission believes that the Proposal will not have a significant economic impact on a substantial number of small entities, as defined in the RFA.

Accordingly, the Chairman, on behalf of the Commission, hereby certifies pursuant to 5 U.S.C. 605(b) that the Proposal will not have a significant economic impact on a substantial number of small entities. The Commission invites comment on the impact of the Proposal on small entities.

B. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (''PRA'') [14] imposes certain requirements on Federal agencies, including the Commission, in connection with their conducting or sponsoring any collection of information, as defined by the PRA. The Commission 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 (''OMB'') control number.

The Commission has previously received a control number from OMB that includes the collection of information associated with the General Requirement. The title for this collection of information is ''Privacy of Consumer Financial Information, OMB control number 3038–0055''.[15] Collection 3038–0055 is currently in force with its control number having been provided by OMB. Because in restoring the inadvertently deleted Detailed Requirements, the Proposal would simply set forth what is necessary to satisfy the General Requirement that already applies to Covered Persons, the Commission believes that the Proposal would not impose any new recordkeeping or information collection requirements, or other collections of information that require approval of OMB under the PRA.

The Commission invites the public and other Federal agencies to comment on any aspect of the proposed information collection requirements discussed above. Refer to the **ADDRESSES** section of this notice for comment submission instructions to the Commission. A copy of the supporting statements for the collection of information discussed above may be obtained by visiting *www.RegInfo.gov.*

C. Cost-Benefit Considerations

Section 15(a) of the CEA requires the Commission to consider the costs and benefits of its actions before promulgating a regulation under the CEA. Section 15(a) further specifies that the costs and benefits shall be evaluated in light of the following five broad areas of market and public concern: (1) Protection of market participants and the public; (2) efficiency, competitiveness, and financial integrity of futures markets; (3) price discovery; (4) sound risk management practices; and (5) other public interest considerations. The Commission considers the costs and benefits resulting from its discretionary determinations with respect to the section 15(a) considerations.

As discussed above, the Commission is proposing to restore the inadvertently deleted Detailed Requirements in § 160.30. Below, the Commission discusses the costs and benefits of the Proposal.[16] The baseline against which the costs and benefits are considered is the current status quo for Covered Persons with respect to their obligation to satisfy the General Requirement under § 160.30.[17] The Commission recognizes that there are inherent costs and benefits to Covered Persons in providing requirements for specific customer privacy policies and procedures, which Congress took into account in codifying the GLB Act.

The inadvertent deletion of the Detailed Requirements in § 160.30 affected entities that were required to comply with the Detailed Requirements prior to the 2011 Amendment as well as the two types of entities (SDs and MSPs) the rule was being revised to include. Due to the inadvertent nature of the deletion of the Detailed Requirements, and that they applied prior to the 2011 Amendment, the Commission expects the number of entities affected by the Proposal to be negligible, if any. Consequently, to the extent the Proposal restores the Detailed Requirements in § 160.30, consistent with the § 160.30 Guidance and the GLB Act, the Proposal would not alter existing benefits and costs. The Commission, however, recognizes that the Proposal may benefit certain Covered Persons by, consistent with the GLB Act, specifying what types of policies and procedures are necessary to satisfy the General Requirement. In doing so, the Proposal may reduce any potential confusion and allow Covered Persons to design and maintain their policies and procedures to focus on the specified areas mandated by the GLB Act. In this regard, the Proposal may allow Covered Persons to more efficiently utilize their resources in developing policies and procedures in compliance with § 160.30. The Proposal also will, consistent with the GLB Act,[18] result in § 160.30 being more similar to regulations adopted by the SEC and FTC pursuant to the GLB Act and to which certain Covered Persons may be subject.[19]

The Commission recognizes that, as a result of the Proposal, certain Covered Persons may become subject to more specific requirements under § 160.30 than they are currently. However, given that the General Requirement currently applies to Covered Persons, and the § 160.30 Guidance that remains in effect takes into account the substance of the Detailed Requirements, the Commission believes that the burden of the Proposal on Covered Persons will not be significant.

1. Section 15(a) Considerations

In light of the foregoing, the CFTC has evaluated the costs and benefits of the Proposal pursuant to the five considerations identified in section 15(a) of the CEA as follows:

(1) Protection of Market Participants and the Public

The Proposal's restoration of the Detailed Requirements may protect market participants and the public by ensuring that the policies and procedures required under § 160.30 are reasonably designed to address the

[14] 44 U.S.C. 3501 *et seq.*

[15] *See* OMB Control No. 3038–0055, *http://www.reginfo.gov/public/do/PRAOMBHistory?ombControlNumber=3038-0055#* (last visited Nov. 5, 2019).

[16] The Commission endeavors to assess the expected costs and benefits of its proposed rules in quantitative terms where possible. Where estimation or quantification is not feasible, the Commission provides its discussion in qualitative terms. Given a general lack of relevant data, the Commission's assessment is generally provided in qualitative terms.

[17] The Commission notes that the consideration of costs and benefits below is based on the understanding that the markets function internationally, with many transactions involving United States firms taking place across international boundaries; with some Commission registrants being organized outside of the United States; with some leading industry members typically conducting operations both within and outside the United States; and with industry members commonly following substantially similar business practices wherever located. Where the Commission does not specifically refer to matters of location, the discussion of costs and benefits below refers to the effects of this proposal on all activity subject to the proposed and amended regulations, whether by virtue of the activity's physical location in the United States or by virtue of the activity's connection with or effect on United States commerce under CEA section 2(i). In particular, the Commission notes that some Covered Persons are located outside of the United States.

[18] *See* Section 6804(a)(2) of the GLB Act. 15 U.S.C. 6804(a)(2).

[19] *See* n.11, *supra.*

specific areas mandated by Congress in the GLB Act.

(2) Efficiency, Competitiveness, and Financial Integrity of Markets

The Proposal may reduce confusion and allow Covered Persons to design and maintain their policies and procedures to focus on the specified areas mandated by the GLB Act. This may allow Covered Persons to more efficiently utilize their resources in developing policies and procedures in compliance with § 160.30. In addition, consistent with the GLB Act, the Proposal will further align the consumer privacy regulations of the Commission, FTC, and SEC, which may lower costs for certain Covered Persons.

(3) Price Discovery

The Commission has not identified an impact on price discovery as a result of the Proposal.

(4) Sound Risk Management

The Commission has not identified an impact on sound risk management as a result of the Proposal.

(5) Other Public Interest Considerations

Consistent with the GLB Act, the Proposal will further align the consumer privacy regulations of the Commission, FTC, and SEC.

2. Request for Comments on Cost-Benefit Considerations

The Commission invites public comment on its cost-benefit considerations, including the section 15(a) factors described above. Commenters are also invited to submit any data or other information that they may have quantifying or qualifying the costs and benefits of the Proposal with their comment letters.

D. Antitrust Considerations

Section 15(b) of the CEA [20] requires the Commission to take into consideration the public interest to be protected by the antitrust laws and endeavor to take the least anticompetitive means of achieving the objectives of the CEA, as well as the policies and purposes of the CEA, in issuing any order or adopting any Commission rule or regulation (including any exemption under section 4(c) or 4c(b)), or in requiring or approving any bylaw, rule, or regulation of a contract market or registered futures association established pursuant to section 17 of the CEA.

The Commission believes that the public interest to be protected by the antitrust laws is generally to protect competition. The Commission requests comment on whether the Proposal implicates any other specific public interest to be protected by the antitrust laws.

The Commission has considered the Proposal to determine whether it is anticompetitive and has preliminarily identified no anticompetitive effects. The Commission requests comment on whether the Proposal is anticompetitive and, if it is, what the anticompetitive effects are.

Because the Commission has preliminarily determined that the Proposal is not anticompetitive and has no anticompetitive effects, the Commission has not identified any less anticompetitive means of achieving the purposes of the CEA. The Commission requests comment on whether there are less anticompetitive means of achieving the relevant purposes of the CEA that would otherwise be served by adopting the Proposal.

[20] 7 U.S.C. 19(b).

List of Subjects in 17 CFR Part 160

Brokers, Consumer protection, Privacy, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, the Commodity Futures Trading Commission proposes to amend 17 CFR part 160 as set forth below:

PART 160—PRIVACY OF CONSUMER FINANCIAL INFORMATION UNDER TITLE V OF THE GRAMM-LEACH-BLILEY ACT

■ 1. The authority citation for part 160 continues to read as follows:

Authority: 7 U.S.C. 7b–2 and 12a(5); 15 U.S.C 6801, *et seq.,* and sec. 1093, Pub. L. 111–203, 124 Stat. 1376.

■ 2. Revise § 160.30 to read as follows:

§ 160.30 Procedures to safeguard customer records and information.

Every futures commission merchant, retail foreign exchange dealer, commodity trading advisor, commodity pool operator, introducing broker, major swap participant, and swap dealer subject to the jurisdiction of the Commission must adopt policies and procedures that address administrative, technical and physical safeguards for the protection of customer records and information. These policies and procedures must be reasonably designed to:

(a) Insure the security and confidentiality of customer records and information;

(b) Protect against any anticipated threats or hazards to the security or integrity of customer records and information; and

(c) Protect against unauthorized access to or use of customer records or information that could result in substantial harm or inconvenience to any customer.

Issued in Washington, DC, on November 6, 2019, by the Commission.

Christopher Kirkpatrick,

Secretary of the Commission.

Note: The following appendix will not appear in the Code of Federal Regulations.

Appendix to Privacy of Consumer Financial Information—Commission Voting Summary

On this matter, Chairman Tarbert and Commissioners Quintenz, Behnam, Stump, and Berkovitz voted in the affirmative. No Commissioner voted in the negative.

[FR Doc. 2019–24581 Filed 11–8–19; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1141

[Docket No. FDA–2019–N–3065]

RIN 0910–AI39

Tobacco Products; Required Warnings for Cigarette Packages and Advertisements; Additional Materials; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; additional materials; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is reopening the comment period for the proposed rule that appeared in the **Federal Register** of August 16, 2019. The Agency is providing additional information in the docket and reopening the public comment period for 15 days to afford the public an opportunity to comment on this additional information.

DATES: FDA is reopening the comment period on the proposed rule published August 16, 2019 (84 FR 42754). Submit either electronic or written comments by November 27, 2019. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 27, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until

11:59 p.m. Eastern Time at the end of November 27, 2019.

ADDRESSES: You may submit comments as follows. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–N–3065 for ''Tobacco Products; Required Warnings for Cigarette Packages and Advertisements.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Courtney Smith, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002, email: *CTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 16, 2019 (84 FR 42754), FDA published a proposed rule that will, once finalized, implement a provision of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) that requires FDA to issue regulations requiring color graphics depicting the negative health consequences of smoking to accompany new textual warning statements. The Tobacco Control Act amends the Federal Cigarette Labeling and Advertising Act of 1965 to require each cigarette package and advertisement to bear one of the new required warnings. This proposed rule, once finalized, will specify the color graphics that must accompany the new textual warning statements. The proposed new textual warnings include some that are specified in the Tobacco Control Act and some new textual warning statements that FDA is proposing to promote greater public understanding of the negative health consequences of cigarette smoking. FDA's proposed cigarette warning rule was issued pursuant to a court-ordered schedule (see *Am. Acad. Pediatrics* v. *FDA,* No. 16–cv–11985, 2019 U.S. Dist. LEXIS 34946 (D. Mass. Mar. 5, 2019)), which, among other things, requires FDA to submit the proposed rule for publication by August 15, 2019, and to submit the final rule by March 15, 2020.

As described in FDA's proposed rule, in developing the new cigarette health warnings, FDA undertook a science-based, iterative research process. The proposed rule was informed by two quantitative consumer research studies, ''Experimental Study on Warning Statements for Cigarette Graphic Health Warnings'' (Office of Management and Budget (OMB) control number 0910–0848) and ''Experimental Study of Cigarette Warnings'' (OMB control number 0910–0866), that assessed the extent to which FDA's proposed warnings increase understanding of the negative health consequences of cigarette smoking. As part of developing and informing its research, FDA conducted various qualitative focus groups and interviews (''qualitative studies'') to test and refine image concepts and obtain feedback on which textual statements should be selected for further study. Qualitative studies are based on small samples, have exploratory aims and objectives, should not be viewed as nationally representative, and do not yield data that can be generalized. FDA did not originally include the qualitative study reports in the docket as FDA did not rely on these studies as part of the rulemaking. However, because the qualitative studies were used to inform further research, namely, the quantitative consumer research studies, FDA is making these additional materials available as well.

FDA is placing additional materials in the docket and reopening the comment period for the proposed rule for 15 days to allow comment on the additional materials. The Agency believes that a 15-day reopening allows adequate time

for interested persons to submit comments on this additional information without significantly delaying rulemaking.

FDA is adding the following materials to the docket for the proposed rule:

- ''Qualitative Study on Cigarettes and Smoking: Knowledge, Beliefs, and Misperceptions'' (July 2015) (OMB control number 0910–0674, ''Qualitative Study on Cigarettes and Smoking: Knowledge, Beliefs, and Misperceptions'')
- ''Memorandum of Findings from Cognitive Testing of Spanish Warning Labels'' (March 2016)
- ''FDA Graphic Health Warning Image Concept Testing'' (June 2016) (OMB control number 0910–0796, ''Qualitative Study of Perceptions and Knowledge of Visually Depicted Health Conditions'')
- ''Qualitative Study on Consumer Perceptions of Cigarettes Health Warning Images'' (April 2018) (OMB control number 0910–0796, ''Qualitative Study on Consumer Perceptions of Cigarettes Health Warning Images'')

Dated: November 5, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–24511 Filed 11–8–19; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 70

[EPA–R07–OAR–2019–0532; FRL–10000–21–Region 7]

Air Plan Approval; Iowa, Kansas, Missouri, Nebraska and Approval of Operating Permit Program for Iowa and Nebraska; Definition of Chemical Process Plants Under State Prevention of Significant Deterioration Regulations and Operating Permit Programs

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve revisions to the State Implementation Plans (SIP) for Iowa, Kansas, Missouri and Nebraska and is also proposing to approve revisions to the Operating Permit Programs for Iowa and Nebraska. The SIP revisions incorporate changes to the definition of chemical process plants under the States' Prevention of Significant Deterioration (PSD) regulations and change the same definition in the approved State operating permit programs. Consistent with an EPA regulation completed in 2007, this action approves several States' rules that modify the definition of chemical process plant to exclude ethanol manufacturing facilities that produce ethanol by natural fermentation processes. This will clarify that the PSD major source applicability threshold in the SIPs for these ethanol plants is 250 tons per year (tpy) (rather than 100 tpy) and removes the requirement to include fugitive emissions when determining if the source is major for PSD. In addition, this action approves changes to Iowa's and Nebraska's Title V operating permit programs that remove the requirement to include fugitive emissions when determining if a source is major for Title V. The EPA concludes that the changes to the State rules described herein are approvable because they are consistent with EPA regulations governing State PSD and Title V programs and will not interfere with any applicable requirement concerning attainment and reasonable further progress (as defined in section 171 of the Clean Air Act (CAA)), or any other applicable requirement of the CAA.

DATES: Comments must be received on or before December 12, 2019.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–R07–OAR–2019–0532 to *https://www.regulations.gov.* Follow the online instructions for submitting comments.

Instructions: All submissions received must include the Docket ID No. for this rulemaking. Comments received will be posted without change to *https://www.regulations.gov/,* including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the ''Written Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: William Stone, Environmental Protection Agency, Region 7 Office, Air Quality Planning Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219; telephone number (913) 551–7714; email address stone.william@epa.gov.

SUPPLEMENTARY INFORMATION: Throughout this document ''we,'' ''us,'' and ''our'' refer to EPA.

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I. Written Comments

Submit your comments, identified by Docket ID No. EPA–R07–OAR–2019–0532, at *https://www.regulations.gov.* Once submitted, comments cannot be edited or removed from *Regulations.gov*. 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 (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

II. What is being addressed in this document?

The EPA is proposing to approve revisions to SIPs received by EPA from Iowa on November 15, 2007, Kansas on November 23, 2009, Missouri on December 7, 2009, and March 20, 2019, and Nebraska on August 28, 2007, and September 11, 2018. The EPA is also proposing to approve Iowa and Nebraska's Operating Permit Program revisions. These revisions conform the State rules to changes to EPA regulations reflected in the EPA's final rule entitled ''Prevention of Significant Deterioration, Nonattainment New Source Review (NA NSR), and Title V: Treatment of Certain Ethanol Production Facilities Under the ''Major Emitting Facility'' Definition'' (hereinafter referred to as the ''2007 Ethanol Rule'') as published in the **Federal Register** on May 1, 2007 (72 FR

24059). The 2007 Ethanol Rule amends the PSD definition of ''major stationary source'' to exclude certain ethanol facilities from the ''chemical process plant'' source category and clarifies that the PSD major source applicability threshold for certain ethanol plants is 250 tpy (rather than 100 tpy). The 2007 Ethanol Rule also removed the requirement to include fugitive emissions when determining if the source is major for PSD and Title V permitting. On October 21, 2019, the EPA responded to a petition for reconsideration of the 2007 Ethanol Rule, and the EPA denied the petition with respect to the revisions of the PSD Regulations reflected in that rule (as described in more detail below). The EPA is now proposing to approve these SIPs and operating permits program revisions that are based on a part of the 2007 Ethanol Rule.

III. Background

A. PSD Permitting Thresholds for Chemical Processing Plants

Under the CAA, there are two potential thresholds for determining whether a source is a major emitting facility that is potentially subject to the construction permitting requirements under the PSD program; one threshold is 100 tpy per pollutant, and the other is 250 tpy per pollutant. Section 169(1) of the CAA lists twenty-eight source categories that qualify as major emitting facilities if their emissions exceed the 100 tpy threshold. If the source does not fall within one of twenty-eight source categories listed in section 169, then the 250 tpy threshold is applicable.

One of the source categories in the list of twenty-eight source categories to which the 100 tpy threshold applies is chemical process plants. Since the Standard Industrial Classification (SIC) code for chemical process plants includes facilities primarily engaged in manufacturing ethanol fuel, the EPA and States had previously considered such facilities to be subject to the 100 tpy thresholds.

As a result of this classification, pursuant to the EPA regulations adopted under section 302(j), chemical process plants were also required to include fugitive emissions for determining the potential emissions of such sources. Thus, prior to promulgation of the 2007 Ethanol Rule, the classification of fuel and industrial ethanol facilities as chemical process plants had the effect of requiring these plants to include fugitive emissions of criteria pollutants when determining whether their emissions exceed the applicability thresholds for the PSD and non-attainment NSR permit programs.

B. Title V Permitting Thresholds for Chemical Processing Plants

The CAA also establishes requirements for determining whether sources must obtain Title V operating permits. All major sources and sources subject to specific CAA requirements must obtain such permits. For purposes of the Title V operating permit program, a major source is defined as any source that has actual or potential emissions at or above the major source thresholds reflected in other parts of the CAA. Under the general definition of ''major stationary source'' in section 302(j) of the CAA, the major source threshold for any air pollutant is 100 tons/year. Under the NSR program, lower thresholds for major sources can apply in nonattainment areas depending on the pollutant and severity of the nonattainment area classification. In addition, the major source thresholds for ''hazardous air pollutants'' (HAP) are 10 tons/year for a single HAP or 25 tons/year for any combination of HAP. A source with emissions that exceed one of these thresholds (as applicable) is required to obtain a Title V operating permit.

Section 502 of the CAA and EPA regulations provide that sources that belong to one of twenty-eight categories listed in 40 CFR 70.2 must include fugitive emissions in determining whether they exceed the 100 tpy major source threshold for any ''air pollutant.'' This list of twenty-eight source categories may also be included in approved state operating permit regulations.

C. Ethanol Rule

On May 1, 2007, the EPA published in the **Federal Register** the 2007 Ethanol Rule (72 FR 24060). This final rule amended the EPA's PSD and NA NSR regulations to exclude ethanol manufacturing facilities that produce ethanol by natural fermentation processes from the ''chemical process plants'' category under the regulatory definition of ''major stationary source''.

This change to the EPA's NSR regulations affected the threshold used to determine PSD applicability for these ethanol production facilities, clarifying that such facilities were subject to the 250 tpy major source threshold. The 2007 Ethanol Rule also included changes to other provisions which established that ethanol facilities need not count fugitive emissions when determining whether such a source is ''major'' under the Federal PSD, NA NSR, and Title V permitting programs.

D. Petitions for Review and Reconsideration of the 2007 Ethanol Rule

On July 2, 2007, the National Resources Defense Council (NRDC) petitioned the D.C. Circuit to review the 2007 Ethanol Rule. On that same day, the EPA received a petition for administrative reconsideration and request for stay of the 2007 Ethanol Rule from NRDC. On March 27, 2008, the EPA denied NRDC's 2007 administrative petition for reconsideration.

On March 2, 2009, the EPA received a second petition for reconsideration and request for stay from NRDC.

In 2009 NRDC also filed a petition for judicial review challenging the EPA's March 27, 2008, denial of NRDC's 2007 administrative petition in the D.C. Circuit. This challenge was consolidated with NRDC's challenge to the 2007 Ethanol Rule. In August of 2009, the D.C. Circuit granted a joint motion to hold the case in abeyance, and the case has remained in abeyance.

On October 21, 2019, the EPA partially granted and partially denied NRDC's 2009 administrative petition for reconsideration. Specifically, the EPA granted the request for reconsideration with regard to NRDC's claim that the Ethanol Rule did not appropriately address the CAA section 193 anti-backsliding requirements for nonattainment areas.

IV. What SIP revisions are being proposed by the EPA?

The EPA is proposing to approve revisions to SIPs received from Iowa on November 15, 2007; Kansas on November 23, 2009; Missouri on December 7, 2009, and March 20, 2019; and Nebraska on August 28, 2007, and September 11, 2018. These revisions adopt language that is the same or consistent with that contained in the EPA's 2007 Ethanol Rule. (72 FR 24060, May 1, 2007). The EPA is not taking action on any revisions with respect to Nonattainment New Source Review. The State regulations that EPA is proposing to approve exclude ethanol production facilities that produce ethanol by natural fermentation from the ''chemical process plants'' category. The revisions thus clarify that an ethanol facility is subject to a PSD major source threshold of 250 tpy and that such sources need not count fugitive emissions to determine potential emissions that are compared to this threshold. The revisions proposed for approval in this action do not affect Nonattainment New Source Review.

The EPA is proposing to approve the following SIP revisions:

Iowa

Iowa Administrative Code 567–33.3(1)—Definitions ''Major Stationary Source'': ''Any one of the following stationary sources of air pollutants which emits, or has the potential to emit, 100 tons per year or more of any regulated NSR pollutant: . . . Chemical process plants (which does not include ethanol production facilities that produce ethanol by natural fermentation included in NAICS codes 325193 or 312140) . . .''

Chapter 33 of the Iowa Administrative Code, which contains Iowa's PSD regulations, applies to new or modified ''major stationary sources'', as that term is defined in 567–33.3(1). As stated above, 567–33.3(1) was revised to exclude ethanol production facilities from the ''chemical process plants'' major stationary source category such that ethanol facilities emitting less than 250 tpy of a regulated air pollutant are not subject to PSD. The State effective date of Iowa's revision to the definition of ''chemical process plants'' in chapter 33.3(1) is October 4, 2007.

Iowa's definition of ''major stationary source'' also states that ''(t)he fugitive emissions of a stationary source shall not be included in determining for any of the purposes of this rule whether it is a major stationary source, unless that source belongs to one of the categories of stationary sources listed (in the definition of ''major stationary source'') . . .''. As such, fugitive emissions from ethanol facilities are not considered in determining whether the facility is subject to PSD.

Kansas

Kansas Administrative Regulations 28–19–350—Prevention of significant deterioration (PSD) of air quality. This regulation adopts by reference 40 CFR 52.21, as revised and amended on July 1, 2011, (76 FR 43507) and October 25, 2012, (77 FR 65107 (see 77 FR 65118–77 FR 65119)) with exceptions.

The term ''major stationary source'' is defined in 40 CFR 52.21(b)(1)(i)(a) as any of the following stationary sources of air pollutants which emits, or has the potential to emit, 100 tons per year or more of any regulated NSR pollutant: Chemical process plants (which does not include ethanol production facilities that produce ethanol by natural fermentation included in NAICS codes 325193 or 312140). Title 40 CFR 52.21(b)(1)(iii) excludes fugitive emissions from ethanol production facilities from the ''chemical process plants'' category such that fugitive emissions are not considered in determining whether the facility is subject to PSD.

The State effective date of Kansas' incorporation by reference of EPA's 2007 revision of the definition of ''chemical process plants'' in 40 CFR 52.21(b)(1)(i)(a) is October 23, 2009. Because Kansas has adopted 40 CFR 52.21 by reference, ethanol facilities emitting less than 250 tpy of a regulated air pollutant are not subject to PSD, and fugitive emissions from ethanol facilities are not considered in determining whether the facility is subject to PSD.

Missouri

Missouri Code of State Regulations (CSR) 10 CSR 10–6.060, Construction Permits Required. Section (8), Attainment and Unclassified Area Major Permits, has been revised to incorporate all the paragraphs of 40 CFR 52.21 by reference promulgated as of July 1, 2018, other than (a) Plan disapproval, (q) Public participation, (s) Environmental impact statements, and (u) Delegation of authority.

The term ''major stationary source'' is defined in 40 CFR 52.21(b)(1)(i)(a) as any of the following stationary sources of air pollutants which emits, or has the potential to emit, 100 tons per year or more of any regulated NSR pollutant: Chemical process plants (which does not include ethanol production facilities that produce ethanol by natural fermentation included in NAICS codes 325193 or 312140). Title 40 CFR 52.21(b)(1)(iii) excludes fugitive emissions from ethanol production facilities from the ''chemical process plants'' category such that fugitive emissions are not considered in determining whether the facility is subject to PSD.

Because Missouri has adopted 40 CFR 52.21 by reference, ethanol facilities emitting less than 250 tpy of a regulated air pollutant are not subject to PSD, and fugitive emissions from ethanol facilities are not considered in determining whether the facility is subject to PSD.

Missouri also revised 10 CSR 10–6.060, Construction Permits Required, section 7, *Nonattainment Area Major Permits.* Section (7)(A) has been added as follows:

(A) Definitions. Solely for the purposes of this section, the following definitions apply to terms in place of definitions for which the term is defined elsewhere, including the reference to 40 CFR 52.21 in paragraph (7)(B)6. of this rule.

Section (7)(A)(1) has been added as follows:

1. Chemical process plant—These plants include ethanol production facilities that produce ethanol by natural fermentation included in NAICS codes 325193 or 312140.

Section 7(B)(6) of 10 CSR 10–6.060 excludes fugitive emissions from potential to emit calculations if the source is listed in 40 CFR 52.21(i)(1)(vii)(a) through (aa). However, Missouri's revision to section (7), by adding section (7)(A) and section (7)(A)(1), results in the inclusion of quantifiable fugitive emissions from ethanol productions facilities in determining the potential to emit for nonattainment new source review permits.

Nebraska

Nebraska Title 129—Chapter 2—Definition of Major Source—Section 008.01: ''Any of the following stationary sources which emits, or has the potential to emit, 100 tons per year or more of any regulated NSR pollutant: . . . chemical process plants (which does not include ethanol production facilities that produce ethanol by natural fermentation included in North American Industry Classification System (NAICS) codes 325193 or 312140)''.

Chapter 19 of title 129, which contains Nebraska's PSD regulations, applies to the construction of any new ''major stationary source'' or the major modification of any existing''major stationary source'', as that term is defined in chapter 2, Section 008. As stated above, section 008.01 was revised, with a State effective date of February 6, 2008, to exclude ethanol production facilities from the ''chemical process plants'' major stationary source category such that ethanol facilities emitting less than 250 tpy of a regulated air pollutant are not subject to PSD. In addition, chapter 19, sections 005.05, 006.03, and 016.02 exclude fugitive emissions from ethanol production facilities in determining whether the facility is subject to PSD.

In addition to the revisions to chapter 2, in their submittals from November 19, 2010 and September 11, 2018, Nebraska requests for the EPA to approve changes to chapter 17, section 001.02T. These changes relate to the definition of chemical process plants under minor NSR. The EPA is not taking any action on these changes.

V. What operating permit plan revisions are being proposed by the EPA?

The EPA is proposing to approve the following revisions to Iowa and Nebraska's Operating Permit Program

(title V) which result in the exclusion of fugitive emissions title V threshold calculations for certain ethanol facilities:

Iowa

Iowa Administrative Code 567–22.100—Definitions for Title V Operating Permits: Iowa revised the explanation of ''chemical process plants'' that is contained in the definition of ''stationary source categories'' as follows: ''. . . (20) Chemical process plants—The term chemical processing plant shall not include ethanol production facilities that produce ethanol by natural fermentation included in NAICS codes 325193 or 312140''.

Iowa's title V regulation at 567–22.101 requires any major source to obtain a title V operating permit. 567–22.100 defines ''major source'' as, among other things, a source that directly emits or has the potential to emit 100 tpy or more of any air pollutant subject to regulation, including fugitive emissions unless the source belongs to one of the stationary source categories listing in chapter 22. As stated above, 567–22.100 was revised to exclude ethanol production facilities from the ''chemical process plants'' category such that fugitive emissions are not considered in determining whether the facility is subject to title V permitting.

Nebraska

Nebraska title 129—chapter 2—Definition of Major Source—section 002.20 is revised as follows: ''Chemical process plants—The term chemical processing plant shall not include ethanol production facilities that produce ethanol by natural fermentation included in North American Industry Classification System (NAICS) codes 325193 or 312140''.

Nebraska's title V regulation, title 129 chapter 5—Operating Permits—When Required, requires any ''major source'' as defined in chapter 2 to apply for a Class I (major source) Operating permit. Chapter 2 section 002 defines ''major source'' as ''. . . a major stationary source of air pollutants is one that directly emits or has the potential to emit, 100 tpy or more of any air pollutant (including any major source of fugitive emissions of any such pollutant, as determined by rule by the Administrator of EPA).'' The rule goes on to state that ''. . . fugitive emissions of a stationary source shall not be considered in determining whether it is a major stationary source for the purposes of this subsection, unless the source belongs to one of the following categories of stationary source[.]'' As stated above, chapter 2, section 002.20 was revised to exclude ethanol production facilities from the ''chemical process plants'' category such that fugitive emissions are not considered in determining whether the facility is subject to title V permitting.

Kansas and Missouri did not submit revisions to amend their respective title V operating permit regulations and therefore EPA is not taking action to revise Kansas and Missouri's title V Operating Permit Programs.

VI. Have the requirements for approval of a SIP revision been met?

All of the aforementioned regulations are consistent with EPA's PSD program requirements in 40 CFR 51.166 and title V program requirements in 40 CFR part 70, as amended in the 2007 Ethanol Rule. Further, all submissions have met the public notice requirements for SIP submissions in accordance with 40 CFR 51.102.

Iowa published a Notice of Intended Action in the Iowa Administrative Bulletin on August 1, 2007. A public hearing was held on September 5, 2007. The public comment period closed on September 6, 2007. Iowa received six sets of written comments during the public comment period. Iowa provided a response to each public comment but did not change the rule based on the comments.

Kansas published the proposed changes in the Kansas Register May 21, 2009. A public hearing was held on July 29, 2009. Kansas received three comment letters. Only one change was made to the proposed regulations based on public comments and that change was not relevant to this action.

Missouri published the proposed changes in the Missouri Register on December 31, 2008. A public hearing was held on February 3, 2009. Missouri received 15 comments and made changes to the proposed regulations that were not relevant to this action. Missouri made additional changes to the regulations proposed to be approved by the EPA in this action that were published in the Missouri Register on August 1, 2018. Missouri received thirty-seven comments from nine sources including EPA. Missouri made some changes to the proposed regulations that are relevant to this action based on comments received during the public comment period.

Nebraska published the proposed changes in the Omaha World-Herald on July 13, 2007. A public hearing was held on August 17, 2007. Nebraska did not receive any adverse comments for the proposed changes.

The SIP submissions also satisfied the completeness criteria of 40 CFR part 51, appendix V. In addition, these revisions meet the substantive SIP requirements of the CAA, including section 110 and implementing regulations. These revisions are also consistent with applicable EPA requirements of title V of the CAA and 40 CFR part 70.

A Technical Support Document (TSD) for each State revision, available as part of this docket, contains an analysis of the potential impact of the SIP and title V revisions on air quality and whether approval of the SIP revisions will interfere with attainment or maintenance of the NAAQS or any other CAA requirement. Existing ethanol plants are listed with information from their permits, including applicable requirements, current PSD status, and applicable Federal rules that control emissions in lieu of PSD. The existing ethanol plants are mapped along with the ambient air monitors to demonstrate the relationship between ethanol production and air quality.

Emissions from ethanol plants are compared to other emissions data categories for four major pollutants revealing that for the major pollutants associated with ethanol production, ethanol plants make up 1 percent or less of the total anthropogenic emissions of that pollutant in all four States. EPA graphed air quality trends in each State, since the date of promulgation of the 2007 Ethanol Rule, for all criteria pollutants associated with ethanol production. The air quality trends reveal that while ethanol production increased, air quality improved for every pollutant monitored in each of the States.

The EPA also describes requirements for each State's minor source NSR program because the facilities that would be below the 250 tpy PSD major source threshold under this rulemaking will still need to obtain minor source construction permits. EPA further analyzes the impact of increasing the threshold to 250 tpy on ozone and particulate matter (PM) precursors in each State. The analysis for ozone and secondary PM demonstrates that sources of this size will not cause any interference with attainment or maintenance of the standard in these States.

Based on the EPA's analysis in each TSD, the EPA proposes to conclude that approval of this action will not interfere with any applicable requirement concerning attainment and reasonable further progress (as defined in section 171 of the CAA), or any other applicable requirement of the CAA as required under section 110(l).

VII. What action is the EPA taking?

The EPA is proposing to approve revisions to the Iowa, Kansas, Missouri and Nebraska SIPs and the Iowa and Nebraska Operating Permit Programs. We plan to take final action after consideration any comments received on this notice of proposed rulemaking.

The revisions to State rules that EPA proposed to approve change the definition of ''major stationary source'' under the States' PSD regulations and the Operating Permit Program for Iowa and Nebraska. This action would approve changes to State regulations, which make clear that the PSD applicability threshold for certain ethanol plants is 250 tpy and remove the requirement to include fugitive emissions when determining if an ethanol plant is major for PSD and, in Iowa and Nebraska, title V permitting. The EPA has determined that these revisions are consistent with EPA's PSD and title V regulations and that approval of these revisions is consistent with the requirements of CAA section 110(l) and will not adversely impact air quality. The EPA's analysis is available in the individual State TSDs that are part of this docket. This proposed action will ensure consistency between the State and federally-approved rules and ensure Federal enforceability of the State's revised air program rules.

VIII. Incorporation by Reference

In this document, the EPA is proposing to include regulatory text in an EPA final rule that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is proposing to incorporate by reference the Iowa, Kansas, Missouri, and Nebraska Regulations described in the amendments to 40 CFR part 52 set forth below. The EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and at the EPA Region 7 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

IX. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866.
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of the National Technology Transfer and Advancement Act (NTTA) because this rulemaking does not involve technical standards; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects

40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

40 CFR Part 70

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Operating permits, Reporting and recordkeeping requirements.

Dated: October 29, 2019.

James Gulliford,

Regional Administrator, Region 7.

For the reasons stated in the preamble, the EPA proposes to amend 40 CFR parts 52 and 70 as set forth below:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

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

Subpart Q—Iowa

■ 2. In § 52.820, the table in paragraph (c) is amended by revising the entry ''567–33.3'' to read as follows:

§ 52.820 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED IOWA REGULATIONS

Iowa citation	Title	State effective date	EPA approval date	Explanation
Iowa Department of Natural Resources Environmental Protection Commission [567]				
*	*	*	*	*
Chapter 33—Special Regulations and Construction Permit Requirements for Major Stationary Sources—Prevention of Significant Deterioration (PSD) of Air Quality				
*	*	*	*	*
567–33.3	Special Construction Permit Requirements for Major Stationary Sources in Areas Designated Attainment or Unclassified (PSD).	4/18/2018	[Date of publication of the final rule in the **Federal Register**], [**Federal Register** citation of the final rule].	Provisions of the 2010 $PM_{2.5}$ PSD—Increments, SILs and SMCs rule, published in the **Federal Register** on October 20, 2010, relating to SILs and SMCs that were affected by the January 22, 2013, U.S. Court of Appeals decision are not SIP approved. Iowa's rule incorporating EPA's 2008 "fugitive emissions rule" (published in the **Federal Register** on December 19, 2008) is not SIP-approved.
*	*	*	*	*

* * * * *

Subpart R—Kansas

■ 3. In § 52.870, the table in paragraph (c) is amended by revising the entry "K.A.R. 28–19–350" to read as follows:

§ 52.870 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED KANSAS REGULATIONS

Kansas citation	Title	State effective date	EPA approval date	Explanation
Kansas Department of Health and Environment Ambient Air Quality Standards and Air Pollution Control				
*	*	*	*	*
Construction Permits and Approvals				
*	*	*	*	*
K.A.R. 28–19–350.	Prevention of Significant Deterioration (PSD) of Air Quality.	12/28/2012	[Date of publication of the final rule in the **Federal Register**], [**Federal Register** citation of the final rule].	Provisions of the 2010 $PM_{2.5}$ PSD-Increments, SILs and SMCs rule relating to SILs and SMCs that were affected by the January 22, 2013, U.S. Court of Appeals decision are not SIP approved. Provisions of the 2002 NSR reform rule relating to the Clean Unit Exemption, Pollution Control Projects, and exemption from recordkeeping provisions for certain sources using the actual-to-projected-actual emissions projections test are not SIP approved. In addition, we have not approved Kansas rule incorporating EPA's 2008 "fugitive emissions rule" (published in the **Federal Register** on December 19, 2008).
*	*	*	*	*

* * * * *

Subpart AA—Missouri

■ 4. In § 52.1320, the table in paragraph (c) is amended by revising the entry "10–6.060" to read as follows:

§ 52.1320 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED MISSOURI REGULATIONS

Missouri citation	Title	State effective date	EPA approval date	Explanation
Missouri Department of Natural Resources				
*	*	*	*	*
Chapter 6–Air Quality Standards, Definitions, Sampling and Reference Methods, and Air Pollution Control Regulations for the State of Missouri				
*	*	*	*	*
10–6.060	Construction Permits Required.	3/30/2019	[Date of publication of the final rule in the FEDERAL REGISTER], [**Federal Register** citation of the final rule].	Provisions of the 2010 $PM_{2.5}$ PSD—Increments, SILs and SMCs rule relating to SILs and SMCs that were affected by the January 22, 2013 U.S. Court of Appeals decision are not SIP approved. Provisions of the 2002 NSR reform rule relating to the Clean Unit Exemption, Pollution Control Projects, and exemption from recordkeeping provisions for certain sources using the actual-to-projected-actual emissions projections test are not SIP approved. In addition, we have not approved Missouri's rule incorporating EPA's 2008 ''fugitive emissions rule'' (published in the **Federal Register** on December 19, 2008). Although exemptions previously listed in 10 CSR 10–6.060 have been transferred to 10 CSR 10–6.061, the Federally-approved SIP continues to include the following exemption, ''Livestock and livestock handling systems from which the only potential contaminant is odorous gas.'' Section 9, pertaining to hazardous air pollutants, is not SIP approved. EPA previously approved the 3/30/2016 State effective date version of 10 CSR 10–6.060, with the above exceptions, in a **Federal Register** document published October 11, 2016. EPA is only approving Section 7, subsection 7(A)(1), and Section 8 from the 3/30/2019 State effective date version of 10 CSR 10–6.060. All remaining revisions to the 3/30/2019 version of 10 CSR 10–6.060 are not SIP approved.
*	*	*	*	*

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Subpart CC—Nebraska

■ 5. In § 52.1420, the table in paragraph (c) is amended by revising the entry ''129–2'' to read as follows:

§ 52.1420 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED NEBRASKA REGULATIONS

Nebraska citation	Title	State effective date	EPA approval date	Explanation
STATE OF NEBRASKA				
Department of Environmental Quality				
Title 129—Nebraska Air Quality Regulations				

EPA-APPROVED NEBRASKA REGULATIONS—Continued

Nebraska citation	Title	State effective date	EPA approval date	Explanation
*	*	*	*	*
129–2	Definition of Major Source	2/6/2008	[Date of publication of the final rule in the **Federal Register**], [**Federal Register** citation of the final rule].	
*	*	*	*	*

* * * * *

PART 70—STATE OPERATING PERMIT PROGRAMS

■ 6. The authority citation for part 70 continues to read as follows:

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

■ 7. Appendix A to part 70 is amended by:

■ a. Adding paragraph (u) under ''Iowa''.

■ b. Adding paragraph (q) under ''Nebraska; City of Omaha; Lincoln-Lancaster County Health Department''.

The additions read as follows:

Appendix A to Part 70—Approval Status of State and Local Operating Permits

* * * * *

Iowa

* * * * *

(u) The Iowa Department of Natural Resources submitted revisions to Iowa Chapter 22.100 ''Definitions for Title V Operating Permits'' on November 15, 2007. The State revised the definition of ''Stationary source categories'' by revising the definition of ''Chemical process plants'' such that fugitive emissions from certain ethanol production facilities are not considered in determining whether the facility is subject to Title V permitting. The State effective date is October 4, 2007. The proposed revision effective date is [date 30 days after date of publication of the final rule in the **Federal Register**].

* * * * *

Nebraska; City of Omaha; Lincoln-Lancaster County Health Department

* * * * *

(q) The Nebraska Department of Environmental Quality submitted revisions to the Nebraska Administrative Code, title 129, chapter 2, section 002.20 on November 19, 2010. Chapter 2, section 002.20 was revised to exclude ethanol production facilities from the definition of ''chemical process plants'' such that fugitive emissions are not considered in determining whether the facility is subject to Title V permitting. The State effective date is February 6, 2008. The proposed revision effective date is [date 30 days after date of publication of the final rule in the **Federal Register**].

* * * * *

[FR Doc. 2019–23979 Filed 11–8–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 261

[EPA–R10–RCRA–2019–0662; SW–FRL–10001–79–Region 10]

Hazardous Waste Management System; Proposed Exclusion for Identifying and Listing Hazardous Waste

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule and request for comment.

SUMMARY: The Environmental Protection Agency (also, ''the Agency'' or ''we'' in this preamble) is proposing to grant three petitions submitted jointly by Emerald Kalama Chemical, LLC (Emerald) and Fire Mountain Farms, Inc. (FMF) (Petitioners), in Lewis County, Washington to exclude (or ''delist'') a one-time amount up to 20,100 cubic yards of U019 (benzene) and U220 (toluene) mixed material from the list of federal hazardous wastes. These wastes are limited to those associated with closure of hazardous waste management units at three facilities owned and operated by FMF pursuant to closure plans to be approved by the Washington State Department of Ecology (Ecology). The Agency is proposing to grant the petition based on an evaluation of waste-specific information provided by the Petitioners. This proposed decision, if finalized, conditionally excludes the petitioned waste from the requirements of hazardous waste regulations under the Resource Conservation and Recovery Act.

DATES: Comments must be received on or before December 12, 2019. Requests for an informal hearing must reach the EPA by November 27, 2019.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R10–RCRA–2019–0662 using one of the following methods:

- *www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *Mail:* to Dr. David Bartus, Office of Air and Waste, EPA, Region 10, 1200 6th Avenue, Suite 155, M/S 15–H04, Seattle, Washington 98101.
- *Hand Delivery:* to Dr. David Bartus, Office of Air and Waste, EPA, Region 10, 1200 6th Avenue, Suite 155, OAW–150, Seattle, Washington 98101. Such deliveries are only accepted during normal hours of operation. Please contact David Bartus at (206) 553–2804.

Instructions: Direct your comments to Docket ID No. EPA–R10–RCRA–2019–0662. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or email. The *www.regulations.gov* website is an ''anonymous access'' system, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *www.regulations.gov* 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. If you submit an electronic comment, the EPA recommends that you include your

name and other contact information in the body of your comment and with any physical media you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Any person may request an informal hearing on this proposed decision by filing a request with Timothy Hamlin, Director, Office of Land, Chemicals and Redevelopment Division, EPA, Region 10, 1200 6th Ave., Suite 155, M/S 15–H04, Seattle, Washington 98101. The request must contain the information prescribed in 40 Code of Federal Regulations CFR 260.20(d).

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information may not be publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the RCRA Records Center, 16th floor, U.S. EPA, Region 10, 1200 6th Avenue, Suite 155, M/S 16–C09, Seattle, Washington 98101. This facility is open from 8:30 a.m. to 4:00 p.m., Monday through Friday, excluding legal holidays. We recommend you telephone David Bartus at (206) 553–2804 before visiting the Region 10 office. The public may copy material from the regulatory docket at 15 cents per page.

FOR FURTHER INFORMATION CONTACT: Dr. David Bartus, EPA, Region 10, 1200 6th Avenue, Suite 155, M/S 15–H04, Seattle, Washington 98070; telephone number: (206) 553–2804; fax number (206) 553–8509; email address: *bartus.dave@epa.gov.*

As discussed in Section V below, Ecology is evaluating the Petitioners' petitions under state authority. Information on Ecology's action may be found at *https://fortress.wa.gov/ecy/publications/SummaryPages/1907021.html.*

SUPPLEMENTARY INFORMATION:

The information in this section is organized as follows:

I. Overview Information
II. Background
A. What is are the listed wastes associated with this petition?
B. What is a delisting petition?
C. What factors did EPA consider in deciding whether to grant a delisting petition?
III. EPA's Evaluation of the Waste Information and Data
A. What waste did the Petitioners petition EPA to delist?
B. How did the Petitioners generate the waste?
C. How did the Petitioners sample and analyze the petitioned waste?
D. What were the results of EPA's analysis of the Petitioner's waste?
E. How did the EPA evaluate the risk of delisting this waste?
F. What are EPA's proposed findings regarding the petitioned wastes?
IV. Conditions for Exclusion
A. How will the Petitioners manage the waste if it is delisted?
B. What are the maximum allowable concentrations of hazardous constituents in the waste?
C. How frequently must the Petitioners test the waste?
D. What data must the Petitioners submit?
E. What happens if the Petitioners fail to meet the conditions of the exclusion?
F. What must the Petitioners do if the process changes?
V. When would the EPA finalize the proposed delisting exclusion?
VI. How would this action affect states?
VII. Statutory and Executive Order Reviews

I. Overview Information

The EPA is proposing to grant three petitions submitted jointly by Emerald Kalama Chemical, LLC (Emerald) and Fire Mountain Farms, Inc (FMF) (Petitioners), in Lewis County, Washington to exclude (or ''delist'') a one-time combined amount up to 20,100 cubic yards of U019 (benzene) and U220 (toluene) hazardous wastes from the list of federal hazardous waste set forth in 40 Code of Federal Regulations CFR 261.33.[1] These three petitions apply to three separate facilities owned and operated by FMF, and each manage wastes that are sufficiently similar that the EPA is electing to propose its decision to grant the petitions concurrently through this **Federal Register** notice. The Petitioners claim that each of the petitioned wastes do not meet the criteria for which the EPA listed it, and that there are no additional constituents or factors which could cause the waste to be hazardous. These exclusions apply only to wastes associated with closure of hazardous waste management units at the three FMF facilities pursuant to an approved closure plan. The exclusion is effective when the wastes are removed from the respective hazardous waste management units, or otherwise generated pursuant to the corresponding approved closure plan.

Based on our review described in Section III, we propose to make a determination that the petitioned wastes are non-hazardous with respect to listed waste codes that originally applied. As part of our supporting analysis, we reviewed the description of the process which generated the wastes and the analytical data submitted by the Petitioners. We believe that the petitioned wastes do not meet the criteria for which the waste was originally listed, that they do not exhibit any hazardous waste characteristic, and that there are no other factors which might cause the waste to be hazardous. Accordingly, EPA is proposing to find that the petitioned wastes may be safely managed as non-listed hazardous wastes. EPA notes that while the burden of demonstrating that a delisted waste does not also exhibit a hazardous characteristic remains with the facility, the data provided by the Petitioners demonstrate that the candidate wastes do not exhibit a hazardous characteristic. Subject to state-only requirements within the state of Washington, or federally-authorized or state-only requirements in other states where the subject wastes may be disposed of, the petitioned wastes must be disposed of in a Subtitle D landfill which is permitted, licensed, or registered by a State to manage industrial solid waste.

II. Background

A. What are the listed wastes associated with this petition?

The EPA published an amended list of discarded commercial chemical products, off-specification species, container residues and spill residues thereof on November 25, 1980 (45 FR 78541), as part of its final and interim final regulations implementing § 3001 of Resource Conservation and Recovery Act (RCRA). The EPA has amended this list several times and published it in 40 CFR 261.33.

We list these wastes as hazardous because: (1) They typically and frequently exhibit one or more of the characteristics of hazardous wastes identified in 40 CFR part 261 Subpart C (that is, ignitability, corrosivity, reactivity, and toxicity) or (2) they meet the criteria for listing contained in § 261.11(a)(2) or (3).

B. What is a delisting petition?

Individual waste streams may vary depending on raw materials, industrial processes, and other factors. Thus, while a waste from a source listed in the regulations as ''hazardous'' is by definition hazardous, a specific waste from an individual generating facility and from a source meeting the listing

[1] The facility-specific waste volumes are documented in Section III.A.

description may produce wastes that vary significantly from the wastes EPA considered in establishing the waste listing.

A procedure to exclude or delist a waste is provided in 40 CFR 260.20 and 260.22 which allows a person or a facility to submit a petition to the EPA or to an authorized state demonstrating that a specific waste from a particular generating facility should not be regulated as hazardous.[2]

In a delisting petition, the petitioner must show that a waste does not meet any of the criteria for listed wastes in 40 CFR 261.11 and that the waste does not exhibit any of the hazardous waste characteristics of ignitability, reactivity, corrosivity, or toxicity. The petitioner must present sufficient information for EPA to decide whether any factors in addition to those for which the waste was listed warrant retaining it as a hazardous waste. (See 40 CFR 260.22 and 42 U.S.C. 6921(f).) EPA's basis for originally listing the wastes associated with this petition may be found at 45 FR 78532.

If a delisting petition is granted, the specific waste(s) identified in the delisting will be excluded from the associated lists(s) of hazardous waste in 40 CFR part 261 Subpart D so long as conditions in the delisting are met. A waste which is so excluded, however, may still exhibit a characteristic and thus be a hazardous waste by operation of 40 CFR part 261 Subpart C. EPA notes that while the burden of demonstrating that a delisted waste does not also exhibit a hazardous characteristic remains with the facility, the data provided by the Petitioners demonstrate that the candidate wastes do not exhibit a hazardous characteristic.

C. What factors did EPA consider in deciding whether to grant a delisting petition?

In reviewing this petition, we considered the original listing criteria and the additional factors required by the Hazardous and Solid Waste Amendments of 1984 (HSWA). See § 222 of HSWA, 42 U.S.C. 6921(f), and 40 CFR 260.22(d)(2) through (4). We evaluated the petitioned wastes against the listing criteria and factors cited in § 261.11(a)(2) and (3).

In addition to the criteria in 40 CFR 260.22(a), 261.11(a)(2) and (3), 42 U.S.C. 6921(f), and in the background documents for the listed wastes, EPA also considered any factors (including additional constituents) other than those for which we listed the waste if these additional factors could cause the waste to be hazardous.

Our proposed decision to grant the petitions to delist the waste from the identified FMF facilities in Lewis County, Washington is based on our evaluation of the wastes for factors or criteria which could cause the waste to be hazardous. These factors included: (1) Whether the waste is considered acutely toxic; (2) the toxicity of the constituents; (3) the concentration of the constituents in the waste; (4) the tendency of the constituents to migrate and to bioaccumulate; (5) the persistence in the environment of any constituents once released from the waste; (6) plausible and specific types of management of the petitioned waste; (7) the quantity of waste produced; and (8) waste variability.

The EPA must also consider as hazardous wastes mixtures containing listed hazardous wastes and wastes derived from treating, storing, or disposing of listed hazardous waste. See 40 CFR 261.3(a)(2)(iv) and (c)(2)(i), called the ''mixture'' and ''derived-from'' rules, respectively. Mixture and derived-from wastes are also eligible for exclusion but remain hazardous until excluded.

III. EPA's Evaluation of the Waste Information and Data

A. What waste did the Petitioners petition the EPA to delist?

Emerald manufactures various organic chemicals used as artificial flavors and fragrances, food preservatives, plasticizers, and intermediates at their facility in Kalama, Washington. Most of the chemicals produced are derived from toluene or from the oxidation products of toluene, including benzoic acid and benzaldehyde. Additional products are produced as derivatives of benzoic acid and benzaldehyde. Products are typically purified by continuous or batch distillation. In conjunction with its manufacturing processes, Emerald operates an industrial wastewater treatment system, consisting of an anaerobic digestion process and an aerobic oxidation system, both of which are biological treatment systems very similar to municipal wastewater treatment systems. This treatment system produces industrial wastewater treatment plant biological solids (IWBS). As documented in the Petitioner's delisting petition, the IWBS designates as U019 (benzene) and U220 (toluene).

FMF operates receiving, storage, treatment, and land application facilities in Lewis County, Washington for wastewater treatment plant treatment solids received from municipal, industrial, and private wastewater treatment plants. FMF is not permitted or otherwise authorized to manage, treat, or dispose of hazardous or dangerous wastes.[3] Emerald contracted with FMF to land apply Emerald's IWBS beginning in October 1995. FMF mixed Emerald's IWBS with treatment solids from other facilities and land applied or stored the mixed IWBS/treatment solids wastes at several FMF facilities. The RCRA rules require that listed hazardous wastes, when mixed with other materials, continue to be regulated as listed hazardous wastes (40 CFR 261.3). The mixed IWBS/treatment solids wastes are currently stored at three FMF facilities: Burnt Ridge located at 856 Burnt Ridge Road, Onalaska, Washington; Newaukum Prairie located at 349 State Route 508, Chehalis, Washington; and Big Hanaford located at 307 Big Hanaford Road, Centralia, Washington.[4] Under a separate action (See footnote 4), the Washington State Department of Ecology is requiring that Emerald and FMF remove these wastes from the three units according to closure plans approved pursuant to WAC 173–303–610.

The Petitioners have requested that up to 4,700 cubic yards at the Burnt Ridge facility, 10,400 cubic yards at the Newaukum Prairie facility, and 5,000 cubic yards at the Big Hanaford facility of IWBS/treatment solids be excluded from the list of hazardous wastes.[5]

[2] Washington State's promulgated regulations at WAC 173–303–910(3) correspondence to the federal regulation. However, Washington State has not received final authorization to implement these regulations in lieu of federal program. As such, they are effective concurrent with 40 CFR 260.20 and 260.22 on a state-only basis.

[3] Within Ecology's authorized hazardous waste program, ''hazardous'' refers to those wastes regulated by the federal RCRA program. ''Dangerous'' refers to additional wastes that Ecology's regulates as a broader in scope provision of their program.

[4] The Washington State Department of Ecology has entered into a litigation settlement (Docket Entry 3) with Fire Mountain Farms and Emerald-Kalama that, in part, requires closure of the units managing dangerous waste considered int his proposed delisting rule. In this context, today's proposed delisting rule is a ''one-time'' delisting that, if finalized, will allow the fixed volume of wastes to be generated pursuant to closure of these three units as non-hazardous.

[5] The delisting petitions submitted by the Petitioners requested exclusion of a waste volumes less than those cited in this proposed rule. Because these wastes will be managed on a one-time basis as part of closure of the respective waste management units at the three FMF facilities, the EPA and Ecology have determined that it is appropriate to propose exclusion of a waste volume double that in the respective delisting petitions as a safety measure that will account for any additional wastes that may be generated pursuant to closure activities such as liners, debris, etc. The EPA notes that the requested quantity of wastes in

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B. How did the Petitioners generate the waste?

In a delisting petition for its IWBS wastes separate from today's proposed exclusions, Emerald documented that its industrial wastewater treatment system from which IWBS is derived manages wastewaters from multiple sources within the facility. The first source consists of contaminated groundwater from an extensive groundwater recovery system to prevent contaminated water from leaving the plant site. Water pumped from the North Impact Area (NIA), West Impact Area (WIA), and Intermediate Sand Recovery Wells (ISRW) contains commercial product toluene from historical releases and therefore the IWBS carry the listed hazardous waste code U220 (toluene). Historical data from 2014 through 2017 indicates that an average of 33.1 million gallons per year with a maximum of 38.6 million gallon per year was treated in the wastewater treatment unit (WWTU) that generates IWBS. The second source consists of stormwater that falls on the manufacturing process areas of the facility, which may become contaminated by spills or releases of the various raw materials, intermediates, products or byproducts of its manufacturing operations. The third source consists of process wastewater from manufacturing processes. These second and third sources may be impacted by trace amounts of pure product benzene from *de minimus* spills that are captured by the treatment system; therefore, the IWBS from the second and third source categories carry the listed hazardous waste code U019 (benzene).

Emerald provided the EPA with a detailed process flow diagram (Docket Entry 1) of the overall wastewater management system that documents the source of all wastewaters from which the candidate IWBS are generated and the various management processes that are applied to the wastewaters. Generally, process wastewater expected to have higher quantities of organic constituents from process units is routed to either the anaerobic digesters (ANTs) or to the aerobic digesters (BIOX), depending upon the types and concentrations of chemicals present. All of the effluent from ANTs is routed to BIOX for final treatment. Groundwater and stormwater[6] with a low chemical oxygen demand (COD) are routed to the aerobic digesters (BIOX). This process flow arrangement, including flexibility to re-route wastewaters depending on their chemical makeup, helps ensure that concentrated free product from manufacturing process wastes or from spills is not introduced into the balance of the wastewater treatment system, and that the concentration of waste constituents entering the treatment system is maintained in a range that fosters microbial degradation. Wastewaters from the API separator are then routed to the aerobic digester system. The use of the API separator for wastewaters expected to have higher levels of organic constituents helps ensure that significant excursions in waste composition do not adversely affect performance of the wastewater treatment system. The effluent of the ANTS system is then routed to the aerobic digester and sludge filtration systems. Groundwater and stormwater expected to have lower COD levels bypass the API separator and are fed directly to the aerobic digester treatment system.

At the Burnt Ridge facility, FMF mixed IWBS from Emerald, treatment solids from municipal and industrial wastewater treatment plants, and cow manure water runoff from a barn in a surface impoundment that has approximate dimensions of 220 feet on each side and 14 feet deep. Once FMF mixed the IWBS with the other material, the mixed material became regulated as U019 and U220 listed hazardous wastes as noted earlier.

At the Newaukum Prairie facility, FMF mixed IWBS from Emerald and treatment solids from municipal and industrial wastewater treatment plants in a surface impoundment that has approximate dimensions of 220 feet on each side and 12 feet deep. Once FMF mixed the IWBS with the other material, the mixed material became regulated as U019 and U220 listed hazardous wastes.

At the Big Hanaford facility, FMF mixed IWBS from Emerald and treatment solids from municipal and private wastewater treatment plants in a roofed concrete panel storage unit that has approximate dimensions of 100 feet by 60 feet and 11.5 feet deep. Once FMF mixed the IWBS with the other material, the mixed material became regulated as U019 and U220 listed hazardous wastes.

C. How did the Petitioners sample and analyze the petitioned wastes?

FMF conducted an investigation of the wastes at each of the three storage units in September 2014.[7] Three composite samples of the mixed IWBS/treatment solids wastes were collected from each storage unit. At Burnt Ridge and Newaukum Prairie, each composite sample consisted of nine grab samples collected from various depths. Each composite sample collected at Big Hanaford consisted of six grab samples collected from various depths.

Each composite sample was analyzed for the following constituents or constituent groups: Volatile organic compounds (VOCs), semivolatile organic compounds (SVOCs), total metals, total cyanide, and total solids. The specific analytes included in the analysis are defined by the analytical method used for each group.

In addition, two composite samples from the Newaukum Prairie storage unit and one composite sample each from the Burnt Ridge and Big Hanaford storage units were analyzed for the following parameters or constituent groups: Pesticides; polychlorinated biphenyl (PCB) Aroclors; dioxins and furans, reported as 2,3,7,8-tetrachlorodibenzodioxin toxicity equivalence quotient (2,3,7,8–TCDD TEQ); ammonia; Total Kjeldahl Nitrogen (TKN); pH, nitrite; and nitrate + nitrite (the concentration of nitrate was calculated by the analytical laboratory). Fourteen grab samples from the Newaukum Prairie storage unit and seven grab samples each from the Burnt Ridge and Big Hanaford storage units were analyzed for total fecal coliform.

Emerald conducted additional sampling of the mixed IWBS/treatment solids wastes at each of the three storage units in August and October 2017.[8] Emerald performed the additional sampling based on the preliminary delisting levels and the September 2014 investigation. Samples from the storage units at Burnt Ridge, Newaukum Prairie, and Big Hanaford were analyzed for selected volatile organic compounds (acetone, benzene, methanol, and toluene), total solids, and pH. Samples from Big Hanaford were analyzed for total acrylonitrile; cobalt; 4-methylphenol; 2,4-dinitrotoluene; 2,6-dinitrotoluene; and naphthalene.

the delisting petition itself was expressed on a mass (ton) basis. The ''Waste Characterization Plan, Fire Mountain Farms, Mixed Material Storage Units, Lewis County, Washington'' included in the petition, however, estimates the quantity of waste on a volumetric basis. The expanded waste volume in this proposed delisting reflect a doubling of the volumetric waste volumetric estimate documented in the Waste Characterization Plan.

[6] Emerald also provide the EPA with a map of the facility indicating areas where stormwater is collected from various areas of the facility. See Docket Entry 2.

[7] This investigation is documented in the first report in Appendix C of the three delisting petitions (Docket Entries 7–9).

[8] Results of these sampling activities are documented in the third report in Appendix C of the three delisting petitions (Docket Entries 7–9).

D. What were the results of EPA's analysis of the Petitioner's waste?

The first step in the EPA's analysis of the petitioned wastes was to establish a list of potential constituents of concern (COCs) to guide further analysis of the waste and to establish initial delisting exclusion criteria. The EPA applied four criteria for identifying potential constituents of concern: (1) Whether the constituent is used as an input to, or created as an intermediate, byproduct or finished product from Emerald's production processes; (2) whether the IWBS designates as hazardous for a particular constituent; (3) the expected frequency of occurrence in the IWBS; and (4) the toxicity of the constituent of concern. The EPA also considered results of the 2014 waste characterization study in Appendix C of the three petitions, as well as any additional constituents that may be typically found in municipal wastewater treatment biosolids.

The EPA first considered organic COCs. Based on the hazardous waste codes associated with wastewater that ultimately results in generation of IWBS (D018, U019, U220, U154 and U001), the EPA determined that benzene, toluene, methanol and acetaldehyde are COCs.[9] The EPA notes that benzene is generally regarded as difficult to treat and is an excellent indicator of overall performance of the WWTU processes, and the ability of the WWTU to effectively treat other organic constituents other than benzene. Based on principal products of Emerald's processes, the EPA determined that additional organic constituents including benzaldehyde, benzoic acid, formic acid, benzyl alcohol, and phenol should be retained as COCs. While at least some of these constituents are associated with products for human consumption or exposure, they have a level of toxicity that warrants retention as COCs for purposes of evaluating the candidate waste stream. Although several additional organic constituents are associated with Emerald's production processes, they are associated with products for human consumption or exposure, such as food preservatives and vitamins, fragrances and perfumes, and sunscreens, and do not have a degree of toxicity that warrants retention as COCs (Docket Entry 17). In addition, most if not all these additional organic constituents are highly amenable to biological treatment in the WWTS and are not expected to be present in the IWBS at levels anywhere near health-based levels that would be of concern in the delisting process.

Emerald's production process uses a range of catalysts, including several metallic catalysts that include cobalt, copper and nickel. On this basis, cobalt, copper and nickel are identified as constituents of concern. Although these three metals are not hazardous constituents, they are retained as ''other factors'' that may cause the waste to be retained as hazardous. Other metallic constituents are reported to have been detected in the IWBS waste stream that do not have a clear source related to Emerald's organic manufacturing process. These constituents include barium and zinc. Barium is a hazardous constituent and is present at levels in the IWBS so barium is retained as an ''other factor'' that may cause the waste to be retained as hazardous. Zinc is a common contaminant in industrial wastewater and is found in the IWBS at concentrations as high as 1,350 ppm dry weight, so zinc is retained as a constituent as an ''other factor'' that may cause the waste to be retained as hazardous.

In Emerald's production process, cobalt is used as a catalyst in both its metallic form (sponge cobalt) and as cobalt acetate. Although cobalt acetate poses environmental and human health risks, the acetate functional group is expected to be readily degraded in the WWTS, leaving metallic cobalt in the IWBS. Further, cobalt acetate is soluble in water, so that any remaining cobalt acetate that is not degraded to metallic cobalt in the WWTS is likely to partition into the effluent wastewater managed separately from the IWBS. Thus, all forms of cobalt are considered to be metallic for purposes of the delisting evaluation of Emerald's IWBS.

Emerald's IWBS only constitute a small percentage (between 5% and 8%) of the total mixed IWBS/treatment solids wastes at each of the three storage units.

With respect to the biosolids component of the petitioned waste, the 2014 waste characterization report in Appendix C of the delisting petitions considered a very broad range of potential constituents of concern. The EPA first compared these characterization data reports to preliminary delisting levels (See the second report in Appendix C of the delisting petitions) calculated using the Delisting Risk Assessment Software (DRAS) model.[10] Any detected constituents at concentrations less than the preliminary delisting levels were removed from further consideration.[11] The remaining detected constituents exceeding a preliminary delisting level were retained for further evaluation in the 2017 waste characterization plan, also included in the second report in Appendix C of the delisting petitions. Results from this latter characterization work were then used as input to the DRAS modelling program discussed in the following section. After consideration of constituents typically found in biosolids (for example, as documented in the U.S. EPA National Sewage Sludge Survey available at *https://www.epa.gov/biosolids/sewage-sludge-surveys*), the EPA determined that no additional constituents of concern should be added for consideration in the delisting process.

The final list of constituents of concern evaluated in the delisting process are documented in Tables 2–4 below.

E. How did the EPA evaluate the risk of delisting this waste?

For this delisting determination, we evaluated the risk that the waste would be disposed of as a non-hazardous waste in a RCRA Subtitle D landfill and we considered transport of waste constituents through ground water, surface water and air. We evaluated the Petitioner's analysis of petitioned waste using the DRAS software to predict the concentration of hazardous constituents that might be released from the petitioned waste and to determine if the waste would pose a threat to human health and the environment. The DRAS software and associated documentation can be found at *www.epa.gov/hw/hazardous-waste-delisting-risk-assessment-software-dras.*

To predict the potential for release to groundwater from landfilled wastes and subsequent routes of exposure to a receptor, the DRAS uses dilution attenuation factors derived from the EPA's Composite Model for leachate migration with Transformation Products. From a release to ground water, the DRAS considers routes of exposure to a human receptor through ingestion of contaminated groundwater,

[9] As noted in the delisting petition, IWBS designate only for U019 (benzene) and U220 (toluene) because due to an exception to RCRA's derived from rule, certain codes applicable to the wastewater do not carry through to the IWBS. However, as part of its evaluation of the IWBS waste stream and identification of COCs, the EPA also considered hazardous waste codes applicable to the wastewaters managed by the WWTU generating IWBS.

[10] Preliminary delisting levels were obtained for all DRAS constituents on a unit-specific basis considering the expected waste volume associated with each unit to be closed.

[11] The specific decision criteria that considered total concentrations, bounding leachability, and laboratory analysis detection limits are documented in the second report in Appendix C of the delisting petitions.

inhalation from groundwater while showering and dermal contact from groundwater while bathing.

From a release to surface water by erosion of waste from an open landfill into storm water run-off, DRAS evaluates the exposure to a human receptor by fish ingestion and ingestion of drinking water. From a release of waste particles and volatile emissions to air from the surface of an open landfill, DRAS considers routes of exposure of inhalation of volatile constituents, inhalation of particles, and air deposition of particles on residential soil and subsequent ingestion of the contaminated soil by a child. The technical support document and the user's guide to DRAS are available at *https://www.epa.gov/hw/hazardous-waste-delisting-risk-assessment-software-dras.*

The EPA used the following inputs to its DRAS analysis of the Petitioner's wastes, as summarized in Table 2.

TABLE 1—EMERALD AND FMF DELISTING DRAS INPUT

DRAS Input parameter	Value	Assumptions
Waste Management Unit Type	Landfill [12]	Waste planned for disposal in a municipal solid waste landfill.
Waste Volume—one-year batch	4,700 cubic yards for Burnt Ridge; 10,400 cubic yards for Newaukum Prairie; 5,000 cubic yards for Big Hanaford.	Conservative estimation value based on facility-specific information.
Waste Management Unit Active Life	One Year Batch	N/A—DRAS does not allow a year input for the One Year Batch.
Target risk—carcinogenic risk level	1×10^{-5}	Based on risk ranges in the EPA's RCRA Delisting Technical Support Document (2008).
Target risk—health quotient	1.0	Based on risk ranges in the EPA's RCRA Delisting Technical Support Document (2008).

At a target cancer risk of 1×10^{-5} and a target hazard quotient of 1.0, the DRAS program determined maximum allowable concentrations for each constituent in both the waste and the leachate. The EPA used the maximum estimated waste volumes and the maximum reported total and estimated leachate concentrations as inputs to estimate the constituent concentrations in the ground water, soil, surface water or air. Tables 2, 3, and 4 document the constituent-specific maximum total and TCLP sample results used as input to the DRAS analysis, and the resulting modeling results from DRAS for the Burnt Ridge, Newaukum Prairie, and Big Hanaford storage units, respectively.

TABLE 2—SAMPLING DATA AND DRAS MODELING RESULTS FOR BURNT RIDGE

Constituent of concern	Maximum observed concentration [1]		Modeling results			
			Total concentrations		TCLP concentration	
	Total [1] (mg/kg)	TCLP (mg/L) [4]	Limiting concentration (mg/kg) [2]	Limiting pathway [3]	Limiting concentration (mg/L) [2]	Limiting pathway [3]
Barium	N/A	N/A	21,100,000	Air Particulate Inhalation	1,090	Maximum Contaminant Level.
Cobalt	48	0.108	94,400	Air Particulate Inhalation	6.28	Groundwater Ingestion.
Copper	417	N/A	18,200,000	Fish Ingestion	716	Maximum Contaminant Level.
Nickel	45	N/A	3,540,000	Air Particulate Inhalation	408	Groundwater Ingestion.
Zinc	969	N/A	47,100,000	Fish Ingestion	6,170	Groundwater Ingestion.
Benzaldehyde	N/A	N/A	2,320,000,000	Soil Ingestion	1,760	Groundwater Ingestion.
Benzene	0.00101	N/A	1,600,000	Air Volatile Inhalation	2.35	Maximum Contaminant Level.
Benzoic Acid	N/A	N/A	83,100,000,000	Fish Ingestion	70,400	Groundwater Ingestion.
Formic Acid	N/A	N/A	8,080,000	Air Volatile Inhalation	1,130	Groundwater Inhalation.
Benzyl alcohol	N/A	N/A	11,600,000,000	Soil Ingestion	8,800	Groundwater Ingestion.
Methanol	<0.01 U	N/A	11,600,000,000	Soil Ingestion	8,800	Groundwater Ingestion.
Phenol	<0.310 U	N/A	6,950,000,000	Soil Ingestion	5,280	Groundwater Ingestion.
Toluene	0.035	N/A	369,000,000	Fish Ingestion	460	Maximum Contaminant Level.

[1] Maximum concentration documented in the Petitioner's Burnt Ridge delisting petition, Tables B–1, B–3, and B–4.

[2] The Limiting Concentration is the lowest risk-based concentration developed in DRAS for the potential receptor pathways and specified target risk levels. See text in Section IV.C for the EPA's consideration of limiting concentrations exceeding 1,000,000 mg/kg for total concentrations or 1,000,000 mg/L for TCLP concentrations.

[3] The Limiting Pathway is the corresponding potential receptor pathway for the Limiting Concentration.

[4] For detected constituents, the maximum analytical result was used. For non-detect constituents (annotated with a "U"), the practical quantitation limit (PQL) was used.

[12] Although two of the petitioned waste streams originate in a surface impoundment, the wastes being delisted will be removed from the surface impoundments through an approved closure process. The removed wastes will be managed in accordance with the closure plan to allow disposal in a solid waste landfill. Therefore, the waste management unit used for modelling waste performance using DRAS is "Landfill" for all three units.

TABLE 3—SAMPLING DATA AND DRAS MODELING RESULTS FOR NEWAUKUM PRAIRIE

Constituent of concern	Maximum observed concentration [1]		Modeling results			
			Total concentrations		TCLP concentration	
	Total [1] (mg/kg)	TCLP (mg/L) [4]	Limiting concentration (mg/kg) [2]	Limiting pathway [3]	Limiting concentration (mg/L) [2]	Limiting pathway [3]
Barium	N/A	N/A	11,000,000	Air Particulate Inhalation	498	Maximum Contaminant Level.
Cobalt	89	0.184	49,100	Air Particulate Inhalation	2.92	Groundwater Ingestion.
Copper	503	N/A	9,290,000	Fish Ingestion	332	Maximum Contaminant Level.
Nickel	30	N/A	1,840,000	Air Particulate Inhalation	184	Groundwater Ingestion.
Zinc	1,060	N/A	24,000,000	Fish Ingestion	2,820	Groundwater Ingestion.
Benzaldehyde	N/A	N/A	1,210,000,000	Soil Ingestion	809	Groundwater Ingestion.
Benzene	<0.0039 U	N/A	955,000	Air Volatile Inhalation	1.08	Maximum Contaminant Level.
Benzoic Acid	N/A	N/A	42,500,000,000	Fish Ingestion	32,400	Groundwater Ingestion.
Formic Acid	N/A	N/A	4,830,000	Air Volatile Inhalation	519	Groundwater Inhalation.
Benzyl alcohol	N/A	N/A	6,060,000,000	Soil Ingestion	4,040	Groundwater Ingestion.
Methanol	<0.01 U	N/A	6,060,000,000	Soil Ingestion	4,040	Groundwater Ingestion.
Phenol	0.63	N/A	3,640,000,000	Soil Ingestion	2,430	Groundwater Ingestion.
Toluene	150	N/A	189,000,000	Fish Ingestion	211	Maximum Contaminant Level.

[1] Maximum concentration documented in the Petitioner's Newaukum Prairie delisting petition, Tables B–1, B–3, and B–4.
[2] The Limiting Concentration is the lowest risk-based concentration developed in DRAS for the potential receptor pathways and specified target risk levels. See text in Section IV.C for the EPA's consideration of limiting concentrations exceeding 1,000,000 mg/kg for total concentrations or 1,000,000 mg/L for TCLP concentrations.
[3] The Limiting Pathway is the corresponding potential receptor pathway for the Limiting Concentration.
[4] For detected constituents, the maximum analytical result was used. For non-detect constituents (annotated with a "U"), the practical quantitation limit (PQL) was used.

TABLE 4—SAMPLING DATA AND DRAS MODELING RESULTS FOR BIG HANAFORD

Constituent of concern	Maximum observed concentration [1]		Modeling results			
			Total concentrations		TCLP concentration	
	Total [1] (mg/kg)	TCLP (mg/L) [4]	Limiting concentration (mg/kg) [2]	Limiting pathway [3]	Limiting concentration (mg/L) [2]	Limiting pathway [3]
Barium	N/A	N/A	20,100,000	Air Particulate Inhalation	1,030	Maximum Contaminant Level.
Cobalt	165	1.10	89,900	Air Particulate Inhalation	5.92	Groundwater Ingestion.
Copper	521	N/A	17,300,000	Fish Ingestion	674	Maximum Contaminant Level.
Nickel	42	N/A	3,370,000	Air Particulate Inhalation	384	Groundwater Ingestion.
Zinc	1,100	N/A	44,700,000	Fish Ingestion	5,800	Groundwater Ingestion.
Benzaldehyde	N/A	N/A	2,210,000,000	Soil Ingestion	1,660	Groundwater Ingestion.
Benzene	0.00115	N/A	1,530,000	Air Volatile Inhalation	2.21	Maximum Contaminant Level.
Benzoic Acid	N/A	N/A	78,900,000,000	Fish Ingestion	66,300	Groundwater Ingestion.
Formic Acid	N/A	N/A	7,760,000	Air Volatile Inhalation	1,060	Groundwater Inhalation.
Benzyl alcohol	N/A	N/A	11,000,000,000	Soil Ingestion	8,290	Groundwater Ingestion.
Methanol	<0.01 U	N/A	11,000,000,000	Soil Ingestion	8,290	Groundwater Ingestion.
Phenol	23	N/A	6,620,000,000	Soil Ingestion	4,970	Groundwater Ingestion.
Toluene	120	N/A	350,000,000	Fish Ingestion	433	Maximum Contaminant Level.

[1] Maximum concentration documented in the Petitioner's Big Hanaford delisting petition, Tables B–1 and B–3.
[2] The Limiting Concentration is the lowest risk-based concentration developed in DRAS for the potential receptor pathways and specified target risk levels. See text in Section IV.C for the EPA's consideration of limiting concentrations exceeding 1,000,000 mg/kg for total concentrations or 1,000,000 mg/L for TCLP concentrations.
[3] The Limiting Pathway is the corresponding potential receptor pathway for the Limiting Concentration.
[4] For detected constituents, the maximum analytical result was used. For non-detect constituents (annotated with a "U"), the practical quantitation limit (PQL) was used.

F. What are EPA's proposed findings regarding the petitioned wastes?

The maximum reported concentrations of the hazardous constituents found in these wastes are presented in the tables above. The tables also present the maximum allowable concentrations, above which the waste is not excluded from the applicable hazardous waste listings.

We therefore propose to conclude that the Petitioner's mixed IWBS/treatment solids wastes are not a substantial or potential hazard to human health and the environment when disposed of in a Subtitle D landfill. Further, the data presented by the Petitioners in their petitions support the EPA's proposed conclusion that the petitioned waste does not exhibit any hazardous characteristic for which the waste is listed, and that there are no other factors that would warrant retaining the waste as hazardous. On this basis, we propose to grant the Petitioner's petitions to delist these wastes. If this exclusion is finalized, and subject to the conditions of the final delisting, the Petitioners must dispose of these wastes in a Subtitle D landfill permitted or licensed by a state and will remain obligated to verify that the wastes continue to meet the allowable concentrations set forth here. The Petitioners must also to demonstrate that the wastes do not exhibit any hazardous characteristics pursuant to 40 CFR part 261 Subpart C. The Petitioners may make this demonstration based on the existing characterization data provided in the delisting petition. As noted in Section II.B, the data provided by the Petitioners demonstrate that the candidate wastes do not exhibit a hazardous characteristic.

IV. Conditions for Exclusion

A. How will the Petitioners manage the waste if it is delisted?

If the petitioned wastes are delisted as proposed, the Petitioners must dispose of them in a Subtitle D landfill which is permitted, licensed, or registered by a state to manage industrial waste.

B. What are the maximum allowable concentrations of hazardous constituents in the waste?

Concentrations of the following constituents measured in the wastes located at FMF's Burnt Ridge, Newaukum Prairie, and Big Hanaford facilities, respectively, must not exceed the concentrations in Table 5.

TABLE 5—VERIFICATION CONSTITUENTS AND COMPLIANCE CONCENTRATIONS DRAS MODEL OUTPUT

Constituent	Burnt Ridge		Newaukum Prarie		Big Hanaford	
	Total (mg/kg)	TCLP (mg/l)	Total (mg/kg)	TCLP (mg/l)	Total (mg/kg)	TCLP (mg/l)
Barium	N/A	1,090	N/A	498	N/A	1,030
Cobalt	94,400	6.28	49,100	2.92	89,900	5.92
Copper	N/A	716	N/A	332	N/A	674
Nickel	N/A	408	N/A	184	N/A	384
Zinc	N/A	6,170	N/A	2,820	N/A	5,800
Benzaldehyde	N/A	1,760	N/A	809	N/A	1,660
Benzene	N/A	2.35	N/A	1.08	N/A	2.21
Benzoic Acid	N/A	70,400	N/A	32,400	N/A	66,300
Formic Acid	N/A	1,130	N/A	519	N/A	1,060
Benzyl alcohol	N/A	8,800	N/A	4,040	N/A	8,290
Methanol	N/A	8,800	N/A	4,040	N/A	8,290
Phenol	N/A	5,280	N/A	2,430	N/A	4,970
Toluene	N/A	460	N/A	211	N/A	433

The EPA notes that in multiple instances the maximum allowable total constituent concentrations provided by the DRAS model exceed 100% of the waste—these DRAS results are an artifact of the risk calculations that do not have physical meaning. In instances where DRAS predicts a maximum constituent greater than 100 percent of the waste (that is, greater than 1,000,000 mg/kg or mg/L, respectively, for total and TCLP concentrations), the EPA is not proposing to require the Petitioners to perform sampling and analysis for that constituent and sampling type (total or TCLP). In these instances, the corresponding entry in Table 5 above is ''N/A.''

C. How frequently must the Petitioners test the waste?

The Petitioner's delisting petitions did not provide complete sampling data for some constituents that EPA has retained as constituents of concern. More specifically, characterization data for barium, benzaldehyde, benzoic acid, formic acid, and benzyl alcohol, which are retained as verification constituents, do not have any existing characterization data. Therefore, the candidate wastes are excluded only if the Petitioners analyze three representative composite samples of the mixed IWBS/treatment solids wastes from each FMF facility for these constituents prior to the start of closure activities to demonstrate that the constituents of concern in the petitioned waste do not exceed the concentrations of concern in Section IV.C above. The Petitioners need only sample an extract of the wastes from EPA SW–846 Method 1311 for purposes of comparison to the TCLP standard in Table 5 and Condition 1 of the proposed amendments to 40 CFR part 261. If results of any composite sample do not reflect compliance with delisting exclusion limits, the EPA may require the Petitioners to conduct additional verification sampling to better define the volume of waste with waste constituent concentrations exceeding the delisting exclusion limits. The EPA believes that this sampling rate will provide an appropriate level of certainty for determining whether or not all delisted waste satisfy the delisting criteria presented in Table 5 above. The Petitioners must use methods with appropriate analytical sensitivity quality control procedures, as documented in a written quality assurance project plan. EPA publication SW–846 Method 1311 must be used for generation of the leachate extract used in the testing of the subject waste. SW–846 Method 1311 is incorporated by reference in 40 CFR 260.11.

A total analysis of the waste (accounting for any filterable liquids and the dilution factor inherent in the TCLP method) may be used to estimate the TCLP concentration as provided for in section 1.2 of Method 1311.

D. What data must the Petitioners submit?

The Petitioners must submit the data obtained through verification testing to U.S. EPA Region 10, Office of Land, Chemicals and Redevelopment, 1200 6th Avenue, Suite 155, M/S 15–H04, Seattle, Washington 98101 within 10 days after receiving the final results from the laboratory. The Petitioners must make those records available for inspection. All data must be accompanied by a signed copy of the certification statement in 40 CFR 260.22(i)(12). Provided that the data demonstrate compliance with the verification standards in Condition 1 of the delisting rule, no further action is required of the Petitioners.

E. What happens if the Petitioners fail to meet the conditions of the exclusion?

If the Petitioners violate the terms and conditions established in the exclusion, the Agency may start procedures to withdraw the exclusion. Additionally, the terms of the exclusion provide that ''[a]ny waste volume for which representative composite sampling does not reflect full compliance with the exclusion criteria in Condition 1 must continue to be managed as hazardous.''

If the verification testing of the waste does not demonstrate compliance with the delisting concentrations described in section IV.C above, or other data (including but not limited to leachate data or groundwater monitoring data from the final land disposal facility) relevant to the delisted waste indicates that any constituent is at a concentration in waste above specified delisting verification concentrations in Table 5, the Petitioners must notify the Agency within 10 days, or such later date as the EPA may agree to in writing, after receiving the final verification testing results from the laboratory or of first possessing or being made aware of other relevant data. The EPA may

require the Petitioners to conduct additional verification sampling to better define the particular volume of wastes within the affected unit that does not fully satisfy delisting criteria. For any volume of wastes for which the corresponding representative sample(s) do not reflect full compliance with delisting exclusion levels, the exclusion by its terms does not apply, and the waste must be managed as hazardous.

The EPA has the authority under RCRA and the Administrative Procedures Act, 5 U.S.C. 551 (1978*) et seq.* to reopen a delisting decision if we receive new information indicating that the conditions of this exclusion have been violated or are otherwise not being met.

F. What must the Petitioners do if the process changes?

Since the wastes that are the subject of this proposed de-listing already exist and are not expected to change as part of closure process for each of the units where the wastes are currently stored, there are no proposed requirements addressing process changes.

V. When would the EPA finalize the proposed delisting exclusion?

HSWA specifically requires the EPA to provide notice and an opportunity for comment before granting or denying a final exclusion. Thus, EPA will not make a final decision or grant an exclusion until it has addressed all timely public comments on today's proposal, including any at public hearings. Upon receipt and consideration of all comments, EPA will publish its final determination as a final rule. Since this rule would reduce the existing requirements for persons generating hazardous wastes, the regulated community does not need a six-month period to come into compliance in accordance with § 3010 of RCRA as amended by HSWA.

VI. How would this action affect the states?

Because the EPA is proposing to issue this exclusion under the federal RCRA delisting regulations, only states subject to federal RCRA delisting provisions will be affected. This exclusion may not be effective in states which have received authorization from the EPA to make their own delisting decisions.

RCRA allows states to impose more stringent regulatory requirements than RCRA's under § 3009 of RCRA. These more stringent requirements may include a provision that prohibits a federally issued exclusion from taking effect in the state. We urge petitioners to contact the state regulatory authority to establish the status of their wastes under the state law.

The EPA has also authorized some states to administer a delisting program in place of the federal program, that is, to make state delisting decisions. Therefore, this exclusion does not apply in those states. If the Petitioners manage the wastes in any state with delisting authorization, the Petitioners must obtain delisting authorization or other determination from the receiving state before it can manage the waste as nonhazardous in that state.

While Washington State has received final authorization to implement most of its dangerous waste program regulations in lieu of the federal program, including the listing and identification of U019 and U220 wastes (See 51 **Federal Register** 3782), it has not been authorized to implement its delisting regulations program in lieu of the federal program. The EPA notes that Washington State has provisions in the Washington Administrative Code (WAC) 173–303–910(3) similar to the federal provisions upon which this delisting is based. These provisions are in effect as a matter of state law. Thus, the Petitioners must seek de-listing approval from Washington State in addition to this proposed delisting for this delisting to be effective as a matter of state law in Washington. In the absence of approval from Washington, the wastes proposed for de-listing by EPA in this action will continue to be regulated as ''dangerous waste'' under state law.

VII. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *http://www2.epa.gov/laws-regulations/laws-and-executive-orders.*

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

This proposed action is exempt from review by the Office of Management and Budget because it is a rule of particular applicability, not general applicability. The proposed action approves a delisting petition under RCRA for the petitioned waste at a particular facility.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This proposed action is not an Executive Order 13771 regulatory action because actions such as approval of delisting petitions under RCRA are exempted under Executive Order 12866.

C. Paperwork Reduction Act

This proposed action does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) because it only applies to a particular facility.

D. Regulatory Flexibility Act

Because this rule is of particular applicability relating to a particular facility, it is not subject to the regulatory flexibility provision of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

E. Unfunded Mandates Reform Act

This proposed action does not contain any unfunded mandate as described in the Unfunded Mandates Reform Act (2 U.S.C. 1531–1538) and does not significantly or uniquely affect small governments. The action imposes no new enforceable duty on any state, local, or tribal governments or the private sector.

F. Executive Order 13132: Federalism

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

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

This proposed action does not have tribal implications as specified in Executive Order 13175. This proposed action applies only to a particular facility on non-tribal land. Thus, Executive Order 13175 does not apply to this action.

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

This proposed action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because the EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This proposed action's health and risk assessments using the Agency's Delisting Risk Assessment Software (DRAS), which considers health and safety risks to children, are described in section III.E above. The technical support document and the user's guide for DRAS are included in the docket.

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

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

J. National Technology Transfer and Advancement Act

This proposed action does not involve technical standards as described by the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note).

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

The EPA believes that this proposed action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations, and/or indigenous peoples. The EPA has determined that this proposed action will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or the environment. The Agency's risk assessment, as described in section III.E above, did not identify risks from management of this material in an authorized, solid waste landfill (*e.g.,* RCRA Subtitle D landfill, commercial/industrial solid waste landfill, etc.). Therefore, the EPA believes that any populations in proximity of the landfills used by this facility should not be adversely affected by common waste management practices for this delisted waste.

L. Congressional Review Act

This proposed action is exempt from the Congressional Review Act (5 U.S.C. 801 *et seq.*) because it is a rule of particular applicability.

List of Subjects in 40 CFR Part 261

Environmental protection, Hazardous waste, Recycling, and Reporting and recordkeeping requirements.

Dated: October 11, 2019.

Timothy B. Hamlin,

Director, Land, Chemicals and Redevelopment Division.

For the reasons set out in the preamble, the EPA proposes to amend 40 CFR part 261 as follows:

PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

■ 1. The authority citation for part 261 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, 6922, 6924(y) and 6938.

■ 2. Amend Table 1 of Appendix IX to Part 261 by adding the following waste stream entry ''Emerald Kalama Chemical, LLC and Fire Mountain Farms, Inc'' in alphabetical order to read as follows:

Appendix IX to Part 261—Wastes Excluded Under §§ 260.20 and 260.22.

TABLE 1—WASTES EXCLUDED FROM NON-SPECIFIC SOURCES

Facility	Address	Waste description
*	*	* * * * *
Emerald Kalama Chemical, LLC and Fire Mountain Farms, Inc.	Lewis County, Washington.	Mixtures of hazardous wastewater treatment sludges, U019 (benzene) and U220 (toluene) and other non-hazardous solid wastes to be removed by Emerald Kalama Chemical, LLC and Fire Mountain Farms, Inc (Petitioners) pursuant to closure plans approved by the Washington State Department of Ecology and currently in storage in Fire Mountain Farm's Burnt Ridge, Newaukum Prarie and Big Hanford facilities in Lewis County, Washington. The maximum amount of wastes that may be managed pursuant to this exclusion is 4,700 cubic yards at the Burnt Ridge facility, 10,400 cubic yards at the Newaukum Prairie facility, and 5,000 cubic yards at the Big Hanaford facility, present at each facility as of the effective date of this exclusion, subject to the conditions below. Wastes managed under this exclusion must be disposed of in a Subtitle D landfill which is licensed, permitted, or otherwise authorized by a state to accept the delisted mixed material. The exclusion becomes effective as of [[the date of final publication].]. 1. Delisting Levels: The constituent concentrations in a representative sample of the waste must not exceed the following levels. For each constituent, the delisting verification level is provided for Burnt Ridge, Newaukum Prarie and Big Hanaford, respectively. Total concentrations (mg/kg): Cobalt—94,400, 49,100, 89,900; TCLP Concentrations (mg/l in the waste extract): Barium—1,090, 498, 1,030; Cobalt—6.28, 2.92, 5.92; Copper—716, 332, 674; Nickel—408, 184, 384; Zinc—6,170, 2,820, 5,800; Benzaldehyde—1,760, 809, 1,660; Benzene—2.35, 1.08, 2.21; Benzoic Acid—70,400, 32,400, 66,300; Formic Acid—1,130, 519, 1,060; Benzyl Alcohol—8,800, 4,040, 8,290; Methanol—8,800, 4,040, 8,290; Phenol—5,280, 2,430, 4,970; Toluene—460, 211, 433.

TABLE 1—WASTES EXCLUDED FROM NON-SPECIFIC SOURCES—Continued

Facility	Address	Waste description
		2. Verification Testing: To verify that the waste does not exceed the delisting concentrations specified in Condition 1, the Petitioners must collect and analyze an extract using EPA SW–846 Method 1311 (TCLP extraction) from three representative composite samples for barium, benzaldehyde, benzoic acid, formic acid, and benzyl alcohol of the mixed IWBS/treatment solids wastes from each FMF facility prior to the start of closure activities to demonstrate that the constituents of concern in the petitioned waste do not exceed the concentrations of concern in Condition 1. If results from analysis of any composite sample do not reflect compliance with delisting exclusion limits, the EPA may require the Petitioners to conduct additional verification sampling to better define the volume of waste with waste constituent concentrations exceeding the delisting exclusion limits. The Petitioners must conduct all verification sampling according to a written sampling plan and associated quality assurance project plan which is approved in advance by the EPA that ensures analytical data are suitable for their intended use. Sampling data must be submitted to the EPA no later than 10 days after receiving the final results from the laboratory, or such later date as the EPA may agree to in writing. Any waste volume for which representative composite sampling does not reflect full compliance with the exclusion criteria in Condition 1 must continue to be managed as hazardous. The Petitioners must also submit to EPA a certification that all wastes satisfying the delisting concentrations in Condition 1 have been disposed of in a Subtitle D landfill which is licensed, permitted, or otherwise authorized by a state to accept the delisted mixed material of wastewater treatment sludge, and the quantity of waste disposed from each facility. This submission must be submitted to EPA within 60 days of completion of closure according to the approved closure plan. 3. Data Submittals: The Petitioners must submit the data obtained through verification testing and as required by other conditions of this rule, to the Director, Land, Chemical, & Redevelopment Division, U.S. EPA Region 10, 1200 6th Avenue Suite 155, M/S 15–H04, Seattle, Washington, 98070 or his or her equivalent. Electronic submission via electronic mail, physical electronic media (*e.g.,* USB flash drive), or an electronic file transfer system is acceptable. The Petitioners must compile, summarize, and maintain for a minimum of five years, records of analytical data and waste disposal required by this rule. The Petitioners must make these records available for inspection. All data must be accompanied by a signed copy of the certification statement in 40 CFR 260.22(i)(12). If the Petitioners fail to submit the required data within the specified time or maintain the required records for the specified time, the EPA may, at its discretion, consider such failure a sufficient basis to reopen the exclusion as described in Condition 4. 4. Reopener Language: (A) If, any time after disposal of the delisted waste, the Petitioners possess or are otherwise made aware of any data, including but not limited to leachate data or groundwater monitoring data from the final land disposal facility, relevant to the delisted waste indicating that any constituent is at a higher than the specified delisting concentration, then the Petitioners must report such data, in writing, to the Director, Land, Chemical, & Redevelopment Division, EPA Region 10 at the address above, or his or her equivalent, within 10 days of first possessing or being made aware of those data. (B) Based on the information described in Condition 4(A) and any other information received from any source, the EPA will make a preliminary determination as to whether the reported information requires Agency action to protect human health or the environment. Further action may include suspending, or revoking the exclusion, or other appropriate response necessary to protect human health and the environment. (C) If the EPA determines that the reported information does require Agency action, the EPA will notify the Petitioners in writing of the actions it believes are necessary to protect human health and the environment. The notice shall include a statement of the proposed action and a statement providing the Petitioners with an opportunity to present information as to why the proposed Agency action is not necessary or to suggest an alternative action. The Petitioners shall have 30 days from the date of the EPA's notice to present the information. (D) If after 30 days the Petitioners present no further information or after a review of any submitted information, the EPA will issue a final written determination describing the Agency actions that are necessary to protect human health or the environment. Any required action described in the EPA's determination shall become effective immediately unless the EPA provides otherwise.
*	*	* * * * *

[FR Doc. 2019–23830 Filed 11–8–19; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Chapter I

[EPA–HQ–OPPT–2019–0490; FRL–10001–34]

TSCA Section 21 Petition To Prohibit the Use of Hydrofluoric Acid at Oil Refineries; Reasons for Agency Response

AGENCY: Environmental Protection Agency (EPA).

ACTION: Petition for rulemaking; denial.

SUMMARY: This document announces the availability of EPA's response to an August 7, 2019 petition it received under section 21 of the Toxic Substances Control Act (TSCA) from Public Employees for Environmental Responsibility (PEER). PEER petitioned EPA to prohibit the use of hydrofluoric acid in manufacturing processes at oil refineries under TSCA section 6(a) and require a phase-out of use at such facilities within two years. After careful consideration, EPA has denied the TSCA section 21 petition for the reasons discussed in this document.

DATES: EPA's response to this TSCA section 21 petition was signed November 4, 2019.

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Robert Courtnage, National Program Chemicals Division, Mailcode 7404T, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: 202–566–1081, email address: *courtnage.robert@epa.gov*.

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general. This action may, however, be of interest to those persons who are using or may use hydrofluoric acid in manufacturing processes at oil refineries. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. How can I access information about this petition?

The docket for this TSCA section 21 petition, identified by docket identification (ID) number EPA–HQ–OPPT–2019–0490, is available at *http://www.regulations.gov* or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

II. TSCA Section 21

A. What is a TSCA section 21 petition?

Under TSCA section 21 (15 U.S.C. 2620), any person can petition EPA to initiate a rulemaking proceeding for the issuance, amendment, or repeal of a rule under TSCA sections 4, 6 or 8, or an order under TSCA sections 4, 5(e) or 5(f). A TSCA section 21 petition must set forth the facts that are claimed to establish the necessity for the action requested. EPA is required to grant or deny the petition within 90 days of its filing. If EPA grants the petition, the Agency must promptly commence an appropriate proceeding. If EPA denies the petition, the Agency must publish its reasons for the denial in the **Federal Register**. A petitioner may commence a civil action in a U.S. district court to compel initiation of the requested rulemaking proceeding within 60 days of either a denial or, if EPA does not issue a decision, within 60 days of the expiration of the 90-day period.

B. What criteria apply to a decision on a TSCA section 21 petition?

Section 21(b)(1) of TSCA requires that the petition ''set forth the facts which it is claimed establish that it is necessary to issue, amend, or repeal a rule.'' 15 U.S.C. 2620(b)(1). Thus, TSCA section 21 implicitly incorporates the statutory standards that apply to the requested actions. In addition, TSCA section 21(b)(4)(B) establishes standards a court must use to decide whether to order EPA to initiate rulemaking in the event of a lawsuit filed by the petitioner. 15 U.S.C. 2620(b)(4)(B). TSCA sections 6(b) and 26 contain substantive legal and scientific requirements for making a risk determination under section 21(b)(4)(B)(ii) in the case of a proceeding for the issuance of a TSCA section 6(a) rule. Accordingly, EPA has relied on the standards in TSCA sections 26 and 6 to evaluate this TSCA section 21 petition and issue its decision to deny it.

III. Summary of the TSCA Section 21 Petition

A. What action was requested?

On August 7, 2019, PEER petitioned EPA under TSCA section 21 to promulgate regulations pursuant to TSCA section 6(a), and under the Administrative Procedure Act (APA) to take the same action pursuant to section 112 of the Clean Air Act (CAA). PEER petitioned EPA to prohibit the use of hydrofluoric acid in manufacturing processes at oil refineries and require oil refineries to phase out the use of hydrofluoric acid within two years. This **Federal Register** notice specifically addresses PEER's TSCA section 21 petition, not the petition under the APA.

B. What support does the petitioner offer?

PEER requests that EPA promulgate a TSCA section 6(a) rule, asserting that: (1) Hydrofluoric acid is inherently dangerous; (2) the potential for industrial accidents presents too great a risk; (3) there is the potential for terrorist attacks targeting chemical plants, including refineries; and (4) there are safer alternatives to hydrofluoric acid for use at oil refineries. In its petition, PEER provides information from the National Institute of Occupational Safety and Health on the hazardous properties of hydrofluoric acid and the significant hazard posed if released accidentally.

PEER cites events in Torrance, California, South Korea, and Philadelphia to support concerns that additives may be ineffective in reducing cloud formation or addressing the potential for dangerous concentrations of hydrofluoric acid to persist miles away from the refinery. In the Torrance case, a valve failure unrelated to hydrofluoric acid caused an explosion and a projectile landed near tanks containing hydrofluoric acid; however, no injuries were reported, and no hydrofluoric acid was released. In the South Korea case, worker error led to an escape of gaseous hydrofluoric acid. Five worker deaths resulted, as well as many injuries to first responders. In this case, however, there was an unawareness of hydrofluoric acid being present and proper personal protective equipment was not worn, due to a

difference in standards for how hydrofluoric acid is used in South Korea.

The most recent incident PEER referenced was a fire at a refinery in Philadelphia in June 2019. Although 5,000 pounds of hydrofluoric acid were released due to equipment failure unrelated to hydrofluoric acid, there were no deaths and only minor injuries (Ref. 1). A second fire in a Richmond, California, refinery in 2012 is also referenced by PEER as a near-miss.

PEER states that a prohibition on use of hydrofluoric acid at refineries is warranted because there are safer alternatives that can be readily substituted (Ref. 1). The petition offers minimal information about these alternatives; it briefly mentions two options: Solid acid catalyst alkylation, and ionic liquid alkylation, both of which use non-hazardous chemicals (Ref. 1). However, PEER presents limited information about these alternatives.

C. Background

Hydrofluoric acid is a solution of hydrogen fluoride in water and a precursor to fluorine compounds. In oil refineries, hydrofluoric acid is used as a catalyst in a process called alkylation. Due to its hazard properties, hydrofluoric acid is regulated by the federal government under several authorities, including related to preparation for emergency response to accidental and other nonroutine releases. The authorities include the Superfund Amendments and Reauthorization Act, the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, the Emergency Planning and Community Right-to-Know Act, the Resource Conservation and Recovery Act and the CAA, which are all under the EPA's jurisdiction. Hydrofluoric acid is also regulated under the Hazardous Materials Transportation Act under the jurisdiction of the Department of Transportation. As PEER acknowledges, hydrofluoric acid is regulated under the Chemical Accident Prevention Provisions, 40 CFR part 68 (commonly referred to as the Risk Management Plan (RMP) rule pursuant to CAA section 112(r), (42 U.S.C. 7412(r)). The RMP rule requires facilities that have certain extremely hazardous substances, such as hydrofluoric acid, above a threshold quantity, to develop a risk management program that identifies the potential effects of a chemical accident, and steps the facility is taking to prevent an accident and spells out emergency response procedures should an accident occur. The RMP rule also requires facilities to report to EPA a summary of the actions described in an RMP. In addition to the RMP rule, the General Duty Clause under CAA section 112(r)(1) requires facilities to identify hazards present from accidental releases of extremely hazardous substances such as hydrofluoric acid, design and maintain a safe facility, and minimize the consequences of accidental releases.

There are also several Occupational Safety and Health Administration (OSHA) health and safety standards that employers must follow that apply to hydrogen fluoride, including implementing a process safety management program under 29 CFR 1910.119; determining the appropriate level of employee respiratory protection under 29 CFR 1910.134; implementing a hazard communication program under 29 CFR 1910.120, implementing a program of engineering controls, work practices and personal protective equipment to control exposure under 29 CFR 1910.132 and 1910.1000); and developing and implementing an emergency response plan, including emergency procedures and training of personnel under 29 CFR 1910.120 and 1910.38.

The Department of Homeland Security's Cybersecurity and Infrastructure Security Agency (CISA), through the Chemical Facility Anti-Terrorism Standards (CFATS) program, requires facilities that use chemicals of interest (COI) such as hydrofluoric acid to report to CISA when a threshold of the COI is reached. Based on the assessed risk, CISA determines whether the facility is a high-risk facility and is then ranked into Tiers 1, 2, 3, and 4, with Tier 1 being the highest risk. If a facility is tiered, it must submit a Security Vulnerability Assessment (SVA) and a Site Security Plan (SSP)—or an Alternative Security Program (ASP)—that meets the risk-based performance standards (RBPS). More information is available at *https://www.dhs.gov/cisa/risk-based-performance-standards-rbps.* Among other things the RBPS address are security issues such as perimeter security, access control, personnel security, and cybersecurity.

IV. Disposition of TSCA Section 21 Petition

EPA is denying the petition based on the petition's lack of sufficient facts establishing that it is necessary for the Agency to issue a rule under TSCA section 6(a).

TSCA section 21 requires EPA to respond to a petition within 90 days of filing of the petition. If that petition requests a TSCA section 6(a) rulemaking and EPA grants that petition, TSCA section 21 requires EPA to promptly commence an appropriate proceeding under TSCA section 6. To grant a petition for a TSCA section 6(a) rulemaking, a petition would need to provide the facts establishing that the requested rulemaking is necessary. *See, e.g., Trumpeter Swan Soc.* v. *EPA,* 774 F.3d 1037, 1040 (D.C. Cir. 2014) (explaining that TSCA section 21 requires that a petition ''set forth facts establishing the need for the requested rule''). Those facts would need to be sufficiently clear and robust for EPA to be able to conclude, within 90 days of filing the petition, that the chemical presents an unreasonable risk of injury to health or the environment and that issuance of a TSCA section 6(a) rule is the appropriate response to the petition. To make the threshold finding, EPA would need hazard and exposure data and other information that enables the Agency to assess risk and conclude whether the risk is unreasonable. In the absence of that information, EPA would need additional factual information to make a determination, which would require a denial and resubmittal by petitioners. Petitioners should look to and utilize the congressionally mandated, and EPA issued, ''Guidance to Assist Interested Persons in Developing and Submitting Draft Risk Evaluations Under the Toxic Substances Control Act.'' (EPA 740–R17–001, June 22, 2017) *See* TSCA section 26(l)(5). This guidance document sets forth the ''quality of the information submitted and the process to be followed in developing draft risk evaluations.'' *Id.*

The petition would need to include, for example, some analysis of the methods used to identify the data or information submitted or used, hazard thresholds recommended or chosen, and exposure estimates and patterns contemplated or addressed. This factual information is necessary for EPA to be able to determine whether there is an unreasonable risk of injury to health or the environment, consistent with the best available science, based on the weight-of-the-scientific-evidence, and taking into account reasonably available information, as required by TSCA sections 26(h), (i) and (k), respectively. The petition would also need to include other factual information necessary to address whether or why the requested TSCA section 6(a) rule is the appropriate response to the petition. These are critical threshold requirements applicable to a finding of unreasonable risk and a determination that TSCA section 6(a) rulemaking is

necessary. A petition without such information is facially incomplete because it fails to provide minimum factual information for EPA to make the threshold findings needed to respond to and act on the petition as contemplated by TSCA section 21.

In this case, PEER's petition refers to hazard databases and makes conclusory statements of toxicity but provides little further information that would support granting a TSCA section 6(a) rulemaking request. The petition lacks analysis that would be expected in a TSCA risk evaluation preceding a section 6(a) rulemaking. For example, there is no discussion of the appropriate hazard threshold, exposure estimates, assessment of risks, or how the facts presented allow EPA to comply with its duties under section 26 or other statutory requirements in making an unreasonable risk determination. Absent such minimal factual information, EPA cannot make the threshold determinations necessary to substantively assess and grant a petition for a TSCA section 6(a) rulemaking. As a result, EPA denies PEER's petition request as facially incomplete.

V. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

Whitehouse, Timothy, Public Employees for Environmental Responsibility (PEER) to the Administrator of the Environmental Protection Agency. Re: Ban on Hydrofluoric Acid in Refineries: Petition for Rulemaking. Received August 7, 2019.

List of Subjects in 40 CFR Chapter I

Environmental protection, Hydrofluoric Acid, Oil Refineries, Chemicals, Hazardous substances, Prohibition on Chemicals.

Dated: November 4, 2019.

Alexandra Dapolito Dunn,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2019–24406 Filed 11–8–19; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 207, 212, 215, 227, and 252

[Docket DARS–2019–0064]

RIN 0750–AK79

Defense Federal Acquisition Regulation Supplement: Negotiation of Price for Technical Data and Preference for Specially Negotiated Licenses (DFARS Case 2018–D071)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Advance notice of proposed rulemaking.

SUMMARY: DoD is seeking information that will assist in the development of a revision to the Defense Federal Acquisition Regulation Supplement to implement sections of the National Defense Authorization Acts for Fiscal Years 2018 and 2019. In brief, for DoD only, those provisions provide for the negotiation of a price for technical data to be delivered under contracts for the engineering and manufacturing development, production, or sustainment of a major weapon system; and a preference for specially negotiated licenses for customized technical data to support the product support strategy of a major weapon system or subsystem thereof.

DATES: Interested parties should submit written comments to the address shown below on or before January 13, 2020, to be considered in the formation of any proposed rule.

DoD is also hosting public meetings to obtain the views of interested parties in accordance with the notice published in the **Federal Register** on August 16, 2019, at 84 FR 41953.

ADDRESSES: Submit written comments identified by DFARS Case 2018–D071, using any of the following methods:

○ *Federal eRulemaking Portal: http://www.regulations.gov.* Search for ''DFARS Case 2018–D071.'' Select ''Comment Now'' and follow the instructions provided to submit a comment. Please include ''DFARS Case 2018–D071'' on any attached documents.

○ *Email: osd.dfars@mail.mil.* Include DFARS Case 2018–D071 in the subject line of the message.

○ *Fax:* 571–372–6094.

○ *Mail:* Defense Acquisition Regulations System, Attn: Ms. Jennifer D. Johnson, OUSD(A–S)DPC/DARS, Room 3B941, 3060 Defense Pentagon, Washington, DC 20301–3060.

Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Ms. Jennifer D. Johnson, telephone 571–372–6100.

SUPPLEMENTARY INFORMATION:

I. Background

DoD is seeking information from the public, particularly experts and interested parties in Government and the private sector, that will assist in the development of a revision to the Defense Acquisition Regulation Supplement (DFARS) to implement section 835 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2018 (Pub. L. 115–91) and section 867 of the NDAA for FY 2019 (Pub. L. 115–232). Both sections are for DoD only; they do not impact other Federal agencies. Section 835 enacted a new provision into permanent law (10 U.S.C. 2439) and added a new subsection (f) to 10 U.S.C. 2320. Section 867 expanded the scope of 10 U.S.C. 2439. As a result, 10 U.S.C. 2439 now requires that the Secretary of Defense ensure, to the maximum extent practicable, that DoD, before selecting a contractor for the engineering and manufacturing development of a major weapon system, production of a major weapon system, or sustainment of a major weapon system, negotiates a price for technical data to be delivered under a contract for such development, production, or sustainment. 10 U.S.C. 2320(f) now provides for a preference for specially negotiated licenses for customized technical data to support the product support strategy of a major weapon system or subsystem of a major weapon system.

II. Discussion and Analysis

An initial draft of the proposed revisions to the DFARS to implement section 835 of the NDAA for FY 2018 and section 867 of the NDAA for FY 2019 is available in the Federal eRulemaking Portal at *http://www.regulations.gov,* by searching for ''DFARS Case 2018–D071'', selecting ''Open Docket Folder'' for RIN 0750–AK79, and viewing the ''Supporting Documents''. The strawman is also available at *https://www.acq.osd.mil/*

dpap/dars/change_notices.html under the publication notice for November 12, 2019, and DFARS Case 2018–D071. The following is a summary of DoD's proposed approach and the feedback DoD is seeking from industry and the public.

A. Negotiation of Price for Technical Data (10 U.S.C. 2439)

DoD is considering revising the DFARS to require the contracting officer to negotiate a price for data (including technical data and computer software) and associated license rights to be delivered or otherwise provided under a contract for services or for the development, production, or sustainment of a system, subsystem, or component. The contracting officer would be required to negotiate this price to the maximum extent practicable and before making a source selection decision or awarding a sole-source contract. Currently, the DFARS does not require the contracting officer to negotiate a price for data and associated license rights before the source selection decision or award of a sole-source contract. Prices for data and associated license rights are often negotiated after contract award.

The primary proposed change regarding mandatory negotiation of prices for data is found in proposed DFARS 215.470(a). The primary proposed change seeks to apply the new statutory requirement of 10 U.S.C. 2439 in a manner that is consistent with the implementation of other statutory requirements (*e.g.,* 10 U.S.C. 2320–2321) related to data (including technical data and computer software) and associated license rights (*e.g.,* rights to use technical data to repair damage to a system). DoD's intent is to foster consistency in treatment amongst contracts awarded by DoD that require the delivery of data (including technical data and computer software) and associated license rights. The change would clarify that price negotiations must occur whether or not the resulting contract is competed. Although 10 U.S.C. 2439 requires negotiation of prices for data for major weapon systems, the regulatory coverage would include commercial technical data, noncommercial technical data, and computer software (and associated license rights), consistent with the manner in which DoD has implemented 10 U.S.C. 2320–2321 in the DFARS over the past 24 years. Current DoD policy is to acquire needed technical data and computer software and associated license rights under contracts for the acquisition of supplies, services, and business systems. Accordingly, the primary proposed change would extend the scope of regulatory coverage to encompass contracts other than those for engineering and manufacturing development, production, or sustainment (including services contracts).

The House Armed Services Committee report accompanying the provision of the NDAA Bill that became section 835 of the NDAA for FY 2018 ''urge[d] program managers when seeking technical data to consider the particular data that is required, the level of detail necessary, the purpose for which it will be used, with whom the government needs to share it, and for how long the government needs it.'' H.Rep. No. 115–200, at 165 (2017). Thus, Congress intended that a DoD contract must require the contractor to:

- Deliver or otherwise provide (*i.e.,* make available to the Government) technical data and computer software; *and*
- Grant license rights to that technical data and computer software.

Accordingly, to foster consistency in treatment, the proposed DFARS 215.470(a) would require that contracting officers negotiate a fair and reasonable price for all data (including technical data and computer software) *and* associated license rights to be delivered or otherwise provided under a DoD contract for services or for the development, production, or sustainment of a system, subsystem, or component. The requirement for price negotiation would not be limited to technical data to be delivered under a DoD contract for the engineering and manufacturing development, production, or sustainment of, a major weapon system.

The proposed DFARS 215.470(a) also seeks to address the concerns identified in Tension Point Papers 1, 4, and 5 of the Final Report of the Government-Industry Advisory Panel on Technical Data Rights (Section 813 Panel) submitted to the Congressional Defense Committees in mid-November 2018 pursuant to section 813(b) of the NDAA for FY 2016 (Pub. L. 114–92), as amended by section 809 of the NDAA for FY 2017 (Pub. L. 114–328). In brief, those Tension Point Papers state that offerors should provide in their proposals a detailed discussion of their intellectual property (IP) evaluation techniques and assumptions, and that contracting officers should be required to consider commercial IP valuation practices and standards when determining a fair and reasonable price for the requested IP.

The three valuation practices and standards traditionally used by commercial entities to calculate the value of IP for transactional and litigation purposes are the market method, the cost method, and the income method. The market method consists of a comparison of proposed prices to other prices for similar IP, for example, a comparison of proposed prices to historical prices paid. The cost method involves a review and evaluation of the separate cost elements and profit or fee that make up the proposed prices. The income method considers the income a contractor's IP could generate in the future and the costs of generating that income, *i.e.,* the economic benefit of the IP to the contractor.

Currently, contracting officers must comply with existing regulations at Federal Acquisition Regulation (FAR) 15.404–1, DFARS 212.209, and DFARS 215.404–1, which require contracting officers to use the market method first, followed by the cost method if it is not feasible to use the market method. The proposed DFARS 215.470(a) directs contracting officers to consult FAR 15.404–1, DFARS 212.209, and DFARS 215.404–1 when negotiating a fair and reasonable price for all data (including technical data and computer software) and associated license rights, delivered or otherwise provided under a DoD contract. Although nothing prohibits the contracting officer from using the income method, use of the income method is not discussed in the DFARS.

B. Preference for Specially Negotiated License Rights (10 U.S.C. 2320(f))

New paragraph (f) of 10 U.S.C. 2320 establishes a preference for specially negotiated license rights (SNLR) through two new requirements, both of which relate to and require revisions to existing DFARS coverage. The DFARS currently authorizes, but does not express a preference for, the use of SNLR.

First, new 10 U.S.C. 2320(f) requires that the assessments and planning for a program's long-term needs for technical data for sustainment (required by 10 U.S.C. 2320(e)) must now include consideration of the use of specially negotiated licenses for customized technical data that supports DoD's strategy for sustainment of the major weapon system or subsystem being purchased. The underlying requirement to assess and plan for long-term technical data needs is implemented at DFARS 207.106(S–70), which applies to the program's needs for computer software and associated license rights, as well as data for major weapon systems and subsystems. Accordingly, the new requirements of 2320(f) are

proposed to be implemented in a similar manner. Specifically, the new 10 U.S.C. 2320(f) requirement is proposed for insertion as new DFARS 207.106(S–70)(2)(ii), with existing paragraphs (ii)–(iv) renumbered accordingly.

Second, new 10 U.S.C. 2320(f) requires that, to the maximum extent practicable, programs for major weapon systems or subsystems thereof shall use specially negotiated licenses for technical data to support DoD's strategy for sustainment of the systems or subsystems. While the current DFARS coverage does not include a preference for specially negotiated licenses, the DFARS authorizes the use of SNLR for all types of technical data and computer software, both noncommercial and commercial. The current DFARS enables the parties to enter into special licenses only by voluntary mutual agreement, and reinforces that any rights granted to the Government must be enumerated in an agreement that is incorporated into the contract. The DFARS currently identifies the minimum license rights that the Government is authorized to accept. For example, DFARS 227.7103–5, Government rights, specifies that, when negotiating specific license rights for technical data, the Government may not accept less than limited rights.

The proposed approach for implementing the new statutory preference for SNLR is to incorporate an appropriate statement of preference into the existing DFARS sections and clauses that already authorize and address, but do not currently express a preference for, SNLR. This implementation requires consideration of how a ''preference'' for SNLR can be integrated appropriately into the current regulatory structure that allows for SNLR on the basis of voluntary, mutual agreement. The proposed approach expresses a preference for use of SNLR ''whenever doing so will more equitably address the parties' interests than the standard license rights'' provided in the applicable clause or allocation of rights. However, to ensure that SNLR are not merely authorized and encouraged, but are required to be considered, the approach also includes an affirmative requirement that, to the maximum extent practicable, the parties must enter into good faith negotiations whenever *either party* desires a special license. Thus, it is only in the case when neither party desires a special license agreement (*e.g.,* because neither party anticipates doing so would more equitably address the parties' relative interests), that the parties are not required to negotiate.

The proposed approach also maintains the existing DFARS coverage, which reinforces that neither party can be forced to relinquish its standard license rights. Additionally, the proposed approach retains the DFARS statement of mandatory minimum license rights, as applicable (*e.g.,* currently there is no required minimum license for commercial computer software or commercial computer software documentation). The approach includes the requirement from 10 U.S.C. 2320(f) that the special license must support the program's strategy for sustainment of the major weapon system or subsystem being purchased. The proposed approach also states that DoD may still challenge the basis for a contractor's assertions upon which a special license is based. DoD may challenge a contractor's assertions pursuant to DFARS 252.227–7019, Validation of Asserted Restrictions–Computer Software, and 252.227–7037, Validation of Restrictive Markings on Technical Data, as applicable. Finally, the approach also seeks to standardize the nomenclature for such negotiated licenses using variations of the term ''special'' (*e.g.,* special license, specially negotiated license rights), rather than the term ''specifically,'' which is used inconsistently in the current DFARS.

This proposed implementation resulted in revisions to the existing DFARS coverage regarding SNLR for all forms of technical data and computer software, as follows:

(1) For commercial technical data, at 227.7102–2(b) and the associated clause at 252.227–7015(c).

(2) For noncommercial technical data, at 227.7103–5, and –5(d), and the associated clause at 252.227–7013(b)(4).

(3) For commercial computer software, at 227.7202–3(b) (for which there is no associated clause).

(4) For noncommercial computer software, at 227.7203–5, and –5(d), and the associated clause at 252.227–7014(b)(4).

(5) For the Small Business Innovation Research (SBIR) Program, at new 227.7104(d), and associated clause at 252.227–7018(b)(5).

Note that in the case of the SBIR Program, the proposed revisions limit the preference and authorization to negotiate special license agreements to be only after contract award, in accordance with section 8, paragraph 6, of the SBIR Program and Small Business Technology Transfer Program Policy Directive, published in the **Federal Register** on April 2, 2019, (84 FR 12794), and which became effective on May 2, 2019.

C. Seeking Public Comment on Additional Topics

In addition to seeking public comment on the substance of the draft DFARS revisions, DoD is also seeking information regarding any corresponding change in the burden, including associated costs or savings, resulting from contractors and subcontractors complying with the draft revised DFARS implementation. More specifically, DoD is seeking information regarding any anticipated increase or decrease in such burden and costs relative to the burden and costs associated with complying with the current DFARS implementing language.

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 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). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is a significant regulatory action and, therefore, was subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. Executive Order 13771

This Advance Notice of Proposed Rulemaking is not subject to E.O. 13771.

List of Subjects in 48 CFR Parts 207, 212, 215, 227, and 252

Government procurement.

Jennifer Lee Hawes,

Regulatory Control Officer, Defense Acquisition Regulations System.

[FR Doc. 2019–24585 Filed 11–8–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

49 CFR Part 396

[Docket No. FMCSA–2019–0075]

RIN 2126–AC29

Passenger Carrier No-Defect Driver Vehicle Inspection Reports

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: FMCSA proposes to rescind the requirement that drivers of passenger-carrying commercial motor vehicles (CMVs) operating in interstate commerce, submit, and motor carriers retain, driver-vehicle inspection reports (DVIRs) when the driver has neither found nor been made aware of any vehicle defects or deficiencies (no-defect DVIRs). This proposed rule would remove an information collection burden without adversely impacting safety.

DATES: You must submit comments on or before January 13, 2020. Comments sent to the Office of Information and Regulatory Affairs (OIRA) at the Office of Management and Budget (OMB) on the collection of information must be received by OMB on or before January 13, 2020.

ADDRESSES: You may submit comments identified by docket number FMCSA–2019–0075 using any one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.*
- *Fax:* (202) 493–2251.
- *Mail:* Docket Operations (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.
- *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays.

To avoid duplication, please use only one of these four methods. See the ''Public Participation and Request for Comments'' heading under the **SUPPLEMENTARY INFORMATION** section for instructions on submitting comments, including information collection comments for OIRA at OMB.

FOR FURTHER INFORMATION CONTACT: Mr. Michael Huntley, Chief, Vehicle and Roadside Operations Division, Office of Carrier, Driver & Vehicle Safety Standards, at Federal Motor Carrier Safety Administration 1200 New Jersey Avenue SE, Washington, DC 20590–0001; *Michael.Huntley@dot.gov,* (202) 366–4325. If you have questions on viewing or submitting material to the docket, contact Docket 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 notice of proposed rulemaking (NPRM) (FMCSA–2019–0075), indicate the specific section of this document to which your comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov/#!docketDetail;D=FMCSA-2019-0075,* 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, 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 change this proposed rule based on your comments. FMCSA may issue a final rule at any time after the close of the comment period.

Confidential Business Information

Confidential Business Information (CBI) is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this 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 that constitutes CBI as ''PROPIN'' to indicate it contains proprietary information. FMCSA 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 Mr. Brian Dahlin, Chief, Regulatory Analysis Division, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE, Washington DC 20590. Any comments that FMCSA receives which are not specifically designated as CBI will be placed in the public docket for this rulemaking.

B. Viewing Comments and Documents

To view comments, as well as any documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov/#!docketDetail;D=FMCSA-2019-0075* and choose the document to review. If you do not have access to the internet, you may view the docket online by visiting Docket Operations in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

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 *https://www.transportation.gov/privacy.*

D. Waiver of Advance Notice of Proposed Rulemaking

Under 49 U.S.C. 31136(g)(1), 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.[1] As this proposed rule is not likely to result in the promulgation of a major rule, the Agency is not required to issue an ANPRM or to proceed with a negotiated rulemaking.

E. Comments on the Collection of Information

If you have comments on the collection of information discussed in this NPRM, you must also send those comments to the Office of Information and Regulatory Affairs at OMB. To ensure that your comments are received on time, the preferred methods of submission are by email to *oira_submissions@omb.eop.gov* (include docket number ''FMCSA–2019–0075'' and ''Attention: Desk Officer for

[1] A ''major rule'' means any rule that the Administrator of OIRA at OMB finds has resulted in or is likely to result in (a) an annual effect on the economy of $100 million or more; (b) a major increase in costs or prices for consumers, individual industries, Federal agencies, State agencies, local government agencies, or geographic regions; or (c) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets (5 U.S.C. 804(2)).

FMCSA, DOT'' in the subject line of the email) or fax at 202–395–6566. An alternative, though slower, method is by United States mail to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503, ATTN: Desk Officer, FMCSA, DOT. Although comments can be received up to the close of the comment period, comments will be most useful if received by OIRA within 30 days of publication of this NPRM.

II. Executive Summary

Purpose of the Regulatory Action

As part of the Agency's ongoing effort to review existing regulations to evaluate their continued necessity and effectiveness, FMCSA proposes rescinding the requirement that drivers of passenger-carrying CMVs operating in interstate commerce, submit, and motor carriers retain, DVIRs when the driver has neither found nor been made aware of any vehicle defects or deficiencies. This proposed rule would remove an information collection burden without impacting safety adversely.

Benefits and Costs

The proposed rule would affect all passenger carriers currently subject to 49 CFR 396.11. Current regulations require drivers employed by passenger carriers—except drivers for private (nonbusiness) passenger carriers, driveaway-towaway operations, or those operating only one CMV—to report on the DVIR any vehicle defects in need of repair noted or discovered during a driving day. Drivers must submit this report to the employing passenger carrier so that repairs can be made. Regulations currently require drivers of passenger-carrying CMVs to file the DVIR even if there are no vehicle defects to report. Motor carriers are required to maintain the original DVIR, the certification of repairs, and the certification of the driver's review for 3 months from the date the written report was prepared. The proposed rule would eliminate the need for a driver to file, and a motor carrier to maintain, a no-defect DVIR.

The Agency estimates that passenger-carrying CMV drivers spend approximately 2.4 million hours each year completing no-defect DVIRs, and that the proposed rule would result in a cost savings of $74 million per year. There is no discernible safety benefit to this burden.

If finalized, the proposed rulemaking would result in reduced government-imposed costs, and therefore would be a deregulatory action under Executive Order (E.O.) 13771, ''Reducing Regulation and Controlling Regulatory Costs'' (issued January 30, 2017, and published February 3, 2017, at 82 FR 9339). The present value of the cost savings, measured on an infinite time horizon at a 7 percent discount rate, expressed in 2016 dollars, would be $1 billion. On an annualized basis, these cost savings would be $71 million.

III. Legal Basis for the Rulemaking

This proposed rule is based on the authority of the Motor Carrier Act of 1935 (1935 Act) (49 U.S.C. 31502(b)) and the Motor Carrier Safety Act of 1984 (1984 Act) (49 U.S.C. 31136(a)), both of which are broadly discretionary.

The 1935 Act provides that the Secretary of Transportation (Secretary) may prescribe requirements for the following:

- Qualifications and maximum hours of service of employees of, and safety of operation and equipment of, a motor carrier (§ 31502(b)(1)), and
- Qualifications and maximum hours of service of employees of, and standards of equipment of, a motor private carrier, when needed to promote safety of operation (§ 31502(b)(2)).

This rulemaking is based on the Secretary's authority under both § 31502(b)(1) and (2).

The 1984 Act authorizes the Secretary to regulate drivers, motor carriers, and vehicle equipment. Section 31136(a) requires the Secretary to publish regulations on CMV safety. Specifically, the Act sets forth minimum safety standards to ensure that: (1) CMVs are maintained, equipped, loaded, and operated safely (49 U.S.C. 31136(a)(1)); (2) the responsibilities imposed on operators of CMVs do not impair their ability to operate the vehicles safely (49 U.S.C. 31136(a)(2)); (3) the physical condition of CMV operators is adequate to enable them to operate the vehicles safely (49 U.S.C. 31136(a)(3)); and (4) the operation of CMVs does not have a deleterious effect on the physical condition of the operators (49 U.S.C. 31136(a)(4)). Section 32911 of the Moving Ahead for Progress in the 21st Century Act (MAP–21) [Pub. L. 112–141, 126 Stat. 405, 818, July 6, 2012] enacted a fifth requirement, *i.e.,* to ensure that ''(5) an operator of a commercial motor vehicle is not coerced by a motor carrier, shipper, receiver, or transportation intermediary to operate a commercial motor vehicle in violation of a regulation promulgated under this section, or chapter 51 or chapter 313 of this title'' (49 U.S.C. 31136(a)(5)). The 1984 Act grants the Secretary broad power in carrying out motor carrier safety statutes and regulations to ''prescribe recordkeeping and reporting requirements'' and to ''perform other acts the Secretary considers appropriate'' (49 U.S.C. 31133(a)(8) and (10)).

This proposed rule implements, in part, the Administrator's authority under § 31136(a)(1) to ensure that CMVs are maintained, equipped, loaded, and operated safely. The NPRM is also based on the broad recordkeeping and implementation authority of § 31133(a)(8) and (10). This proposed rule addresses only CMV equipment and reporting requirements. It does not address the question whether drivers' responsibilities affect their ability to operate CMVs safely (49 U.S.C. 31136(a)(2)). The provisions of the 1984 Act dealing with the physical condition of drivers (§ 31136(a)(3)–(4)) do not apply. Finally, as to ensuring that operators of CMVs are not coerced by motor carriers, shippers, receivers, or transportation intermediaries to operate a CMV in violation of a regulation, the rule would eliminate only the requirement for drivers of passenger-carrying CMVs to prepare reports when there are no defects or deficiencies; it would keep in place the rule requiring reports when there are defects or deficiencies, as well as the requirement for motor carriers to take appropriate action on receipt of the report when problems with the vehicle are noted. Because the rule would remove a regulatory burden criticized by both drivers and motor carriers (and irrelevant to passenger brokers or tour groups), there is virtually no possibility that the driver of a passenger-carrying CMV would be coerced to violate the rule itself. A passenger carrier may require a driver to continue filing no-defect DVIRs even in the absence of a regulatory requirement, but that would be a condition of employment to perform duties not required by a safety regulation, and would therefore not constitute coercion to violate a safety regulation.

IV. Background

In response to a joint petition for rulemaking submitted by the Ocean Carrier Equipment Management Association and the Institute of International Container Lessors, FMCSA published a final rule on June 12, 2012 (77 FR 34846), eliminating the requirement for drivers operating intermodal equipment (IME) to submit—and intermodal equipment providers to retain—DVIRs when the driver has neither found nor been made aware of any defects in the IME. The Agency estimated that approximately 95 percent of DVIRs for IME do not identify

defects and concluded that requiring DVIRs to be filed only on the roughly 5 percent of IME with defects would focus attention on the IME that needs it—rather than the 95 percent with no defects. FMCSA emphasized that the rule did not change a driver's obligation to assess the condition of IME at the end of a workday to determine whether the IME has defects or deficiencies that could affect operational safety. Although FMCSA removed the requirement for a driver to complete a DVIR if no defects or deficiencies had been discovered by or reported, the driver must still inspect the IME to make this determination and prepare a DVIR if defects or deficiencies are discovered or reported. The Agency stated that it did not believe that implementation of the rule would lead to an increase in safety risk because there are multiple opportunities for IME to be inspected for potential safety defects. FMCSA estimated the time and cost savings associated with the rule due to reduced paperwork burdens to be 1.636 million hours and $54 million dollars annually.

Subsequently, and in response to Executive Order 13563, ''Improving Regulation and Regulatory Review'' (issued January 18, 2011, and published January 21, 2011, at 76 FR 3821), FMCSA published an NPRM on August 7, 2013 (78 FR 48125) that proposed extending the same relief regarding no-defect DVIRs to all interstate motor carriers subject to part 396 of the FMCSRs, except operators of passenger-carrying CMVs. FMCSA published a final rule on December 18, 2014 (79 FR 75437), adopting the changes proposed in the NPRM. As with the June 2012 final rule regarding no-defect DVIRs for IME, FMCSA concluded that the no-defect DVIR requirements impose a substantial time and paperwork burden on the trucking industry with no discernible safety benefit. FMCSA estimated that non-passenger-carrying CMV drivers spend approximately 46.7 million hours each year completing no-defect DVIRs, and estimated that the monetized value of this time was $1.7 billion per year.

V. Discussion of Proposed Rulemaking

The Agency proposes to rescind, for operators of passenger-carrying CMVs, the requirement in 49 CFR 396.11(a)(2) that CMV drivers submit, and motor carriers retain, DVIRs when the driver has neither found nor been made aware of any vehicle defects or deficiencies.

Drivers and motor carriers have long been required to share the safety responsibility for operating CMVs and for assessing the condition of CMVs and documenting deficiencies and repairs. Section 392.7(a) states that ''No commercial motor vehicle shall be driven unless the driver is satisfied that the following parts and accessories are in good working order . . .'' Section 393.1(b)(1) provides that ''[e]very motor carrier and its employee must be knowledgeable of and comply with the requirements and specifications of this part,'' and § 393.1(c) states that ''No motor carrier may operate a commercial motor vehicle, or cause or permit such vehicle to be operated, unless it is equipped in accordance with the requirements and specifications of this part.'' Section 396.3(a)(1) requires that ''[p]arts and accessories shall be in safe and proper operating condition at all times.'' Section 396.11(a) states that every motor carrier must ''require its drivers to report, and every driver shall prepare a report in writing at the completion of each day's work on each vehicle operated,'' covering a specific list of parts and accessories. Section 396.11(c) states that ''Prior to requiring or permitting a driver to operate a vehicle, every motor carrier or its agent shall repair any defect or deficiency listed on the driver vehicle inspection report which would be likely to affect the safety of operation of a vehicle.''

FMCSA emphasizes that the Agency is not foregoing the fundamental requirements of part 393, Parts and Accessories Necessary for Safe Operation, nor is it proposing to change any other element of the inspection, repair, and maintenance requirements of part 396. Drivers will still be required to perform pre-trip evaluations of equipment condition and complete DVIRs if any defects or deficiencies are discovered or reported during the day's operations. Motor carriers will still be required to have systematic inspection, repair, and maintenance (including preventative maintenance) programs and maintain records to prove measures are being taken to reduce to the extent practicable, the risk of mechanical problems occurring while the vehicle is in operation. In addition, motor carriers will still be required to review DVIRs that list defects or deficiencies and take appropriate action before the vehicle is dispatched again. The Agency will retain the requirement that carriers complete periodic or annual inspections and maintain documentation for the individuals who perform periodic inspections and individuals responsible for performing brake-related inspection, repair, and maintenance tasks. Furthermore, these CMVs will remain subject to roadside inspections.

In excluding passenger-carrying CMVs from the December 2014 final rule, FMCSA noted that (1) a passenger carrier crash is a low-probability but high-consequence event in terms of potential deaths and injuries, so vehicle maintenance is paramount, (2) motorcoach drivers often need to interact with their passengers at the beginning and end of their workday, and often during the trip as well, which may impact the driver's ability to properly document defects and deficiencies in the mechanical condition of the vehicle, and (3) because they are carrying the most valuable cargo, motor carriers of passengers must exercise heightened diligence over their operations, including CMV maintenance.

FMCSA has reviewed available data spanning several years regarding vehicle out-of-service rates for both trucks and passenger-carrying vehicles, including data before and after implementation of the December 2014 final rule. FMCSA's Motor Carrier Management Information System (MCMIS) data show that the vehicle out-of-service rate for trucks is consistently about 21 percent annually—both before and after implementation of the December 2014 final rule. While the Agency received several public comments during development of the December 2014 rule expressing concern that eliminating the requirement for no-defect DVIRs would result in (1) a reduced level of safety and maintenance and (2) a higher percentage of vehicle violations and out-of-service orders, the data show that the vehicle out-of-service rate for trucks has remained nearly constant before and after implementation of the rule.

The MCMIS data also show that the vehicle out-of-service rate for passenger-carrying vehicles is approximately 6.6 percent annually—consistently less than one-third of the corresponding vehicle out-of-service rate for trucks. From this data, motor carriers of passengers—because of the nature of their operations and sensitive cargo that they transport—have established and implemented comprehensive inspection, repair and maintenance programs that help ensure that their vehicles are in safe and proper operating condition at a rate that far exceeds that of other CMVs. As noted above, implementation of the December 2014 rule eliminating the requirement for no-defect DVIRs for trucks has not resulted in a reduced level of maintenance and safety or a higher percentage of vehicle violations and out-of-service violations. Given that passenger-carrying vehicles have a significantly lower vehicle out-of-service rate generally, the Agency does not believe that extending to them the same relief from the preparation and

retention of no-defect DVIRs will result in any degradation in safety. Further, FMCSA emphasizes that it is not proposing to prohibit motor carriers of passengers from requiring their drivers to prepare no-defect DVIRs if they wish, but is only proposing to eliminate the current requirement for a no-defect DVIR.

V. International Impacts

The FMCSRs, and any exceptions to the FMCSRs, apply only within the United States (and, in some cases, United States 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.

VI. Section-by-Section Analysis

FMCSA proposes amending 49 CFR part 396 by deleting a portion of the last sentence in § 396.11(a)(2) that reads ''The driver of a passenger-carrying CMV subject to this regulation must prepare a report even if no defect or deficiency is discovered by or reported to the driver; the drivers of all other commercial motor vehicles are not required to prepare a report if no defect or deficiency is discovered by or reported to the driver.'' FMCSA would revise the sentence to read ''Drivers are not required to prepare a report if no defect or deficiency is discovered by or reported to the driver.''

VII. Regulatory Analyses

A. E.O. 12866 (Regulatory Planning and Review), E.O. 13563 (Improving Regulation and Regulatory Review), and DOT Regulatory Policies and Procedures

This proposed rule is not a significant regulatory action under section 3(f) of E.O. 12866, Regulatory Planning and Review, as supplemented by E.O. 13563 (76 FR 3821, January 21, 2011), and is also not significant within the meaning of DOT regulatory policies and procedures (DOT Order 2100.6, Dec. 18, 2018) and does not require an assessment of potential costs and benefits under section 6(a)(4) of that Order. The Office of Management and Budget has not reviewed it under that Order.

Baseline for the Analysis

Under § 396.11, interstate passenger carriers [except private (nonbusiness) carriers, driveaway-towaway operations, or those operating only one CMV] must require their drivers to prepare a DVIR at the completion of work each day for each vehicle operated that covers at a minimum:

- Service brakes including trailer brake connections
- Parking brake
- Steering mechanism
- Lighting devices and reflectors
- Tires
- Horn
- Windshield wipers
- Rear vision mirrors
- Coupling devices
- Wheels and rims
- Emergency equipment.

The report must list any defect or deficiency discovered by or reported to the driver which would affect the safety of operation or result in mechanical breakdown. The driver must prepare and submit the report even if no defect or deficiency is identified and the carrier must retain the report for three months from the date the written report was prepared.

Passenger carriers use various means of compliance with this requirement including paper DVIRs and associated processes for tracking and filing (*e.g.,* separating DVIRs that identify defects from those that do not; maintaining separate files of each) and electronic systems for completing a DVIR and retaining the record.[2]

FMCSA does not have information on the ratio of electronic versus paper-based DVIR processes used by passenger carriers. Regardless of the means of compliance, the burden associated with the existing requirement to complete no-defect DVIRs is estimated at 155 seconds per report in the most recent approved supporting statement for Information Collection Request (ICR), OMB control number 2126–0003.

The supporting statement estimated that there are 247,496 passenger-carrying CMVs in operation and subject to the current DVIR requirements. As such, the no-defect DVIR rule imposes a substantial time and paperwork burden on passenger carriers with no discernible safety benefit.

Costs

In 2014, the Agency estimated cost savings associated with eliminating the requirement for no-defect DVIRs for property carrying CMVs. As that rule is analogous to the proposed rule, this analysis follows the same approach. The Agency's 2018 approved supporting statement for ICR 2126–0003 states that there are 247,496 passenger-carrying CMVs for which DVIRs must be prepared, submitted, and reviewed. Consistent with the methodology of the supporting statement and the 2014 analysis, the Agency assumes that each of these vehicles is used 65 percent of the year, and that 95 percent of DVIRs are no-defect DVIRs for which it estimated a burden of 155 seconds. Therefore, the Agency estimated a paperwork burden of 2,401,747 hours [247,496 vehicles × (0.65 × 365) × 0.95 × 155 = 8,646,288,229 seconds or 2,401,747 hours]. Using a labor rate of $31 per hour,[3] the Agency estimates a potential cost savings of $74 million per year. Because some carriers might choose to continue to require their drivers to submit no-defect DVIRs, the actual cost savings could be less than the potential. The Agency, however, assumes that a rational agent would seek to reduce costs, and that all carriers subject to the proposed rule would cease to require no-defect DVIRs. Therefore, the proposed rule would result in cost savings of $74 million per year (Table 1). The Agency welcomes input on the degree to which carriers subject to the proposed rule would retain no-defect reporting.

TABLE 1—CALCULATION OF ANNUAL COST SAVINGS

Variable	Value
Number of CMVs	247,496
Frequency of daily usage	65%
Frequency of no-defect DVIRs	95%
Time to complete a no-defect DVIR (seconds)	155
Total time saved (hours)	2,401,747
Wage rate (per hour) [1]	$31
Total savings	$73,665,012

[1] Source: Bureau of Labor Statistics (BLS). 2019. May 2018 National Industry-Specific Occupational Employment and Wage Estimates. *https://www.bls.gov/bls/blswage.htm.* Based on occupational code 53–3021, Bus Drivers, Transit and Intercity. The wage rate is scaled up to reflect an estimate of the total labor costs; wages and salaries accounted for 70.0% of total employee cost for private industry workers in December 2018 (BLS, 2019; *https://www.bls.gov/news.release/pdf/ecec.pdf*).

Benefits

The potential for the proposed rule to result in benefits relates to the change in crash risk, if any, that would result

[2] J.J. Keller provides a sample paper report available at *https://www.jjkellertraining.com/Samples/28146_JJK_Motor_Coach_Vehicle_Inspections_DEMO/story_content/external_files/DVIR.pdf.* A wide variety of vendors supply electronic DVIR systems, such as *https://www.teletracnavman.com/our-solutions/compliance/dvir, https://www.verizonconnect.com/resources/article/electronic-inspection-form-dvir/,* and *https://fleetrevolution.com/fleetrevolution-bus-dvir.*

[3] This wage is specific to bus drivers. Note that this rate differs from that used in the approved supporting statement which reflected the wage for a business operations specialist in the truck transportation industry.

from allowing a defect-based DVIR approach. The Agency has no information to suggest that preparation, submission, and review of no-defect DVIRs produces a greater level of safety than that of a defect-based approach. Further, no degradation in safety attributable to the 2014 elimination of the no-defect DVIR requirement for trucks has been observed. Both the baseline approach and the defect-based approach ensure that vehicles are inspected so that defects are noted and addressed. Therefore, the proposed rule would be expected to maintain the same level of safety. The Agency, however, seeks comment on the safety impact of the proposed rule and notes that commenters to the analogous rule for trucks had varied opinions regarding whether no-defect DVIRs are of value with respect to safety (see Docket No. FMCSA–2012–0036).

B. E.O. 13771 (Reducing Regulation and Controlling Regulatory Costs)

This proposed rule would have total costs less than zero, and is therefore an E.O. 13771 deregulatory action.[4] The present value of the cost savings of this rule, measured on an infinite time horizon at a 7 percent discount rate, expressed in 2016 dollars, and discounted to 2020 (the year the rule goes into effect and cost savings would first be realized), is $1 billion. On an annualized basis, these cost savings are $71 million.

For E.O. 13771 accounting, the April 5, 2017, OMB guidance requires that agencies also calculate the costs and cost savings discounted to year 2016.[5] In accordance with this requirement, the present value of the cost savings of this rule, measured on an infinite time horizon at a 7 percent discount rate, expressed in 2016 dollars, and discounted to 2016, is $771 million. On an annualized basis, these cost savings are $54 million.

C. Regulatory Flexibility Act (Small Entities)

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601 *et seq.*) requires Federal agencies to consider the effects of a regulatory action on small business and other small entities and to minimize any significant economic impact. The term ''small entities'' comprises small businesses and not-for-profit organizations that are independently owned and operated and are not dominant in their fields and governmental jurisdictions with a population of less than 50,000.[6]

Accordingly, DOT policy requires an analysis of the impact of all regulations on small entities, and mandates that agencies try to minimize any adverse effects on these entities. Under the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (Pub. L. 104–121, 110 Stat. 857), the proposed rule is expected to have a positive economic impact on small entities in the form of cost savings through the elimination 2.4 million paperwork burden hours.

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.

Initial Regulatory Flexibility Analysis (IRFA)

(1) A description of the reason why action by the Agency is being considered.

FMCSA proposes rescinding the requirement that drivers of passenger-carrying CMVs submit, and motor carriers retain, a DVIR when the driver has neither found nor been made aware of any vehicle defects or deficiencies (no-defect DVIR). This proposed rule would remove a significant information collection burden without adversely impacting safety.

(2) A succinct statement of the objectives of, and legal basis for, the proposed rule.

The objective of the NPRM is to eliminate a paperwork burden on passenger-carrying motor carriers currently subject to 49 CFR 396.11. This proposed rule is based on the authority of the 1935 Act and the 1984 Act, both of which are broadly discretionary. The rule implements, to some extent, the Administrator's authority under § 31136(a)(1) to ensure that CMVs are maintained, equipped, loaded, and operated safely. The NPRM is also based on the broad recordkeeping and implementation authority of § 31133(a)(8) and (10). The removal of the obligation to prepare and retain no-defect DVIRs would not compromise drivers' ability to report vehicle problems to the carrier, or relieve carriers of the responsibility to act to correct such problems.

(3) A description of and, where feasible, an estimate of the number of small entities to which the proposed rule would apply.

The Small Business Administration (SBA) has established size standards for various types of economic activities, or industries, under the North American Industry Classification System (NAICS). These size standards generally define small businesses based on the number of employees or annual receipts. For example, the SBA defines a small business in the transit and ground passenger transportation subsectors (NAICS 485) as an entity with annual revenue of less than $15 million (13 CFR 121.201). The SBA definition of a small business applies to a firm's highest domestic parent entity and all affiliates as a single entity. The business size is determined based on the primary economic sector of the parent company, which is not necessarily NAICS 485.

FMCSA data indicate a total of 8,189 interstate and intrastate passenger carriers. However, the Agency does not have data on company affiliations, NAICS, and revenues or employees with which to determine how many of these carriers are small entities.

(4) A description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which would be subject to requirements and the type of professional skills necessary for preparation of the report or record.

The proposed rule eliminates the need for drivers of passenger-carrying CMVs to complete a DVIR on days during which they do not identify any defects. The companies for which these drivers work would also be spared the burden of maintaining no-defect reports. The proposed rule would apply to interstate passenger carriers (except private (nonbusiness) carriers, driveaway-towaway operations, or those operating only one CMV). The skills necessary for drivers to complete the report are knowledge of vehicle operation and maintenance. The skills necessary for motor carrier staff maintaining these records may be administrative as well as those of a safety or regulatory compliance clerk.

(5) Identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap, or conflict with the proposed rule.

This proposed rule does not duplicate, overlap, or conflict with any Federal rules.

(6) A description of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize

[4] Executive Office of the President. Office of Management and Budget. *Memorandum M–17–21. Guidance Implementing Executive Order 13771.* April 5, 2017. Q4 on page 4.

[5] Executive Office of the President. Office of Management and Budget. *Memorandum M–17–21. Guidance Implementing Executive Order 13771.* April 5, 2017. Q25 on page 11.

[6] 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.*

any significant economic impact of the proposed rule on small entities.

The Agency has concluded that there are no significant alternatives to the proposed rule that would eliminate the paperwork burden without requiring additional investment (*e.g.,* in electronic DVIR systems).

D. Assistance for Small Entities

Pursuant to section 213 of SBREFA, FMCSA wants to assist small entities in understanding this proposed rule so that they can better evaluate its effects on them 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 FMCSA point of contact, listed in the **FOR FURTHER INFORMATION CONTACT** section of this proposed rule.

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. 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 in this preamble.

F. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires FMCSA to consider the impact of paperwork and other information collection burdens imposed on the public. This proposed rule would result in a reduction of burden hours for the ''Inspection, Repair, and Maintenance'' ICR, OMB control number 2126–0003. This ICR comprises ten individual information collections, each corresponding to a different area of the inspection, repair, and maintenance requirements. This proposed rule affects only the ICR section dealing with the Driver Vehicle Inspection Reports for Burden for No-Defect DVIRs for Passenger-Carrying Vehicles.

In 2018, based on data from its Motor Carrier Management Information System (MCMIS) and Licensing and Insurance System (L&I), FMSCA estimated that there are approximately 247,496 passenger-carrying CMVs. Consistent with past analyses of this ICR, the Agency assumed that these CMVs are used on average 65 percent of the year.

FMCSA has divided the DVIR process into two steps. The Agency estimated the first step, filling out a DVIR, to take 2 minutes, 30 seconds. The Agency estimated the second step, reviewing and signing a DVIR, to take 20 seconds when defects are reported and 5 seconds when no defects are reported. When there are no defects to note, there is nothing to review on the DVIR, and the form requires only a signature. The Agency estimates that 5 percent of DVIRs note defects and 95 percent of DVIRs note no defects.

If this proposed rule were to be finalized, the burden associated with no-defect DVIRs for passenger-carrying CMVs would be eliminated. The table below illustrates how this result is calculated.

TABLE 2—DETAIL OF NO-DEFECT DVIR PRA CALCULATIONS

Activity	Number of passenger-carrying CMVs	Utilization rate (of 365 calendar days)	Percent of CMVs affected	Total DVIRs (CMVs × utilization rate × percent of CMVs affected × 365)	Burden per DVIR (seconds)	Total annual hourly burden
No Defect DVIRS, passenger-carrying CMVs.	247,496	65%	95%	152,829	155	2,401,747

If this proposed rule were to be finalized, the annual reduction in hourly burdens associated with elimination of no defect DVIRs for passenger carrying CMVs is estimated to be 2,401,747 (247,496 CMVs × 65% utilization × 365 days × 95% of CMVs × 155 seconds ÷ 3,600 seconds per hour). The monetary value of this annual burden reduction, calculated using an hourly labor cost of $31, is $73,665,012 million (2,401,747 hours × $31, per hour).[7]

G. E.O. 13132 (Federalism)

A rule has implications for Federalism under Section 1(a) of E.O. 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. E.O. 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.

[7] 1. Source: Bureau of Labor Statistics (BLS). 2019. May 2018 National Industry-Specific Occupational Employment and Wage Estimates. *https://www.bls.gov/bls/blswage.htm.* Based on occupational code 53–3021, Bus Drivers, Transit and Intercity. The wage rate is scaled up to reflect an estimate of the total labor costs; wages and salaries accounted for 70.0% of total employee cost for private industry workers in December 2018 (BLS, 2019; *https://www.bls.gov/news.release/pdf/ecec.pdf*).

I. E.O. 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. FMCSA determined this proposed rule is not economically significant. Therefore, no analysis of the impacts on children is required. In any event, FMCSA does not anticipate that this regulatory action could in any respect present an environmental or safety risk that could disproportionately affect children.

J. E.O. 12630 (Taking of Private Property)

FMCSA reviewed this proposed rule in accordance with E.O. 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights, and has determined it would not effect a taking of private property or otherwise have taking implications.

K. Privacy

The Consolidated Appropriations Act, 2005, (Pub. L. 108–447, 118 Stat. 2809, 3268, 5 U.S.C. 552a note) requires the Agency to conduct a privacy impact assessment of a regulation that will affect the privacy of individuals. The Agency will complete a Privacy Threshold Assessment (PTA) to evaluate the risks and effects the proposed rulemaking might have on collecting, storing, and sharing personally identifiable information. The PTA will be submitted to FMCSA's Privacy Officer for review and preliminary adjudication and to DOT's Privacy Officer for review and final adjudication.

L. E.O. 12372 (Intergovernmental Review)

The regulations implementing E.O. 12372 regarding intergovernmental consultation on Federal programs and activities do not apply to this program.

M. E.O. 13211 (Energy Supply, Distribution, or Use)

FMCSA has analyzed this proposed rule under E.O. 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. FMCSA 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 E.O. 13211.

N. E.O. 13175 (Indian Tribal Governments)

This rule does not have tribal implications under E.O. 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 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. Environment (NEPA)

FMCSA analyzed this NPRM consistent with 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 (Mar. 1, 2004)), Appendix 2, paragraph (6)(aa). The Categorical Exclusion (CE) in paragraph (6)(aa) relates to regulations requiring motor carriers, drivers, and others to ''inspect, repair, and provide maintenance for every CMV used on a public road,'' which is the focus of this rulemaking. The proposed requirements in this rule are covered by this CE, there are no extraordinary circumstances present, and the proposed action does not have the potential to significantly affect the quality of the environment. The CE determination is available for inspection or copying in the regulations.gov website listed under **ADDRESSES**.

List of Subjects in 49 CFR Part 396

Highway safety, Motor carriers, Motor vehicle safety, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, FMCSA proposes amending title 49 CFR, Code of Federal Regulations, chapter III, to read as follows:

PART 396—INSPECTION, REPAIR, AND MAINTENANCE

■ 1. The authority citation for part 396 continues to read as follows:

Authority: 49 U.S.C. 504, 31133, 31136, 31151, and 31502; sec. 32934, Pub. L. 112–141, 126 Stat. 405, 830; sec. 5524, Pub. L. 114–94, 129 Stat. 1312, 1560; and 49 CFR 1.87.

■ 2. Amend § 396.11 by revising paragraph (a)(2) to read as follows:

§ 396.11 Driver vehicle inspection report(s).

(a) * * *

(2) *Report content.* (i) The report must identify the vehicle and list any defect or deficiency discovered by or reported to the driver which would affect the safety of operation of the vehicle or result in its mechanical breakdown. If a driver operates more than one vehicle during the day, a report must be prepared for each vehicle operated. Drivers are not required to prepare a report if no defect or deficiency is discovered by or reported to the driver.

(ii) The driver must sign the report. On two-driver operations, only one driver needs to sign the driver vehicle inspection report, provided both drivers agree as to the defects or deficiencies identified.

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Issued under authority delegated in 49 CFR 1.87 on: November 4, 2019.

Jim Mullen,

Acting Administrator.

[FR Doc. 2019–24525 Filed 11–8–19; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 10

[Docket No. FWS–HQ–MB–2018–0047; FXMB 12320900000//189//FF09M29000]

RIN 1018–BC67

General Provisions; Revised List of Migratory Birds

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Revised proposed rule; reopening of comment period.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), propose additions to the November 28, 2018, proposed rule to update the List of Migratory Birds protected by the Migratory Bird Treaty Act (MBTA). The proposed revisions in this document consist of further updates to taxonomy and distribution published in 2019. The net increase of 8 additional species (10 added and 2 removed) to the November 28, 2018, proposed rule would bring the total number of species protected by the MBTA to 1,093. We request public comments on the revisions described in this document, as well as on our November 28, 2018, proposed rule. If you previously submitted comments on our November 28, 2018, proposed rule, please do not resubmit them, as we will fully consider those comments when preparing our final rule.

DATES: The comment period for the November 28, 2018, proposed rule (83 FR 61288) is reopened. We will accept comments received or postmarked on or before December 12, 2019. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES**, below) must be received by 11:59 p.m. Eastern Time on the closing date.

ADDRESSES: You may submit comments by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov.* In the Search box, enter FWS–HQ–MB–2018–0047, which is the docket number for this rulemaking. Then, click on the Search button. On the resulting page, in the Search panel on the left side of the screen, under the Document Type heading, click on the Proposed Rule box to locate this document. You may submit a comment by clicking on ''Comment Now!''

(2) *By hard copy:* Submit by U.S. mail or hand-delivery to: Public Comments Processing, Attn: FWS–HQ–MB–2018–0047, U.S. Fish and Wildlife Service, MS: BPHC, 5275 Leesburg Pike, Falls Church, VA 22041–3803.

We request that you send comments only by the methods described above. We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see *Public Comments*, below, for more information).

FOR FURTHER INFORMATION CONTACT: Eric L. Kershner, Chief of the Branch of Conservation, Permits, and Regulations; Division of Migratory Bird Management; U.S. Fish and Wildlife Service; MS: MB; 5275 Leesburg Pike, Falls Church, VA 22041–3803; (703) 358–2376.

SUPPLEMENTARY INFORMATION:

Background

For background information on our statutory authorities and on the List of Migratory Birds protected by the MBTA (16 U.S.C. 703–712), see our November 28, 2018, proposed rule (83 FR 61288).

Previous Federal Actions

On November 28, 2018, we published a proposed rule (83 FR 61288) to revise the List of Migratory Birds protected by the MBTA by both adding and removing species. The List of Migratory Birds (50 CFR 10.13) was last revised on November 1, 2013 (78 FR 65844). Reasons for the changes to the list include adding species based on new taxonomy and new evidence of natural occurrence in the United States or U.S. territories, removing species no longer known to occur within the United States or U.S. territories, and changing names to conform to accepted use. An accurate and up-to-date list of species protected by the MBTA is essential for public notification and regulatory purposes.

Revised Proposed Changes to the List of Migratory Birds

The November 28, 2018, proposed rule (83 FR 61288) included revisions to the List of Migratory Birds that would result in a net increase of 59 species (66 added and 7 removed) and would bring the total number of species protected by the MBTA to 1,085. With this document, we propose to revise our November 28, 2018, proposed rule to come into conformance with updates in taxonomy and distribution recently published by the American Ornithological Society (AOS 2019). The revisions, described below under *Revised Provisions,* involve a net increase of 8 additional species (10 added and 2 removed) and would bring the total number of species protected by the MBTA to 1,093.

Retained Provisions of the November 28, 2018, Proposed Rule

As set forth in the November 28, 2018, proposed rule (83 FR 61288), we continue to propose to:

(1) Add 16 of the 17 species included in the 2018 proposed rule that qualify for protection under the MBTA but have not been added previously (please note: We are removing one species that was proposed to be added in the November 28, 2018, proposed rule; the European Turtle-Dove, discussed below under *Revised Provisions*);

(2) Correct the spelling of 3 species names on the alphabetized list;

(3) Correct the spelling of 3 species names on the taxonomic list;

(4) Add 22 species based on new distributional records documenting their natural occurrence in the United States or U.S. territories since 2010;

(5) Add one species moved from a family that was not protected to a family now protected under the MBTA as a result of taxonomic changes;

(6) Add 26 species newly recognized as a result of recent taxonomic changes;

(7) Remove 7 species not known to occur within the boundaries of the United States or U.S. territories as a result of recent taxonomic changes;

(8) Revise the common (English) names of 40 species to conform to accepted use; and

(9) Revise the scientific names of 114 species to conform to accepted use.

Revised Provisions

The revisions we are proposing to our November 28, 2018, proposed rule (83 FR 61288) in this document consist of:

(1) Removing European Turtle-Dove, *Streptopelia turtur* (AOU 2007), from species that qualify for protection under the MBTA but have not been added previously, based on our review of the evidence available for natural occurrence of the species in the United States;

(2) Correcting the spelling of the species name of White-throated Ground-Dove from *Alopecoenas xanthonura* to *Alopecoenas xanthonurus* on the alphabetized and taxonomic lists;

(3) Correcting the citation for Cackling Goose, *Branta hutchinsii* (AOU 2003) to (AOU 2004);

(4) Revising the citations for Pink-footed Goose, *Anser brachyrhynchus* (AOU 1983) to (AOS 2019), and Nazca Booby, *Sula granti* (AOU 2000) to (AOS 2019);

(5) Adding the following 8 additional species based on new distributional records documenting their natural occurrence in the United States or U.S. territories (AOS 2019):

European Storm-Petrel, *Hydrobates pelagicus*—North Carolina and Florida;

Great Black Hawk, *Buteogallus urubitinga*—Texas and Maine;

Thick-billed Warbler, *Arundinax aedon*—Alaska;

River Warbler, *Locustella fluviatilis*—Alaska;

European Robin, *Erithacus rubecula*—Pennsylvania;

Pied Wheatear, *Oenanthe pleschanka*—Alaska;

Pallas's Rosefinch, *Carpodacus roseus*—Alaska; and

Black-backed Oriole, *Icterus abeillei*—Pennsylvania, Massachusetts, Connecticut;

(6) Adding the following 2 additional species newly recognized as a result of recent taxonomic changes (AOS 2019):

Stejneger's Scoter, *Melanitta stejnegeri*—formerly considered conspecific with Velvet Scoter, *Melanitta fusca;* and

Gray-faced Petrel, *Pterodroma gouldi*—formerly considered conspecific with Great-winged Petrel, *Pterodroma macroptera;*

(7) Removing the following 1 additional species not known to occur within the boundaries of the United States or U.S. territories as a result of recent taxonomic changes (AOS 2019):

Great-winged Petrel, *Pterodroma macroptera;*

(8) Revising the common (English) names of the following 4 additional species to conform to accepted use (AOS 2019):

Common Ground-Dove, *Columbina passerina* becomes Common Ground Dove, *Columbina passerina;*

Ruddy Ground-Dove, *Columbina talpacoti* becomes Ruddy Ground Dove, *Columbina talpacoti;*

Amethyst-throated Hummingbird, *Lampornis amethystinus* becomes Amethyst-throated Mountain-gem, *Lampornis amethystinus;* and

Blue-throated Hummingbird, *Lampornis clemenciae* becomes Blue-throated Mountain-gem, *Lampornis clemenciae;* and

(9) Revising the scientific names of the following 20 additional species to conform to accepted use (AOS 2019):

White-winged Scoter, *Melanitta fusca* becomes White-winged Scoter, *Melanitta deglandi;*

Bahama Woodstar, *Calliphlox evelynae* becomes Bahama Woodstar, *Nesophlox evelynae;*

Fork-tailed Storm-Petrel, *Oceanodroma furcata* becomes Fork-tailed Storm-Petrel, *Hydrobates furcatus;*

Ringed Storm-Petrel, *Oceanodroma hornbyi* becomes Ringed Storm-Petrel, *Hydrobates hornbyi;*

Swinhoe's Storm-Petrel, *Oceanodroma monorhis* becomes Swinhoe's Storm-Petrel, *Hydrobates monorhis;*

Leach's Storm-Petrel, *Oceanodroma leucorhoa* becomes Leach's Storm-Petrel, *Hydrobates leucorhous;*

Townsend's Storm-Petrel, *Oceanodroma socorroensis* becomes Townsend's Storm-Petrel, *Hydrobates socorroensis;*

Ashy Storm-Petrel, *Oceanodroma homochroa* becomes Ashy Storm-Petrel, *Hydrobates homochroa;*

Band-rumped Storm-Petrel, *Oceanodroma castro* becomes Band-rumped Storm-Petrel, *Hydrobates castro;*

Wedge-rumped Storm-Petrel, *Oceanodroma tethys* becomes Wedge-rumped Storm-Petrel, *Hydrobates tethys;*

Black Storm-Petrel, *Oceanodroma melania* becomes Black Storm-Petrel, *Hydrobates melania;*

Tristram's Storm-Petrel, *Oceanodroma tristrami* becomes Tristram's Storm-Petrel, *Hydrobates tristrami,*

Least Storm-Petrel, *Oceanodroma microsoma* becomes Least Storm-Petrel, *Hydrobates microsoma;*

Tennessee Warbler, *Oreothlypis peregrina* becomes Tennessee Warbler, *Leiothlypis peregrina*

Orange-crowned Warbler, *Oreothlypis celata* becomes Orange-crowned Warbler, *Leiothlypis celata;*

Colima Warbler, *Oreothlypis crissalis* becomes Colima Warbler, *Leiothlypis crissalis;*

Lucy's Warbler, *Oreothlypis luciae* becomes Lucy's Warbler, *Leiothlypis luciae;*

Nashville Warbler, *Oreothlypis ruficapilla* becomes Nashville Warbler, *Leiothlypis ruficapilla;*

Virginia's Warbler, *Oreothlypis virginiae* becomes Virginia's Warbler, *Leiothlypis virginiae;* and

Black-faced Grassquit, *Tiaris bicolor* becomes Black-faced Grassquit, *Melanospiza bicolor.*

What scientific authorities are used to amend the list of migratory birds?

Although bird names (common and scientific) are relatively stable, staying current with standardized use is necessary to avoid confusion in communications. In making our determinations, we primarily relied on the American Ornithological Society's (AOS's) Checklist of North American birds (AOU 1998), as amended annually (AOU 1999 through 2016, AOS 2017 through 2019), on matters of taxonomy, nomenclature, and the sequence of species and other higher taxonomic categories (Orders, Families, Subfamilies) for species that occur in North America. The AOU (now AOS) Checklist of North American birds (Checklist), developed by the AOU Committee on Classification and Nomenclature, has been the recognized taxonomic authority for North American birds since publication of the first edition of the Checklist in 1886. The committee compiles the taxonomic foundation for ornithology in North America; evaluating and codifying the latest scientific developments in the systematics, classification, nomenclature, and distribution of North American birds. Thus, the AOS's Checklist represents the best information available for developing the North American component of this List of Migratory Birds. In keeping with the increasing numbers of study areas on which taxonomy relies, the committee incorporates expertise in phylogenetics, genomics, vocalizations, morphology, behavior, and geographical distribution, as well as general ornithological knowledge. The AOS Checklist contains all bird species that have occurred in North America from the Arctic through Panama, including the West Indies and the Hawaiian Islands, and includes distributional information for each species, which specifies whether the species is known to occur in the United States, and the Committee on Classification and Nomenclature also keeps and updates a list of species known to occur in the United States. The 2019 update of the AOS Checklist made this revised proposed rule necessary, as the 2019 update became available after the publication of our November 28, 2018, proposed rule.

For the species that occur outside the geographic area covered by the AOS Checklist, we relied on the Clements Checklist of Birds of the World (Clements Checklist) (Clements *et al.* 2017), and peer-reviewed literature. The Clements Checklist, originally published in 1974, serves as a comprehensive list of bird species of the world, incorporating updates and advances in taxonomy and distribution published by regional scientific authorities. The Clements Checklist relies on the AOS for North American updates, but for U.S. territories beyond the geographic scope of the AOS, the Clements Checklist relies on other regional scientific authorities.

Although we primarily rely on the above sources, when informed taxonomic opinion is inconsistent or controversial, we evaluate available published and unpublished information and come to our own conclusion regarding the validity of taxa.

What criteria are used to identify individual species protected by the MBTA?

A species qualifies for protection under the MBTA by meeting one or more of the following criteria:

(1) It occurs in the United States or U.S. territories as the result of natural biological or ecological processes and is currently, or was previously listed as, a species or part of a family protected by one of the four international treaties or their amendments. Any species that occurs in the United States or U.S. territories solely as a result of intentional or unintentional human-assisted introduction does not qualify for the MBTA list, regardless of whether the family the species belongs to is listed in any of the treaties, unless:

- It was native to the United States or its territories and extant in 1918;
- It was extirpated after 1918 throughout its range in the United States and its territories; and
- After such extirpation, it was reintroduced in the United States or its territories as part of a program carried out by a Federal agency.

(2) Revised taxonomy results in it being newly split from a species that was previously on the list, and the new species occurs in the United States or U.S. territories as the result of natural biological or ecological processes. If a newly recognized native species is considered extinct (following the classification of the AOS or, for species not covered by the AOS, the Clements checklist or peer-reviewed literature), that species will still be included if either of the following criteria apply:

- The species resembles extant species included in the list that may be affected by trade if the species is not included; or
- Not including the species may create difficulties implementing the MBTA and its underlying Conventions.

(3) New evidence exists for its natural occurrence in the United States or U.S. territories resulting from new or natural distributional changes and the species occurs in a protected family. Records must be documented, accepted, and published by the AOS committee. For the U.S. Pacific territories that fall outside the geographic scope of the AOS and for which there is no identified ornithological authority, new evidence of a species' natural occurrence will be based on the Clements checklist and then published peer-reviewed literature, in that order.

In accordance with the Migratory Bird Treaty Reform Act of 2004 (MBTRA) (Pub. L. 108–447, 118 Stat. 2809, 3071–72), we only include migratory bird species that are native to the United States or U.S. territories. A native migratory bird species is one that is present as a result of natural biological or ecological processes. The List of Migratory Birds protected by the MBTA in title 50 of the Code of Federal Regulations (CFR) at part 10, section 13 (50 CFR 10.13), does not include nonnative species that occur in the United States or U.S. territories solely as a result of intentional or unintentional human-assisted introduction(s). A Notice of Availability of a draft list to update the list of all nonnative, human-introduced bird species to which the MBTA does not apply published on November 28, 2018 (83 FR 61161).

Public Comments

Any final action resulting from our November 28, 2018, proposed rule (83 FR 61288) and this revised proposed rule must be based on the best scientific and commercial data available and be as accurate and as effective as possible. We will address the comments we received during the original comment period on the November 28, 2018, proposed rule (83 FR 61288), as well as any comments we receive during the reopened comment period for this revised proposed rule, in our final rule for this action. During this reopened comment period, we request comments or information from other concerned governmental agencies, the scientific community, industry, or any other interested parties concerning our November 28, 2018, proposed rule (83 FR 61288) and this revised proposed rule.

Please include sufficient information with your submission (such as electronic copies of scientific journal articles or other publications, preferably in English) to allow us to verify any scientific or commercial information you include.

You may submit your comments and materials concerning this proposed rule by one of the methods listed in **ADDRESSES**. We request that you send comments only by the methods described in **ADDRESSES**.

If you submit information via *http://www.regulations.gov,* your entire submission—including any personal identifying information—will be posted on the website. If your submission is made via a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on *http://www.regulations.gov.*

Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection on *http://www.regulations.gov,* or by appointment, during normal business hours, at the U.S. Fish and Wildlife Service, Division of Migratory Bird Management (see **FOR FURTHER INFORMATION CONTACT**).

Required Determinations

We are affirming our required determinations made in our November 28, 2018, proposed rule (83 FR 61288); for descriptions of our actions to ensure compliance with the following statutes and Executive Orders, see that proposed rule:

- National Environmental Policy Act;
- Endangered Species Act;
- Regulatory Flexibility Act;
- Small Business Regulatory Enforcement Fairness Act;
- Paperwork Reduction Act of 1995;
- Unfunded Mandates Reform Act;
- Executive Orders 12630, 12866, 12988, 13132, 13175, 13211, 13563, and 13771.

List of Subjects in Part 10

Exports, Fish, Imports, Law enforcement, Plants, Transportation, Wildlife.

Proposed Regulation Promulgation

For the reasons stated in the preamble, we propose to further amend title 50, chapter I, subchapter B, part 10 of the Code of Federal Regulations, as proposed to be amended at 83 FR 61288 (November 28, 2018), as set forth below:

PART 10—GENERAL PROVISIONS

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

Authority: 16 U.S.C. 668a–d, 703–712, 742a–j–l, 1361–1384, 1401–1407, 1531–1543, 3371–3378; 18 U.S.C. 42; 19 U.S.C. 1202.

■ 2. Amend § 10.13, as proposed to be amended on November 28, 2018 (83 FR 61288), as follows:

■ a. By revising the introductory text of paragraph (c);

■ b. In paragraph (c)(1), by:

■ i. Under the entry DOVE, adding, in alphabetical order, the words ''Common Ground, *Columbina passerina*'' and ''Ruddy Ground, *Columbina talpacoti*''*;*

■ ii. Under the entry GRASSQUIT, removing the words ''Black-faced, *Tiaris bicolor*'' and adding in their place the words ''Black-faced, *Melanospiza bicolor*''*;*

■ iii. Under the entry GROUND-DOVE, by:

■ *1.* Removing the words ''Common, *Columbina passerina*''*;*

■ *2.* Removing the words ''Ruddy, *Columbina talpacoti*''*;* and
■ *3.* Removing the words ''White-throated, *Alopecoenas xanthonura*'' and adding in their place the words ''White-throated, *Alopecoenas xanthonurus*''*;*
■ iv. Under the entry HAWK, adding, in alphabetical order, the words ''Great Black, *Buteogallus urubitinga*''*;*
■ v. Under the entry HUMMINGBIRD, removing the words ''Amethyst-throated, *Lampornis amethystinus*'' and ''Blue-throated, *Lampornis clemenciae*''*;*
■ vi. Adding, in alphabetical order, an entry MOUNTAIN-GEM, and adding ''Amethyst-throated, *Lampornis amethystinus*'' and ''Blue-throated, *Lampornis clemenciae*'' under that entry;
■ vii. Under the entry ORIOLE, adding, in alphabetical order, the words ''Black-backed, *Icterus abeillei*''*;*
■ viii. Under the entry PETREL, by:
■ *1.* Adding, in alphabetical order, the words ''Gray-faced, *Pterodroma gouldi*''*;* and
■ *2.* Removing the words ''Great-winged, *Pterodroma macroptera*''*;*
■ ix. Under the entry ROBIN, adding, in alphabetical order, the words ''European, *Erithacus rubecula*''*;*
■ x. Under the entry ROSEFINCH, adding, in alphabetical order, the words ''Pallas's, *Carpodacus roseus*''*;*
■ xi. Under the entry SCOTER, by:
■ *1.* Adding, in alphabetical order, the words ''Stejneger's, *Melanitta stejnegeri*''*;* and
■ *2.* Removing the words ''White-winged, *Melanitta fusca*'' and adding in their place the words ''White-winged, *Melanitta deglandi*''*;*
■ xii. Revising the entry STORM-PETREL;
■ xiii. Under the entry TURTLE-DOVE, removing the words ''European, *Streptopelia turtur*''*;*
■ xiv. Under the entry WARBLER, by:
■ *1.* Removing the words ''Colima, *Oreothlypis crissalis*'' and adding in their place the words ''Colima, *Leiothlypis crissalis*''*;*
■ *2.* Removing the words ''Lucy's, *Oreothlypis luciae*'' and adding in their place the words ''Lucy's, *Leiothlypis luciae*''*;*
■ *3.* Removing the words ''Nashville, *Oreothlypis ruficapilla*'' and adding in their place the words ''Nashville, *Leiothlypis ruficapilla*''*;*
■ *4.* Removing the words ''Orange-crowned, *Oreothlypis celata*'' and adding in their place the words ''Orange-crowned, *Leiothlypis celata*''*;*
■ *5.* Adding, in alphabetical order, the words ''River, *Locustella fluviatilis*''*;*
■ *6.* Removing the words ''Tennessee, *Oreothlypis peregrina*'' and adding in their place the words ''Tennessee, *Leiothlypis peregrina*''*;*
■ *7.* Adding, in alphabetical order, the words ''Thick-billed, *Arundinax aedon*''*;* and
■ *8.* Removing the words ''Virginia's, *Oreothlypis virginiae*'' and adding in their place the words ''Virginia's, *Leiothlypis virginiae*''*;*
■ xv. Under the entry WHEATEAR, adding, in alphabetical order, the words ''Pied, *Oenanthe pleschanka*''*;* and
■ xvi. Revising the entry WOODSTAR.
■ c. In paragraph (c)(2), by:
■ i. Under the entries Order ANSERIFORMES, Family ANATIDAE, Subfamily ANATINAE, by:
■ *1.* Removing the words ''*Melanitta fusca,* White-winged Scoter'' and adding in their place the words ''*Melanitta deglandi,* White-winged Scoter''; and
■ *2.* Immediately following the words ''*Melanitta deglandi,* White-winged Scoter'', adding the words ''*Melanitta stejnegeri,* Stejneger's Scoter'';
■ ii. Under the entries Order COLUMBIFORMES, Family COLUMBIDAE, by:
■ *1.* Removing the words ''*Alopecoenas xanthonura,* White-throated Ground-Dove'' and adding in their place the words ''*Alopecoenas xanthonurus,* White-throated Ground-Dove'';
■ *2.* Removing the words ''*Streptopelia turtur,* European Turtle-Dove'';
■ *3.* Removing the words ''*Columbina passerina,* Common Ground-Dove'' and adding in their place the words ''*Columbina passerina,* Common Ground Dove''; and
■ *4.* Removing the words ''*Columbina talpacoti,* Ruddy Ground-Dove'' and adding in their place the words ''*Columbina talpacoti,* Ruddy Ground Dove'';
■ iii. Under the entries Order APODIFORMES, Family TROCHILIDAE, Subfamily TROCHILINAE, by:
■ *1.* Removing the words ''*Lampornis amethystinus,* Amethyst-throated Hummingbird'' and adding in their place the words ''*Lampornis amethystinus,* Amethyst-throated Mountain-gem'';
■ *2.* Removing the words ''*Lampornis clemenciae,* Blue-throated Hummingbird'' and adding in their place the words ''*Lampornis clemenciae,* Blue-throated Mountain-gem''; and
■ *3.* Removing the words ''*Calliphlox evelynae,* Bahama Woodstar'' and adding in their place the words ''*Nesophlox evelynae,* Bahama Woodstar'';
■ iv. Under the entry Order PROCELLARIIFORMES, by:
■ *1.* Revising the entry for Family HYDROBATIDAE; and
■ *2.* Under entry Family PROCELLARIIDAE, by:
■ A. Immediately following the words ''*Fulmarus glacialis,* Northern Fulmar'', adding the words ''*Pterodroma gouldi,* Gray-faced Petrel''; and
■ B. Removing the words ''*Pterodroma macroptera,* Great-winged Petrel''.
■ v. Under the entries Order ACCIPITRIFORMES, Family ACCIPITRIDAE, Subfamily ACCIPITRINAE, immediately following the words ''*Buteogallus anthracinus,* Common Black Hawk'', adding the words ''*Buteogallus urubitinga,* Great Black Hawk''; and
■ vi. Under the entry Order PASSERIFORMES, by:
■ *1.* Immediately following the words ''Family ACROCEPHALIDAE'', adding the words ''*Arundinax aedon,* Thick-billed Warbler'';
■ *2.* Under entry Family LOCUSTELLIDAE, immediately following the words ''*Locustella ochotensis,* Middendorff's Grasshopper-Warbler'', adding the words ''*Locustella fluviatilis,* River Warbler'';
■ *3.* Under entry Family MUSCICAPIDAE, by:
■ A. Immediately following the words ''*Muscicapa sibirica,* Dark-sided Flycatcher'', adding the words ''*Erithacus rubecula,* European Robin''; and
■ B. Immediately following the words ''*Oenanthe oenanthe,* Northern Wheatear'', adding the words ''*Oenanthe pleschanka,* Pied Wheatear'';
■ *4.* Under entries Family FRINGILLIDAE, Subfamily CARDUELINAE, immediately following the words ''*Carpodacus erythrinus,* Common Rosefinch'', adding the words ''*Carpodacus roseus,* Pallas's Rosefinch'';
■ *5.* Under entries Family ICTERIDAE, Subfamily ICTERINAE, immediately following the words ''*Icterus galbula,* Baltimore Oriole'', adding the words ''*Icterus abeillei,* Black-backed Oriole'';
■ *6.* Under entry Family PARULIDAE, by:
■ A. Removing the words ''*Oreothlypis peregrina,* Tennessee Warbler'' and adding in their place the words ''*Leiothlypis peregrina,* Tennessee Warbler'';
■ B. Removing the words ''*Oreothlypis celata,* Orange-crowned Warbler'' and adding in their place the words ''*Leiothlypis celata,* Orange-crowned Warbler'';
■ C. Removing the words ''*Oreothlypis crissalis,* Colima Warbler'' and adding in their place the words ''*Leiothlypis crissalis,* Colima Warbler'';
■ D. Removing the words ''*Oreothlypis luciae,* Lucy's Warbler'' and adding in their place the words ''*Leiothlypis luciae,* Lucy's Warbler'';

■ E. Removing the words ''*Oreothlypis ruficapilla,* Nashville Warbler'' and adding in their place the words ''*Leiothlypis ruficapilla,* Nashville Warbler''; and

■ F. Removing the words ''*Oreothlypis virginiae,* Virginia's Warbler'' and adding in their place the words ''*Leiothlypis virginiae,* Virginia's Warbler''; and

■ *7.* Under entries Family THRAUPIDAE, Subfamily COEREBINAE, removing the words ''*Tiaris bicolor,* Black-faced Grassquit'' and adding in their place the words ''*Melanospiza bicolor,* Black-faced Grassquit''.

The revisions and additions read as follows:

§ 10.13 List of Migratory Birds.

* * * * *

(c) *What species are protected as migratory birds?* Species protected as migratory birds are listed in two formats to suit the varying needs of the user: Alphabetically in paragraph (c)(1) of this section and taxonomically in paragraph (c)(2) of this section. Taxonomy and nomenclature generally follow the 7th edition of the American Ornithologists' Union's (AOU, now recognized as American Ornithological Society (AOS)) *Check-list of North American birds* (1998, as amended through 2019). For species not treated by the AOS *Check-list,* we generally follow *Clements Checklist of Birds of the World* (Clements *et al.* 2017).

(1) * * *

* * * * *

DOVE, Common Ground, *Columbina passerina*

* * * * *

Ruddy Ground, *Columbina talpacoti*

* * * * *

HAWK, * * *

Great Black, *Buteogallus urubitinga*

* * * * *

MOUNTAIN-GEM, Amethyst-throated, *Lampornis amethystinus*

Blue-throated, *Lampornis clemenciae*

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ORIOLE, * * *

Black-backed, *Icterus abeillei*

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PETREL, * * *

Gray-faced, *Pterodroma gouldi*

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ROBIN, * * *

European, *Erithacus rubecula*

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ROSEFINCH, * * *

Pallas's, *Carpodacus roseus*

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SCOTER, * * *

Stejneger's, *Melanitta stejnegeri*

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STORM-PETREL, Ashy, *Hydrobates homochroa*

Band-rumped, *Hydrobates castro*

Black, *Hydrobates melania*

Black-bellied, *Fregetta tropica*

European, *Hydrobates pelagicus*

Fork-tailed, *Hydrobates furcatus*

Leach's, *Hydrobates leucorhous*

Least, *Hydrobates microsoma*

Matsudaira's, *Oceanodroma matsudairae*

Polynesian, *Nesofregetta fuliginosa*

Ringed, *Hydrobates hornbyi*

Swinhoe's, *Hydrobates monorhis*

Townsend's, *Hydrobates socorroensis*

Tristram's, *Hydrobates tristrami*

Wedge-rumped, *Hydrobates tethys*

White-bellied, *Fregetta grallaria*

White-faced, *Pelagodroma marina*

Wilson's, *Oceanites oceanicus*

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WARBLER, * * *

River, *Locustella fluviatilis*

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Thick-billed, *Arundinax aedon*

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WHEATEAR, * * *

Pied, *Oenanthe pleschanka*

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WOODSTAR, Bahama, *Nesophlox evelynae*

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(2) * * *

Order ANSERIFORMES

Family ANATIDAE

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Subfamily ANATINAE

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Melanitta stejnegeri, Stejneger's Scoter

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Order PROCELLARIIFORMES

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Family HYDROBATIDAE

Hydrobates pelagicus, European Storm-Petrel

Fregetta grallaria, White-bellied Storm-Petrel

Nesofregetta fuliginosa, Polynesian Storm-Petrel

Hydrobates furcatus, Fork-tailed Storm-Petrel

Hydrobates hornbyi, Ringed Storm-Petrel

Hydrobates monorhis, Swinhoe's Storm-Petrel

Hydrobates leucorhous, Leach's Storm-Petrel

Hydrobates socorroensis, Townsend's Storm-Petrel

Hydrobates homochroa, Ashy Storm-Petrel

Hydrobates castro, Band-rumped Storm-Petrel

Hydrobates tethys, Wedge-rumped Storm-Petrel

Oceanodroma matsudairae, Matsudaira's Storm-Petrel

Hydrobates melania, Black Storm-Petrel

Hydrobates tristrami, Tristram's Storm-Petrel

Hydrobates microsoma, Least Storm-Petrel

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Family PROCELLARIIDAE

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Pterodroma gouldi, Gray-faced Petrel

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Order ACCIPITRIFORMES

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Family ACCIPITRIDAE

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Subfamily ACCIPITRINAE

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Buteogallus urubitinga, Great Black Hawk

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Order PASSERIFORMES

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Family ACROCEPHALIDAE

Arundinax aedon, Thick-billed Warbler

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Family LOCUSTELLIDAE

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Locustella fluviatilis, River Warbler

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Family MUSCICAPIDAE

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Erithacus rubecula, European Robin

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Oenanthe pleschanka, Pied Wheatear

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Family FRINGILLIDAE

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Subfamily CARDUELINAE

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Carpodacus roseus, Pallas's Rosefinch

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Family ICTERIDAE

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Subfamily ICTERINAE

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Icterus abeillei, Black-backed Oriole

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Dated: September 26, 2019.

Rob Wallace,

Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2019–22978 Filed 11–8–19; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 191105–0075]

RIN 0648–BJ28

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Reef Fish Fishery of the Gulf of Mexico; Red Snapper Management Measures

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes to implement management measures described in a framework action to the Fishery Management Plan (FMP) for the Reef Fish Resources of the Gulf of Mexico (Gulf), as prepared by the Gulf of Mexico Fishery Management Council (Council). This proposed rule would modify the red snapper Federal charter vessel/headboat (for-hire) component's annual catch target (ACT) for the 2020 and subsequent fishing years. The purpose of the framework action is to allow for greater harvest of red snapper by the Federal for-hire component.

DATES: Written comments must be received by December 12, 2019.

ADDRESSES: You may submit comments on the proposed rule identified by ''NOAA–NMFS–2019–0108'' by either of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2019-0108,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit all written comments to Peter Hood, NMFS Southeast Regional Office, 263 13th Avenue South, St. Petersburg, FL 33701.

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

Electronic copies of the framework action, which includes an environmental assessment, a regulatory impact review, and a Regulatory Flexibility Act (RFA) analysis may be obtained from the Southeast Regional Office website at *https://www.fisheries.noaa.gov/action/framework-action-fishery-management-plan-reef-fish-resources-gulf-mexico-modification.*

FOR FURTHER INFORMATION CONTACT: Peter Hood, NMFS Southeast Regional Office, telephone: 727–824–5305, email: *peter.hood@noaa.gov.*

SUPPLEMENTARY INFORMATION: NMFS and the Council manage the Gulf reef fish fishery under the FMP. The FMP, which includes red snapper, was prepared by the Council and is implemented by NMFS through regulations at 50 CFR part 622 under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) (16 U.S.C. 1801 *et seq.*).

The Magnuson-Stevens Act requires NMFS and regional fishery management councils to prevent overfishing and achieve, on a continuing basis, the optimum yield from federally managed fish stocks. These mandates are intended to ensure fishery resources are managed for the greatest overall benefit to the nation, particularly with respect to providing food production and recreational opportunities, and protecting marine ecosystems.

All weights described in this proposed rule are in round (whole) weight.

Background

The current red snapper stock ACL is equal to the acceptable biological catch (ABC) of 13.74 million lb (6.23 million kg); 51 percent is allocated to the commercial sector and 49 percent to the recreational sector. The recreational sector's ACL is further divided into the private angling component (57.7 percent) and Federal for-hire component (42.3 percent). In addition, ACTs are in place for the recreational sector and its respective components. The ACT is a level of catch reduced from the ACL to account for management uncertainty. The separate recreational component ACLs and ACTs were implemented in 2015 and are currently set to expire in 2022 (81 FR 86971, December 2, 2016). However, if approved and implemented, Amendment 50A to the FMP would continue the separation of the private angling and Federal for-hire components. The notice of availability for Amendment 50A published on August 6, 2019 (84 FR 38198) and the proposed rule to implement Amendment 50A published on October 2, 2019 (84 FR 52438).

The regulations require NMFS to project the component fishing seasons based on the respective ACTs. The ACTs were implemented to reduce the likelihood of exceeding the private angling or Federal for-hire component ACLs, as well as the total recreational ACL. The commercial sector does not have an ACT because it is managed under an individual fishing quota program that effectively constrains landings to the commercial ACL.

Because the Federal for-hire component has not exceeded its ACL, the Council developed a framework action in 2018 to reduce the 20 percent buffer between the Federal for-hire component ACL and ACT for 2019 only (84 FR 7828, March 5, 2019). The 2018 framework action set the Federal for-hire component ACT 9 percent less than the component ACL. This buffer was based on the application of the Council's ACL/ACT Control Rule, which recommends a buffer based on factors such as recent harvest overages, the percent standard error in Federal for-hire landing estimates, stock status, and whether in-season accountability measures are used.

The reduction in the Federal for-hire component's ACL/ACT buffer was effective only for 2019 to coincide with the second year of temporary changes to the management of the private angling component. All five Gulf states received exempted fishing permits (EFPs) from NMFS for the 2018 and 2019 fishing years to allow them to test limited state management of the private angling component. Each state was allocated a percentage of the private angling ACL and each state determined whether to manage to a reduced portion of its ACL. The Council determined that the reduction in the Federal for-hire component ACT buffer should be limited to 2019 because of the increased risk of the recreational sector ACL being exceeded after the EFPs are no longer in effect. Under the EFPs, any overages by the private-angling component are deducted from the subsequent year's state ACL.

In the current framework action, the Council did not consider decreasing the private angling component ACT buffer because the Council recently submitted to NMFS for review Amendments 50A–F to the FMP. These amendments, if implemented, would delegate authority to each of the Gulf states to establish specific management measures

applicable to private anglers in Gulf Federal waters who are landing red snapper in that state, including the length of the fishing season. Similar to the EFPs, these amendments would allocate a percentage of the private angling ACL and each state would determine whether to manage to a reduced portion of its ACL. As stated previously, Amendment 50A would also continue the separation of the private angling and Federal for-hire components that is set to end after the 2022 fishing year. Given the proposed changes in private recreational component management described in Amendments 50A–F, the Council determined that it is appropriate to keep the 9 percent Federal for-hire ACL/ACT buffer beyond 2019.

Management Measures Contained in This Proposed Rule

For red snapper, this proposed rule would maintain the Federal for-hire component ACL/ACT buffer at 9 percent below the component ACL. Currently, the buffer would return to 20 percent on January 1, 2020, and the Federal for-hire component ACT would be 2.504 million lb (1.136 million kg). This framework action would maintain the ACT at 2.848 million lb (1.292 million kg). Using the 9 percent buffer results in a Federal for-hire component ACT that is 344,000 lb (156,036 kg) more than if the 20 percent buffer were used. NMFS expects this increase in the ACT to result in a Federal for-hire season that is approximately 7 to 8 days longer in 2020 than if the lower ACT were used to project the season.

NMFS assumes that if Amendments 50A–F are approved, they will be implemented first. Therefore, the regulatory text in this proposed rule reflects certain measures contained in the proposed regulatory text for those amendments. Specifically, the proposed rule for Amendments 50A–F would remove paragraph 50 CFR 622.41(q)(2)(iii)(A), which specifies the red snapper total recreational ACT, because the total recreational ACT would serve no management purpose under the delegation. The proposed rule for Amendments 50A–F would also remove text in 50 CFR 622.41(q)(2)(iii)(B) that would end the separation of the recreational sector components and would add text clarifying the harvest restrictions for the Federal for-hire component when the Federal season in closed. If Amendments 50A–F are not implemented, or this proposed rule is implemented first, the regulatory text in the final rule would be revised accordingly.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has determined that this proposed rule is consistent with the applicable FMP, the Magnuson-Stevens Act, and other applicable laws, subject to further consideration after public comment.

This proposed rule has been determined to be not significant for purposes of Executive Order 12866.

The Magnuson-Stevens Act provides the statutory basis for this proposed rule. No duplicative, overlapping, or conflicting Federal rules have been identified. A description of this proposed rule and its purpose and need are contained in the **SUMMARY** section of the preamble.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. The factual basis for this certification is as follows.

The rule concerns recreational fishing for red snapper in the Gulf exclusive economic zone (EEZ). Anglers (recreational fishers) who fish for red snapper in the Gulf EEZ would be directly affected; however, anglers are not considered small entities as that term is defined in 5 U.S.C. 601(6). The rule would indirectly impact Federal for-hire fishing vessels if it causes changes in angler demand for Federal for-hire fishing services; however, the RFA does not consider indirect impacts. Hence, it is concluded that the rule would not have a significant economic impact on a substantial number of small entities and an initial regulatory flexibility analysis is not required and none has been prepared.

List of Subjects in 50 CFR Part 622

Fisheries, Fishing, Gulf, Recreational, Red snapper.

Dated: November 6, 2019.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 622 is proposed to be amended as follows:

PART 622—FISHERIES OF THE CARIBBEAN, GULF of MEXICO, AND SOUTH ATLANTIC

■ 1. The authority citation for part 622 continues to read as follows:

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

■ 2. In § 622.41, revise paragraph (q)(2)(iii)(B) to read as follows:

§ 622.41 Annual catch limits (ACLs), annual catch targets (ACTs), and accountability measures (AMs).

* * * * *

(q) * * *

(2) * * *

(iii) * * *

(B) *Federal charter vessel/headboat component ACT.* The Federal charter vessel/headboat component ACT applies to vessels that have been issued a valid Federal charter vessel/headboat permit for Gulf reef fish any time during the fishing year. A person aboard a vessel that has been issued a charter vessel/headboat permit for Gulf reef fish any time during the fishing year may not harvest or possess red snapper in or from the Gulf EEZ when the Federal charter vessel/headboat component is closed. The component ACT is 2.848 million lb (1.292 million kg), round weight.

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[FR Doc. 2019–24519 Filed 11–8–19; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register

Vol. 84, No. 218

Tuesday, November 12, 2019

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

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2018–0087]

Concurrence With OIE Risk Designations for Bovine Spongiform Encephalopathy

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our decision to concur with the World Organization for Animal Health's (OIE) bovine spongiform encephalopathy (BSE) risk designations for Nicaragua. The OIE recognizes this region as being of negligible risk for BSE. We are taking this action based on our review of information supporting the OIE's risk designations for this region.

FOR FURTHER INFORMATION CONTACT: Dr. Kari Coulson, Senior Staff Veterinarian, Strategy and Policy, VS, APHIS, 920 Main Campus Drive, Suite 200, Raleigh, NC 27606; (919) 855–7741; email: *kari.f.coulson@usda.gov.*

SUPPLEMENTARY INFORMATION: The regulations in 9 CFR part 92 subpart B, ''Importation of Animals and Animal Products; Procedures for Requesting BSE Risk Status Classification With Regard To Bovines'' (referred to below as the regulations), set forth the process by which the Animal and Plant Health Inspection Service (APHIS) classifies regions for bovine spongiform encephalopathy (BSE) risk. Section 92.5 of the regulations provides that all countries of the world are considered by APHIS to be in one of three BSE risk categories: Negligible risk, controlled risk, or undetermined risk. These risk categories are defined in § 92.1. Any region that is not classified by APHIS as presenting either negligible risk or controlled risk for BSE is considered to present an undetermined risk. The list of those regions classified by APHIS as having either negligible risk or controlled risk can be accessed on the APHIS website at *https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/animal-health-status-of-regions.* The list can also be obtained by writing to APHIS at Regionalization Evaluation Services, 4700 River Road Unit 38, Riverdale, MD 20737.

Under the regulations, APHIS may classify a region for BSE in one of two ways. One way is for regions that have not received a risk classification from the World Organization for Animal Health (OIE) to request classification by APHIS. The other way is for APHIS to concur with the classification given to a country or region by the OIE.

If the OIE has recognized a country as either BSE negligible risk or BSE controlled risk, APHIS will seek information to support our concurrence with the OIE classification. This information may be publicly available information, or APHIS may request that countries supply the same information given to the OIE. APHIS will announce in the **Federal Register**, subject to public comment, its intent to concur with an OIE classification.

In accordance with that process, we published a notice[1] in the **Federal Register** on June 17, 2019 (84 FR 28001, Docket No. APHIS–2018–0087), in which we announced our intent to concur with the OIE recognition of Nicaragua as being a region of negligible risk for BSE. We solicited comments on the notice for 60 days ending on August 16, 2019. We received one comment by that date, from a private citizen.

The commenter voiced doubts about the efficacy of the BSE minimal risk region policy, concerns about other prion diseases such as chronic wasting disease circulating in the United States and the world, and skepticism that the ruminant-to-ruminant feed ban has been effectively enforced. The commenter did not, however, address our preliminary concurrence with the OIE's risk designation for Nicaragua or the documentation made available to support that action.

Therefore, in accordance with the regulations in § 92.5, we are announcing our decision to concur with the OIE risk classification of Nicaragua as a region of negligible risk for BSE.

Authority: 7 U.S.C. 1622 and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC, this 4th day of November 2019.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2019–24455 Filed 11–8–19; 8:45 am]

BILLING CODE 3410–34–P

[1] To view the comment we received, go to *https://www.regulations.gov/docket?D=APHIS-2018-0087.*

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2019–0062]

Notice of Availability of a Pest Risk Analysis for the Importation of Fresh Carrots From the Republic of Korea Into the United States

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of availability.

SUMMARY: We are advising the public that we have prepared a pest risk analysis that evaluates the risks associated with importation of fresh carrots from the Republic of Korea into the United States. Based on the analysis, we have determined that the application of one or more phytosanitary measures will be sufficient to mitigate the risks of introducing or disseminating plant pests or noxious weeds via the importation of fresh carrots from the Republic of Korea. We are making the pest risk analysis available to the public for review and comment.

DATES: We will consider all comments that we receive on or before January 13, 2020.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2019-0062.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2019–0062, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/*

#!*docketDetail;D=APHIS-2019-0062* or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Ms. Carol Kreger, Regulatory Policy Specialist, Regulatory Coordination and Compliance, PPQ, APHIS, 4700 River Road, Unit 133, Riverdale, MD 20737; (301) 851–2356.

SUPPLEMENTARY INFORMATION: Under the regulations in ''Subpart L—Fruits and Vegetables'' (7 CFR 319.56–1 through 319.56–12, referred to below as the regulations), the Animal and Plant Health Inspection Service (APHIS) prohibits or restricts the importation of fruits and vegetables into the United States from certain parts of the world to prevent plant pests from being introduced into or disseminated within the United States.

Section 319.56–4 contains a performance-based process for approving the importation of certain fruits and vegetables that, based on the findings of a pest risk analysis, can be safely imported subject to one or more of the five designated phytosanitary measures listed in paragraph (b) of that section.

APHIS received a request from the national plant protection organization (NPPO) of the Republic of Korea to allow the importation of fresh carrots into the United States. As part of our evaluation of the Republic of Korea's request, we have prepared a pest risk assessment (PRA) to identify pests of quarantine significance that could follow the pathway of importation of fresh carrots into the United States from the Republic of Korea. The PRA identifies two quarantine pests that could follow the pathway: *Helicobasidium mompa* and *Sclerotinia nivalis,* both phytopathogenic fungi. Based on the PRA, we prepared a risk management document (RMD) to identify phytosanitary measures that could be applied to the fresh carrots to mitigate the pest risk.

We have concluded that fresh carrots can be safely imported from the Republic of Korea into the United States using one or more of the five designated phytosanitary measures listed in § 319.56–4(b). The NPPO of the Republic of Korea would have to enter into an operational workplan with APHIS that spells out the daily procedures the NPPO will take to implement the measures identified in the RMD. These measures are summarized below:

- Carrots must be commercially produced and may be imported in commercial consignments only.
- Carrots must be grown in places of production registered and packed in packinghouses registered by the NPPO of the Republic of Korea as part of an export program to the United States.
- The NPPO of the Republic of Korea must review and maintain all forms and documents related to export program activities in registered places of production and packinghouses for at least 1 year and make them available to APHIS upon request.
- If the NPPO of the Republic of Korea finds that a place of production or packinghouse is not complying with the requirements of the systems approach, no carrot from the place of production or packinghouse will be eligible for export to the United States until APHIS and the NPPO of the Republic of Korea conduct an investigation and appropriate remedial actions have been implemented.
- Carrots must originate from a place of production that was inspected for signs of fungi of quarantine concern prior to harvest and found free of disease symptoms or must be treated with a broad-spectrum fungicide during the growing season, inspected prior to harvest, and found free of fungi of quarantine concern.
- Carrot taproots must be washed and disinfected, and free of soil and green tops.
- A biometric sample of carrot taproots (jointly agreed upon by APHIS and the NPPO) must be inspected in the Republic of Korea by the NPPO of the Republic of Korea following any post-harvest processing. The biometric sample must be visually inspected for the quarantine pests *Helicobasidium mompa* and *Sclerotinia nivalis.* If any quarantine fungi is found, the entire lot of carrots is prohibited from import into the United States. APHIS may prohibit the importation into the United States of carrots from the places of production for the season.
- Each consignment of carrots must be accompanied by a phytosanitary certificate issued by the NPPO of the Republic of Korea with an additional declaration (AD) stating that the consignment was produced and prepared for export in accordance with the operational workplan, and inspected and found free of pests of quarantine concern.
- Carrots are subject to inspection at the port of entry into the United States.
- Carrots presented for inspection at the port of entry to the United States must be identified to specify the place of production in which the carrots were produced, and the packinghouse(s), in which the carrots were processed and packed. This identification must be maintained until the carrots are released from the port of first arrival into the United States.

Each of the pest risk mitigation measures that would be required, along with evidence of their efficacy in removing pests of concern from the pathway, are described in detail in the RMD.

Therefore, in accordance with § 319.56–4(c)(3), we are announcing the availability of our PRA and RMD for public review and comment. Those documents, as well as a description of the economic considerations associated with the importation of fresh carrots from the Republic of Korea, may be viewed on the *Regulations.gov* website or in our reading room (see **ADDRESSES** above for a link to *Regulations.gov* and information on the location and hours of the reading room). You may request paper copies of these documents by calling or writing to the person listed under **FOR FURTHER INFORMATION CONTACT**. Please refer to the subject of the analysis you wish to review when requesting copies.

After reviewing any comments we receive, we will announce our decision regarding the import status of fresh carrots from the Republic of Korea in a subsequent notice. If the overall conclusions of our analysis and the Administrator's determination of risk remain unchanged following our consideration of the comments, then we will authorize the importation of fresh carrots from the Republic of Korea into the United States subject to the requirements specified in the RMD.

Authority: 7 U.S.C. 1633, 7701–7772, and 7781–7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 4th day of November 2019.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2019–24535 Filed 11–8–19; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

Adoption of Final Environmental Impact Statement (DOI–BLM–ID–B000–2014–0002–EIS) Prepared for the Bruneau-Owyhee Sage-Grouse Habitat Project

AGENCY: Natural Resources Conservation Service (NRCS), U.S. Department of Agriculture (USDA).

ACTION: Notice of Intent (NOI) to Adopt Final Environmental Impact Statement (FEIS).

SUMMARY: NRCS announces its intent to adopt the FEIS, titled ''Bruneau-Owyhee Sage-grouse Habitat Project'' (BOSH), prepared by the U.S. Department of the Interior Bureau of Land Management (BLM), under the provisions of the Council on Environmental Quality (CEQ) regulations. The proposed action will improve and maintain suitable sage-grouse habitat within southwestern Idaho by removing early stage encroaching western juniper.

DATES: We will consider comments that we receive by December 12, 2019.

ADDRESSES: We invite you to submit comments on this notice. In your comments, include the volume, date, and page number of this issue of the **Federal Register**. Comments may be submitted by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and search for Docket ID NRCS–2019–0018. Follow the instructions for submitting comments.
- *Mail, or Hand Delivery:* Trisha Cracroft, State Biologist, Natural Resources Conservation Service, 9173 or W Barnes Drive, Suite C Boise, Idaho 83709.

NRCS will post all comments on *http://www.regulations.gov.* In general, personal information provided with comments will be posted. If your comment includes your address, phone number, email, or other personal identifying information (PII), your comments, including PII, may be available to the public. You may request that your PII be withheld from public view, but this cannot be guaranteed. The copies of the BOSH FEIS is available at *https://eplanning.blm.gov/epl-front-office/eplanning/planAndProjectSite.do?methodName=dispatchToPatternPage&currentPageId=56816.*

FOR FURTHER INFORMATION CONTACT: Trisha Cracroft, State Biologist, NRCS, at (208) 378–5725 or *trisha.cracroft@id.usda.gov.* Persons with disabilities who require alternative means for communication should contact the USDA Target Center at (202) 720–2600 (voice).

SUPPLEMENTARY INFORMATION: NRCS announces its intent to adopt the Bruneau-Owyhee Sage-grouse Habitat Project Final EIS, as prepared by the U.S. Department of the Interior Bureau of Land Management (BLM), under the provisions of the CEQ regulations (40 CFR 1506.3). In response to the threat of sagebrush steppe habitat loss posed by the encroachment of western juniper, the proposed action is vegetative treatments to address early stage juniper encroachment in southwestern Idaho in order to maintain and improve sagebrush steppe habitat for the benefit of sage-grouse and other wildlife that rely on these habitats. Treatment methods would include cutting junipers with handsaws or chainsaws, lopping with pruning shears, and using heavy equipment such as a track-hoe fitted with a grinding implement (masticator) or a shearing implement (large, powerful pruning shears). Material may be scattered on site and left in place, or the material may be piled and burned or jackpot burned. Jackpot burning is a type of prescribed fire used to reduce concentrations (or jackpots) of vegetative fuel. Jackpot burning consumes surface fuels but not the overstory vegetation and is used following a pre-treatment such as thinning and/or pile burning to further reduce the surface fuels, help maintain the desired vegetation conditions and enhance the overall health and resiliency of the plant community. Old growth juniper would not be cut or burned regardless of encroachment phase, proximity to leks, or proximity to sage-grouse migration corridors. Cut juniper would be burned in areas near roads for public and fire fighter safety, areas where viewshed issues are a concern, and/or areas where fuel loading is a concern. Burning may also be completed to remove slash from meadow areas that would provide suitable sage-grouse brood rearing habitat. Jackpot and pile burning would take place once the juniper biomass has dried sufficiently and when soils are moist, frozen, or covered by snow. Project implementation would be in accordance with the methods (Section 2.2.4 in the FIES) and design features (Section 2.2.5 in the FEIS) to minimize or eliminate adverse impacts by the proposed action to the identified resources (*i.e.,* cultural resources, soils, vegetation, wildlife).

Sage-grouse inhabit sagebrush ecosystems that are at risk from juniper encroachment in areas including southwest Idaho and the BOSH project area. The BOSH project will improve and maintain suitable sage-grouse habitat by removing early stage encroaching western juniper on BLM-managed lands within the Bruneau and Owyhee field office boundaries in southwest Idaho. As described in the FEIS the project is 1.67 million acres with up to 726,000 acres proposed for treatment. Privately-owned land within the project area totals 241,820 acres. Private landowners in the project area may voluntarily choose to conduct the vegetative treatments described above on their own lands. NRCS proposes to provide technical and financial assistance through Farm Bill conservation program contracts with landowners to implement these vegetative treatments to remove early stage encroaching juniper for the purpose of improving sagebrush habitat. Each landowner will be responsible for ensuring that treatment methods meet NRCS conservation practice standards and specifications and may choose to do the work themselves, hire a contractor or coordinate with BLM (or its contractors) to complete the vegetative treatments.

Prior to recommending adoption, NRCS completed an internal checklist per NRCS's Title 190—, National Environmental Compliance Handbook, Part 610, subpart F, section 610.83(D) and subpart H, section 610.134. NRCS was not a cooperating agency on the development of the FEIS. NRCS proposed action is substantially similar to that analyzed in the FEIS therefore, it was determined that the FEIS does not need to be supplemented prior to adoption because circumstances have not changed nor is there new information indicating a new or supplemental EIS should be prepared.

NRCS requests feedback from the public, other agencies, tribes, and other interested parties on the proposal to adopt the BOSH FEIS, the FEIS itself, and any associated issues and concerns.

Mary Goode,

Acting Idaho State Conservationist, Natural Resources Conservation Service.

[FR Doc. 2019–24576 Filed 11–8–19; 8:45 am]

BILLING CODE 3410–16–P

BROADCASTING BOARD OF GOVERNORS

Government in the Sunshine Act Meeting Notice

TIME AND DATE: Thursday, November 14, 2019, 10:30 a.m. ET.

PLACE: Cohen Building, Room 3321, 330 Independence Ave. SW, Washington, DC 20237.

Subject: Notice of Meeting of the Broadcasting Board of Governors.

MATTERS TO BE CONSIDERED: The U.S. Agency for Global Media's (USAGM) Board of Governors (Board) will be meeting at the time and location listed above. The Board will vote on a consent agenda consisting of the minutes of its September 11, 2019 meeting and a resolution proposing Board meeting dates in 2020. The Board will receive a report from the USAGM's Chief Executive Officer and Director.

This meeting will be available for public observation via streamed webcast, both live and on-demand, on the agency's public website at *www.usagm.gov.* Information regarding this meeting, including any updates or adjustments to its starting time, can also be found on the agency's public website.

The public may also attend this meeting in person at the address listed above as seating capacity permits. Members of the public seeking to attend the meeting in person must register at *https://usagmboardmeetingnovember 2019.eventbrite.com* by 12:00 p.m. (ET) on November 13. For more information, please contact USAGM Public Affairs at (202) 203–4400 or by email at *pubaff@ usagm.gov.*

CONTACT PERSON FOR MORE INFORMATION: Persons interested in obtaining more information should contact Oanh Tran at (202) 203–4545.

Oanh Tran,

Executive Director.

[FR Doc. 2019–24627 Filed 11–7–19; 11:15 am]

BILLING CODE 8610–01–P

DEPARTMENT OF COMMERCE

Census Bureau

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

Agency: U.S. Census Bureau, Commerce.

Title: 2020 Census Post-Enumeration Survey Person Interview and Person Followup.

OMB Control Number: 0607–XXXX.

Form Number(s): D–1301, D–1301(PR), D–1400, D–1400(S), D–1709, D–1709(S), D–1409(E/S), D–1609(E/S).

Type of Request: Regular submission.

Number of Respondents: 293,250. This includes 190,000 housing units for Person Interview, 28,500 housing units for Person Interview Reinterview, 65,000 housing units for Person Followup, and 9,750 housing units for Person Followup Reinterview.

Average Hours per Response: 15 minutes.

Burden Hours: 73,313 hours.

Needs and Uses:

The Post-Enumeration Survey (PES) for the 2020 Census will be conducted to provide estimates of census net coverage error and components of census coverage (such as correct enumerations, omissions, and erroneous enumerations, including duplicates) for housing units and people living in housing units to improve future censuses. The primary sampling unit is the Basic Collection Unit, which is the smallest unit of collection geography for 2020 Census listing operations. As in the past, including the 2020 Census Coverage Measurement program, the Post-Enumeration Survey operations and activities must be conducted separate from and independent of the other 2020 Census operations.

The 2020 PES will use the dual-system estimation procedure, which depends on two independent systems of measurement. The independence between the PES and census operations is a fundamental necessity for dual-system estimation. The PES will comprise two independent enumerations of housing units and the household population within the same sample areas. These two enumerations are called the enumeration sample (E sample) and the population sample (P sample). The E sample contains the list of housing units and people enumerated in the 2020 Census within a sample of BCUs. The P sample contains housing units and people in the sample set of sample BCUs, but obtained independently from the census. The independent roster of housing units is obtained during the PES Independent Listing, while the independent roster of people is obtained during the PES Person Interview. The P sample housing units and people will be matched to all census housing units in the sample BCUs and surrounding BCUs.

The results of the housing unit matching operations will be used to determine which PES and census addresses will be eligible to go to the PES Person Followup operation. The Person Followup operation will contain approximately 190,000 sample addresses. The Person Interview Reinterview operation will be a sample of those cases with an estimate 28,500 sample addresses.

The computer-assisted PES Person Followup instrument will collect the following information for the housing units included in this operation:

1. Roster of people living at the housing unit at the time of the PES Person Followup operation.
2. Census Day (April 1, 2020) address information for people who moved into the sample address since Census Day.
3. Other addresses where a person may have been counted on Census Day.
4. Information to determine where each person should have been counted on Census Day (according to Census residence criteria). For example, interviewers will probe for people who might have been left off the household roster, ask additional questions about people who moved from another address on Census Day to the sample address, and collect additional information for people with multiple addresses.
5. Demographic information for each person in the household on Interview Day or Census Day. These data items include name, date of birth, age, sex, Hispanic origin, race, and relationship to the householder.
6. Name and above information for any person who has moved out of the sample address since Census Day (if known).
7. Tenure of the household or address status for unoccupied housing units.

The PES Person Interview Reinterview is a quality control operation that will be conducted on about 15 percent of the PES Person Interview cases. The purpose of the PES Person Interview Reinterview is to confirm that the PES Person Interview interviewer conducted a PES Person Interview with a household member or a proxy respondent and to conduct the complete PES Person Interview as needed if the original interview seems questionable.

For each case identified during matching with discrepancies between the PES Person Followup operation and census, the Census Bureau will conduct a PES Person Followup operation for selected people in the household. During the PES Person Followup operation, interviewers will use paper questionnaires to obtain information about the selected people. The PES Person Followup operation will collect the information needed to determine

where each selected person should be counted on Census Day (according to 2020 Census residence rules). For example, interviewers will probe for additional addresses where the person may have stayed during the year and dates of stay for each address.

The PES Person Followup Reinterview is a quality control operation that will be conducted on about 15 percent of the PES PFU cases. The purpose of the PES Person Followup Reinterview is to confirm that the PES Person Followup interviewer conducted a PES Person Followup interview with a household member or a proxy respondent and to conduct the complete PES Person Followup interview as needed if the original interview seems questionable.

Affected Public: Individuals or Households.

Frequency: One Time.

Respondent's Obligation: Mandatory.

Legal Authority: Title 13, U.S. Code, Sections 141 and 193.

This information collection request may be viewed at www.reginfo.gov. Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Sheleen Dumas,

Departmental Lead PRA Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2019–24587 Filed 11–8–19; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Economic Development Administration

Proposed Information Collection; Comment Request; Semi-Annual and Annual Data Collection Instruments for Economic Development Administration Grantees (Non-Infrastructure Programs)

AGENCY: Economic Development Administration, U.S. Department of Commerce

ACTION: Notice.

SUMMARY: The Department of Commerce, 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 the proposed information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before January 13, 2020.

ADDRESSES: Direct all written comments, requests for additional information, or requests for copies of the proposed information collection instrument and instructions to Ksenia Shadrina, Lead Performance and Program Evaluation Analyst, Performance and National Programs Division, Economic Development Administration U.S. Department of Commerce, 1401 Constitution Avenue NW, Mail Stop 71030, Washington, DC 20230, or via email at *KShadrina@eda.gov* or *PRAcomments@doc.gov.* All comments received are part of the public record. Comments will generally be posted without change. All Personally Identifiable Information (for example, name and address) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information.

All comments submitted in response to this notice are a part of the public record and will be made available to the public, which may include posting them on the *Regulations.gov* website. Comments will generally be posted without change. Please do not include information of a confidential nature, such as sensitive personal information or proprietary information. All Personally Identifiable Information (for example, name and address) voluntarily submitted may be publicly accessible. 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. Please note that comments that include a message stating the confidentiality of the communication will be treated as public comments and will be made available to the public.

SUPPLEMENTARY INFORMATION:

I. Abstract

The Economic Development Administration (EDA) leads the Federal economic development agenda by promoting innovation and competitiveness, preparing American regions for growth and success in the worldwide economy. The Public Works and Economic Development Act of 1965 (PWEDA) (42 U.S.C. 3121 *et seq.*) is EDA's organic authority and is the primary legal authority under which EDA awards grants. Under PWEDA, EDA provides financial assistance to both rural and urban distressed communities by fostering entrepreneurship, innovation and productivity through investments in infrastructure development, capacity building and business development in order to attract private capital investments and new and better jobs to regions experiencing substantial and persistent economic distress.

EDA's expansive portfolio of programs, the changing economy, and advances in the field of program evaluation make updates to EDA's methods for performance measurement and program evaluation necessary in order to ensure transparency, accountability, and effectiveness of EDA investments. The recently passed Foundations for Evidence-Based Policymaking Act of 2018 (Pub. L. 115–435) further emphasizes the importance of updating existing methodologies for performance measurement and program evaluation to align with evolving best practices.

EDA proposes revising Forms ED–916, ED–917, and ED–918, which are currently used to collect limited performance information on sponsored activities and resulting outcomes from the grantees receiving assistance under just three of EDA's non-infrastructure programs: Partnership Planning, University Center, and the Trade and Adjustment Assistance for Firms, respectively. The revised Forms ED–916, ED–917, and ED–918 would instead comprehensively cover all of EDA's non-infrastructure programs: Economic Adjustment Assistance (non-infrastructure projects), including new Revolving Loan Funds; Planning; Local Technical Assistance, including University Centers; Regional Innovation Strategies; Research and National Technical Assistance; and Trade Adjustment Assistance for Firms. The data on program-sponsored activities and associated outcomes will be collected on semi-annual and annual bases, respectively.

The revised data collection instruments were developed through cooperative agreements with a number of leading research institutions, most notably SRI International. The methodology and applications for the instruments are described in the *Innovative Metrics for Economic Development report* and *Toolkit for Economic Development Practitioners* that are available on EDA's website at *www.eda.gov/performance/.*

EDA does not propose to revise the remaining fourth form under this information collection, Form ED–915, which is used to collect information on infrastructure and existing revolving loan fund (RLF) projects funded through awards from EDA's Public works and Economic Adjustment Assistance programs. Form ED–915 would instead

be extended without change; however, EDA plans to revise Form ED–915 in the future to update the information collected on infrastructure projects. Note that all RLF awards made after the implementation of the revised Forms ED–916, ED–917, and ED–918 will be required to report performance information using those Forms; this requirement may be extended to all RLF awards when Form ED–915 is revised.

II. Method of Collection

The information will be collected through online data collection instruments. The information will be used by EDA personnel to monitor recipients' compliance with EDA's statutory and regulatory requirements and specific terms and conditions relating to individual awards, as well as for performance measurement and program evaluation analyses to ensure effectiveness of EDA's programs. The information collected will not be disseminated to the public, except at the aggregated level in studies and reports.

III. Data

OMB Control Number: 0610–0098.

Form Number(s): ED–915, ED–916, ED–917, ED–918.

Type of Review: Revision of a Currently Approved Collection (Forms ED–916, ED–917, ED–918) and Extension (without revision) of a Currently Approved Collection (Form ED–915).

Affected Public: EDA award recipients: State and local governments, institutions of higher education, not-for-profit organizations, and Indian Tribes.

Estimated Number of Respondents:

Revised Forms ED–916, ED–917, and ED–918:

Semi-annual: 550 respondents

Annual: 550 respondents

Extended (without revision) Form ED–915: 500 respondents

Total annual number of responses: (550 × 3) + 500 = 2,150 respondents

Estimated Time per Response:

Revised Forms ED–916, ED–917, and ED–918:

Semi-annual: 2.5 hours × 2 times per year

Annual: 6 hours once per year

Extended (without revision) Form ED–915: 8 hours

Estimated Total Annual Burden Hours:

Revised Forms ED–916, ED–917, and ED–918:

Semi-annual: 2,750 burden hours per year

Annual: 3,300 burden hours per year

Extended Form ED–915: 4,000 hours

Total hours: 10,050 burden hours per year

Estimated Total Annual Cost to Public: $576,568 (cost assumes application of U.S. Bureau of Labor Statistics second quarter 2019 mean hourly wage for professional and related occupations of $57.37).

IV. Request for Comments

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 shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (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 through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection. All public comments will become a matter of public record.

Sheleen Dumas,

Departmental Lead PRA Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2019–24583 Filed 11–8–19; 8:45 am]

BILLING CODE 3510–WH–P

DEPARTMENT OF COMMERCE

Economic Development Administration

Notice of Petitions by Firms for Determination of Eligibility To Apply for Trade Adjustment Assistance

AGENCY: Economic Development Administration, U.S. Department of Commerce.

ACTION: Notice and opportunity for public comment.

SUMMARY: The Economic Development Administration (EDA) has received petitions for certification of eligibility to apply for Trade Adjustment Assistance from the firms listed below. Accordingly, EDA has initiated investigations to determine whether increased imports into the United States of articles like or directly competitive with those produced by each of the firms contributed importantly to the total or partial separation of the firms' workers, or threat thereof, and to a decrease in sales or production of each petitioning firm.

SUPPLEMENTARY INFORMATION:

LIST OF PETITIONS RECEIVED BY EDA FOR CERTIFICATION OF ELIGIBILITY TO APPLY FOR TRADE ADJUSTMENT ASSISTANCE

[10/29/2019 through 11/4/2019]

Firm name	Firm address	Date accepted for investigation	Product(s)
Soy Essentials, LLC d/b/a The SOI Company.	5271 Jerusalem Court, Suite 1, Modesto, CA 95653.	10/31/2019	The firm manufactures candles.
Cadco, Ltd	200 International Way, Winsted, CT 06098.	11/1/2019	The firm manufacturers commercial food service appliances, such as convection ovens, buffet servers, and warming cabinets.
Confluence Outdoor, LLC	575 Mauldin Road, Suite 200, Greenville, SC 29607.	11/4/2019	The firm manufactures kayaks, canoes, paddle boards, paddles, and related accessories.
Vista Group International, Inc.	25 Van Zant Street, Unit 14–7B, Norwalk, CT 06855.	11/4/2019	The firm manufacturers audio systems to accompany museum exhibits and for use by tour guides.

Any party having a substantial interest in these proceedings may request a public hearing on the matter. A written request for a hearing must be submitted to the Trade Adjustment Assistance Division, Room 71030, Economic Development Administration, U.S. Department of Commerce, Washington, DC 20230, no later than ten

(10) calendar days following publication of this notice. These petitions are received pursuant to section 251 of the Trade Act of 1974, as amended.

Please follow the requirements set forth in EDA's regulations at 13 CFR 315.9 for procedures to request a public hearing. The Catalog of Federal Domestic Assistance official number and title for the program under which these petitions are submitted is 11.313, Trade Adjustment Assistance for Firms.

Irette Patterson,

Program Analyst.

[FR Doc. 2019–24488 Filed 11–8–19; 8:45 am]

BILLING CODE 3510–WH–P

DEPARTMENT OF COMMERCE

International Trade Administration

Initiation of Antidumping and Countervailing Duty Administrative Reviews

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

SUMMARY: The Department of Commerce (Commerce) has received requests to conduct administrative reviews of various antidumping (AD) and countervailing duty (CVD) orders and findings with September anniversary dates. In accordance with Commerce's regulations, we are initiating those administrative reviews.

DATES: Applicable November 12, 2019.

FOR FURTHER INFORMATION CONTACT: Brenda E. Brown, AD/CVD Operations, Customs Liaison Unit, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, telephone: (202) 482–4735.

SUPPLEMENTARY INFORMATION:

Background

Commerce has received timely requests, in accordance with 19 CFR 351.213(b), for administrative reviews of various AD and CVD orders and findings with September anniversary dates.

All deadlines for the submission of various types of information, certifications, or comments or actions by Commerce discussed below refer to the number of calendar days from the applicable starting time.

Notice of No Sales

If a producer or exporter named in this notice of initiation had no exports, sales, or entries during the period of review (POR), it must notify Commerce within 30 days of publication of this notice in the **Federal Register**. All submissions must be filed electronically at *http://access.trade.gov* in accordance with 19 CFR 351.303.[1] Such submissions are subject to verification in accordance with section 782(i) of the Tariff Act of 1930, as amended (the Act). Further, in accordance with 19 CFR 351.303(f)(1)(i), a copy must be served on every party on Commerce's service list.

Respondent Selection

In the event Commerce limits the number of respondents for individual examination for administrative reviews initiated pursuant to requests made for the orders identified below, Commerce intends to select respondents based on U.S. Customs and Border Protection (CBP) data for U.S. imports during the POR. We intend to place the CBP data on the record within five days of publication of the initiation notice and to make our decision regarding respondent selection within 30 days of publication of the initiation **Federal Register** notice. Comments regarding the CBP data and respondent selection should be submitted within seven days after the placement of the CBP data on the record of this review. Parties wishing to submit rebuttal comments should submit those comments within five days after the deadline for the initial comments.

In the event Commerce decides it is necessary to limit individual examination of respondents and conduct respondent selection under section 777A(c)(2) of the Act, the following guidelines regarding collapsing of companies for purposes of respondent selection will apply. In general, Commerce has found that determinations concerning whether particular companies should be ''collapsed'' (*e.g.,* treated as a single entity for purposes of calculating antidumping duty rates) require a substantial amount of detailed information and analysis, which often require follow-up questions and analysis. Accordingly, Commerce will not conduct collapsing analyses at the respondent selection phase of this review and will not collapse companies at the respondent selection phase unless there has been a determination to collapse certain companies in a previous segment of this AD proceeding (*e.g.,* investigation, administrative review, new shipper review, or changed circumstances review). For any company subject to this review, if Commerce determined, or continued to treat, that company as collapsed with others, Commerce will assume that such companies continue to operate in the same manner and will collapse them for respondent selection purposes. Otherwise, Commerce will not collapse companies for purposes of respondent selection. Parties are requested to (a) identify which companies subject to review previously were collapsed, and (b) provide a citation to the proceeding in which they were collapsed. Further, if companies are requested to complete the Quantity and Value (Q&V) Questionnaire for purposes of respondent selection, in general, each company must report volume and value data separately for itself. Parties should not include data for any other party, even if they believe they should be treated as a single entity with that other party. If a company was collapsed with another company or companies in the most recently completed segment of this proceeding where Commerce considered collapsing that entity, complete Q&V data for that collapsed entity must be submitted.

Deadline for Withdrawal of Request for Administrative Review

Pursuant to 19 CFR 351.213(d)(1), a party that has requested a review may withdraw that request within 90 days of the date of publication of the notice of initiation of the requested review. The regulation provides that Commerce may extend this time if it is reasonable to do so. Determinations by Commerce to extend the 90-day deadline will be made on a case-by-case basis.

Deadline for Particular Market Situation Allegation

Section 504 of the Trade Preferences Extension Act of 2015 amended the Act by adding the concept of a particular market situation (PMS) for purposes of constructed value under section 773(e) of the Act.[2] Section 773(e) of the Act states that ''if a particular market situation exists such that the cost of materials and fabrication or other processing of any kind does not accurately reflect the cost of production in the ordinary course of trade, the administering authority may use another calculation methodology under this subtitle or any other calculation methodology.'' When an interested party submits a PMS allegation pursuant to section 773(e) of the Act, Commerce will respond to such a submission

[1] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011).

[2] *See* Trade Preferences Extension Act of 2015, Public Law 114–27, 129 Stat. 362 (2015).

consistent with 19 CFR 351.301(c)(2)(v). If Commerce finds that a PMS exists under section 773(e) of the Act, then it will modify its dumping calculations appropriately.

Neither section 773(e) of the Act nor 19 CFR 351.301(c)(2)(v) set a deadline for the submission of PMS allegations and supporting factual information. However, in order to administer section 773(e) of the Act, Commerce must receive PMS allegations and supporting factual information with enough time to consider the submission. Thus, should an interested party wish to submit a PMS allegation and supporting new factual information pursuant to section 773(e) of the Act, it must do so no later than 20 days after submission of initial responses to section D of the questionnaire.

Separate Rates

In proceedings involving non-market economy (NME) countries, Commerce begins with a rebuttable presumption that all companies within the country are subject to government control and, thus, should be assigned a single antidumping duty deposit rate. It is Commerce's policy to assign all exporters of merchandise subject to an administrative review in an NME country this single rate unless an exporter can demonstrate that it is sufficiently independent so as to be entitled to a separate rate.

To establish whether a firm is sufficiently independent from government control of its export activities to be entitled to a separate rate, Commerce analyzes each entity exporting the subject merchandise. In accordance with the separate rates criteria, Commerce assigns separate rates to companies in NME cases only if respondents can demonstrate the absence of both *de jure* and *de facto* government control over export activities.

All firms listed below that wish to qualify for separate rate status in the administrative reviews involving NME countries must complete, as appropriate, either a separate rate application or certification, as described below. For these administrative reviews, in order to demonstrate separate rate eligibility, Commerce requires entities for whom a review was requested, that were assigned a separate rate in the most recent segment of this proceeding in which they participated, to certify that they continue to meet the criteria for obtaining a separate rate. The Separate Rate Certification form will be available on Commerce's website at *http://enforcement.trade.gov/nme/nme-sep-rate.html* on the date of publication of this **Federal Register** notice. In responding to the certification, please follow the ''Instructions for Filing the Certification'' in the Separate Rate Certification. Separate Rate Certifications are due to Commerce no later than 30 calendar days after publication of this **Federal Register** notice. The deadline and requirement for submitting a Certification applies equally to NME-owned firms, wholly foreign-owned firms, and foreign sellers who purchase and export subject merchandise to the United States.

Entities that currently do not have a separate rate from a completed segment of the proceeding [3] should timely file a Separate Rate Application to demonstrate eligibility for a separate rate in this proceeding. In addition, companies that received a separate rate in a completed segment of the proceeding that have subsequently made changes, including, but not limited to, changes to corporate structure, acquisitions of new companies or facilities, or changes to their official company name,[4] should timely file a Separate Rate Application to demonstrate eligibility for a separate rate in this proceeding. The Separate Rate Application will be available on Commerce's website at *http://enforcement.trade.gov/nme/nme-sep-rate.html* on the date of publication of this **Federal Register** notice. In responding to the Separate Rate Application, refer to the instructions contained in the application. Separate Rate Applications are due to Commerce no later than 30 calendar days after publication of this **Federal Register** notice. The deadline and requirement for submitting a Separate Rate Application applies equally to NME-owned firms, wholly foreign-owned firms, and foreign sellers that purchase and export subject merchandise to the United States.

For exporters and producers who submit a Separate Rate Application or Certification and subsequently are selected as mandatory respondents, these exporters and producers will no longer be eligible for separate rate status unless they respond to all parts of the questionnaire as mandatory respondents.

Initiation of Reviews

In accordance with 19 CFR 351.221(c)(1)(i), we are initiating administrative reviews of the following AD and CVD orders and findings. We intend to issue the final results of these reviews not later than September 30, 2020.

	Period to be reviewed
AD Proceedings	
Brazil: Cold-Rolled Steel Flat Products, A–351–843	9/1/18–8/31/19
Aperam Inox America do Sul S.A.	
Armco do Brasil S.A.	
Arvedi Metalfer do Brasil	
Companhia Siderurgica Nacional	
NVent do Brasil Eletrometalurgica	
Signode Brasileira Ltda.	
Usinas Siderurgicas de Minas Gerais (Usiminas)	
Brazil: Emulsion Styrene-Butadience Rubber, A–351–849	9/1/18–8/31/19
ARLANXEO Brasil S.A.	
India: Certain Line Paper Products, A–533–843	9/1/18–8/31/19
Cellpage Ventures Private Limited	
Goldenpalm Manufacturers PVT Limited	
Kokuyo Riddhi Paper Products Pvt. Ltd.	

[3] Such entities include entities that have not participated in the proceeding, entities that were preliminarily granted a separate rate in any currently incomplete segment of the proceeding (*e.g.,* an ongoing administrative review, new shipper review, *etc.*) and entities that lost their separate rate in the most recently completed segment of the proceeding in which they participated.

[4] Only changes to the official company name, rather than trade names, need to be addressed via a Separate Rate Application. Information regarding new trade names may be submitted via a Separate Rate Certification.

	Period to be reviewed
Lodha Offset Limited	
Lotus Global Private Limited	
Magic International Pvt. Ltd.	
Marisa International	
Navneet Education Ltd.	
Pioneer Stationery Pvt. Ltd.	
PP Bafna Ventures Private Limited	
SAB International	
SGM Paper Products	
Super Impex	
India: Oil Country Tubular Goods, A–533–857	9/1/18–8/31/19
Jindal SAW, Ltd.	
Japan: Tin Mill Products [5], A–588–854	8/1/18–7/31/19
Nippon Steel and Sumikin Bussan	
Mexico: Emulsion Styrene-Butadiene Rubber, A–201–848	9/1/18–8/31/19
Dynasol, LLC	
Industrias Negromex S.A. de C.V	
Negromex S.A. de C.V.	
Mexico: Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes, A–201–847	9/1/18–8/31/19
Arco Metal S.A. de C.V.	
Forza Steel S.A. de C.V.	
Industrias Monterrey, S.A. de C.V.	
Maquilacero S.A. de C.V.	
Perfiles y Herrajes LM S.A. de C.V.	
Productos Laminados de Monterrey S.A. de C.V.	
PYTCO S.A. de C.V.	
Regiomontana de Perfiles y Tubos S.A. de C.V.	
Ternium S.A. de C.V.	
Tuberia Nacional, S.A. de C.V.	
Tuberias Procarsa S.A. de C.V.	
Republic of Korea: Certain Cold-Rolled Steel Flat Products, A–580–881	9/1/18–8/31/19
AJU Steel Co., Ltd.	
Ameri Source Korea	
Busung Steel Co., Ltd.	
Cenit Co., Ltd.	
Daewoo Logistics Corporation	
Dai Yang Metal Co., Ltd.	
DK GNS Co., Ltd.	
Dongbu Incheon Steel Co., Ltd.	
Dongbu Steel Co., Ltd.	
Dongkuk Industries Co., Ltd.	
Dongkuk Steel Mill Co., Ltd.	
GS Global Corporation	
Hanawell Co., Ltd.	
Hankum Co., Ltd.	
Hyosung TNC Corporation	
Hyundai BNG Steel Co., Ltd.	
Hyundai Corporation	
Hyundai Glovis Co., Ltd.	
Hyundai Group	
Hyundai HYSCO	
Hyundai Motor Company	
Hyundai Steel Company	
ILJIN Steel Corporation	
ILJIN NTS Co., Ltd.	
Jeen Pung Industrial Co., Ltd.	
Kolon Global Corporation	
Okaya Korea Co., Ltd.	
PL Special Steel Co., Ltd.	
POSCO	
POSCO Coated and Color Steel Co., Ltd.	
POSCO Daewoo Corporation	
POSCO International Corporation	
Samsung C & T Corporation	
Samsung STS Co., Ltd.	
SeAH Steel Corporation	
SK Networks Co., Ltd.	
TGS Pipe Co., Ltd.	
TI Automotive Ltd.	
Republic of Korea: Emulsion Styrene-Butadiene Rubber, A–580–890	9/1/18–8/31/19

	Period to be reviewed
Daewoo International Corporation	
Hyundai Glovis Co.	
Kukje Trading Corp.	
Kumho Petrochemical Co. Ltd.	
LG Chem Ltd.	
Sungsan International Co., Ltd.	
WE International Co., Ltd.	
Republic of Korea: Heavy Walled Rectangular Welded Carbon Pipes and Tubes, A–580–880	9/1/18–8/31/19
Ahshin Pipe & Tube Company	
Bookook Steel Co., Ltd.	
Dong-A Steel Co., Ltd	
Dongbu Steel Co., Ltd.	
G.S. ACE Industry Co., Ltd.	
Ganungol Industries Co. Ltd.	
Hanjin Steel Pipe	
HiSteel Co., Ltd.	
Husteel Co., Ltd.	
Hyosung Corporation	
Hyundai Steel Co.	
Hyundai Steel Pipe Company	
K Steel Co. Ltd.	
Kukje Steel Co., Ltd.	
Miju Steel Manufacturing Co., Ltd.	
NEXTEEL Co., Ltd.	
POSCO DAEWOO	
Sam Kang Industrial Co., Ltd.	
Samson Controls Ltd., Co.	
SeAH Steel Corporation	
Shin Steel Co., Ltd.	
Yujin Steel Industry Co. Ltd.	
Republic of Korea: Oil Country Tubular Goods, A–580–870	9/1/18–8/31/19
AJU Besteel Co., Ltd.	
Blue Sea Precision Tube Co., Ltd.	
Bo Myung Metal Co., Ltd.	
BUMA CE Co., Ltd.	
Busung Steel Co., Ltd.	
Chang Won Bending Co., Ltd.	
Daeho P&C Co., Ltd.	
Daou Precision Ind. Co.	
Dongyang Steel Pipe Co., Ltd.	
Dongbu Incheon Steel Co., Ltd.	
Dongkuk Steel Mill Co., Ltd.	
EEW Korea Co., Ltd.	
Global Solutions Co., Ltd.	
Hansol Metal Co., Ltd.	
HiSteel Co., Ltd.	
HPP Co., Ltd.	
Husteel Co., Ltd.	
Hyundai Group	
Hyundai Corporation	
Hyundai HYSCO	
Hyundai RB Co., Ltd.	
Hyundai Steel Company	
ILJIN Steel Corporation	
Keonwoo Metals Co., Ltd.	
K Steel Corporation	
KF UBIS Co., Ltd.	
Korea Steel Co., Ltd.	
Kukje Steel Co., Ltd.	
KPF Co., Ltd.	
Kumkang Kind Co., Ltd.	
Kumsoo Connecting Co., Ltd.	
Master Steel Corporation	
MCK Co., Ltd.	
MS Pipe Co., Ltd.	
Msteel Co., Ltd.	
Nexen Corporation	
NEXTEEL Co., Ltd.	
Pneumatic Plus Korea Co., Ltd.	
POSCO International Corporation	
PSG Co., Ltd.	
Pusan Fitting Corporation	
SeAH FS Co., Ltd.	

	Period to be reviewed
SeAH Steel Corporation	
Sejong Ind. Co., Ltd.	
Seokyoung Steel & Technology Co., Ltd.	
SIC Tube Co., Ltd.	
ST Tubular Inc.	
Sungkwang Bend Co., Ltd.	
TGS Pipe Co., Ltd.	
TJ Glovsteel Co., Ltd.	
TSP Corporation	
Union Pipe MFG Co., Ltd.	
WSG Co., Ltd.	
Socialist Republic of Vietnam: Oil Country Tubular Goods, A–552–817	9/1/18–8/31/19
Pusan Pipe America, Inc.	
SeAH Steel VINA Corporation	
Taiwan: Forged Steel Fittings, A–583–863	5/17/18–8/31/19
Both-Well Steel Fittings, Co., Ltd.	
Taiwan: Narrow Woven Ribbons With Woven Selvedge, A–583–844	9/1/18–8/31/19
Banduoo Ltd.	
Fujian Rongshu Industry Co., Ltd.	
Maple Ribbon Co., Ltd.	
Roung Shu Industry Corporation	
Xiamen Yi-He Textile Co., Ltd.	
The People's Republic Of China: Certain Magnesia Carbon Bricks, A–570–954	9/1/18–8/31/19
Dandong Xinxing Carbon Co., Ltd.	
Fedmet Resources Corporation	
Fengchi Imp. and Exp. Co., Ltd.	
Fengchi Imp. and Exp. Co., Ltd. of Haicheng City	
Fengchi Mining Co., Ltd. of Haicheng City	
Fengchi Refractories Co., of Haicheng City	
Haicheng Donghe Taidi Refractory Co., Ltd.	
Henan Xintuo Refractory Co., Ltd.	
Liaoning Fucheng Refractories	
Liaoning Zhongmei High Temperature Material Co., Ltd.	
Liaoning Zhongmei Holding Co., Ltd.	
RHI Refractories Liaoning Co., Ltd.	
Shenglong Refractories Co., Ltd.	
Tangshan Strong Refractories Co., Ltd.	
The Economic Trading Group of Haicheng Houying Corp. Ltd.	
Yingkou Heping Samwha Minerals, Co., Ltd.	
Yingkou Heping Sanhua Materials Co., Ltd.	
Turkey: Heavy Walled Rectangular Welded Carbon Steel Pipes, A–489–824	9/1/18–8/31/19
Agir Haddecilik A.S.	
Cag Celik Demir ve Celik Endiistri A.S.	
Cinar Boru Profil San Ve Tic. A.S.	
Mescier Dis Ticaret Ltd. Sti.	
MTS Lojistik ve Tasimacilik Hizmetleri TIC A.S. Istanbul	
Noksel Celik Boru Sanayi A	
Ozdemir Boru Profil San. ve Tic. Ltd. Sti.	
SEBA Dis Ticaret A.S	
Tosyali Toyo Celik A.S.	
Turkey: Oil Country Tubular Goods, A–489–816	9/1/18–8/31/19
Bakır Grup Makine İmalat Bakım Montaj Demontaj Sanayi ve Ticaret Ltd. Şti.	
Cayirova Boru Sanayi ve Ticaret A.S.	
Hydra İnşaat Sanayi ve Ticaret Anonim Şirketi	
Kalibre Boru Sanayi ve Ticaret	
NETBORU San. ve Dış. Tic. Koll. Şti.	
Tosçelik Profil ve Sac Endustrisi A.S.	
Tosyali Dis Ticaret A.S.	
Tosyali Elektrik Enerjisi Toptan Satis Ith. Ihr. A.S.	
Tosyali Holding A.S.	
Tosyali Demir Celik San. A.S.	
Yılmaz Pipo	
Yucel Boru Ithalat-Ihracat ve Pazarlama A.S.	
United Kingdom: Cold-Rolled Steel Flat Products, A–412–824	9/1/18–8/31/19
Liberty Performance Steels Ltd.	
Tata Steel UK Ltd.	

CVD Proceedings Period to be Reviewed

Brazil: Cold-Rolled Steel Flat Products, C–351–844	1/1/18–12/31/18

	Period to be reviewed
Aperam Inox America do Sul S.A.	
Armco do Brasil S.A.	
Arvedi Metalfer do Brasil	
Companhia Siderurgica Nacional	
NVent do Brasil Eletrometalurgica	
Signode Brasileira Ltda.	
Usinas Siderurgicas de Minas Gerais (Usiminas)	
The Republic of Korea: Certain Cold-Rolled Steel Flat Products, C–580–882	1/1/18–12/31/18
AJU Steel Co., Ltd.	
Amerisource Korea	
BC Trade	
Busung Steel Co., Ltd.	
Cenit Co., Ltd	
Daewoo Logistics Corporation	
Dai Yang Metal Co., Ltd.	
DK GNS Co., Ltd.	
Dongbu Steel Co., Ltd.	
Dongbu Incheon Steel Co., Ltd.	
Dong Jin Machinery	
Dongkuk Steel Mill Co., Ltd.	
Dongkuk Industries Co., Ltd.	
Eunsan Shipping and Air Cargo Co., Ltd.	
Euro Line Global Co., Ltd.	
GS Global Corp.	
Hanawell Co., Ltd.	
Hankum Co., Ltd.	
Hyosung TNC Corp.	
Hyuk San Profile Co., Ltd.	
Hyundai Group	
Hyundai Steel Company	
Hyundai Steel Co., Ltd.	
Iljin NTS Co., Ltd.	
Iljin Steel Corp.	
Jeen Pung Industrial Co., Ltd.	
Kolon Global Corporation	
Nauri Logistics Co., Ltd.	
Okaya Korea Co., Ltd.	
PL Special Steel Co., Ltd.	
POSCO	
POSCO C&C Co., Ltd.	
POSCO Daewoo Corp.	
POSCO International Corp.	
Samsung C&T Corp.	
Samsung STS Co., Ltd.	
SeAH Steel Corp.	
SK Networks Co., Ltd.	
Taihan Electric Wire Co., Ltd.	
TGS Pipe Co., Ltd.	
TI Automotive Ltd. 41.	
Xeno Energy	
The People's Republic of China: Magnesia Carbon Bricks, C–570–955	1/1/18–12/31/18
Dandong Xinxing Carbon Co., Ltd.	
Fedmet Resources Corporation	
Fengchi Imp. and Exp. Co., Ltd.	
Fengchi Imp. and Exp. Co., Ltd. of Haicheng City	
Fengchi Mining Co., Ltd. of Haicheng City	
Fengchi Refractories Co., of Haicheng City	
Haicheng Donghe Taidi Refractory Co., Ltd.	
Henan Xintuo Refractory Co., Ltd.	
Liaoning Fucheng Refractories	
Liaoning Zhongmei High Temperature Material Co., Ltd.	
Liaoning Zhongmei Holding Co., Ltd.	
RHI Refractories Liaoning Co., Ltd.	
Shenglong Refractories Co., Ltd.	
Tangshan Strong Refractories Co., Ltd.	
The Economic Trading Group of Haicheng Houying Corp., Ltd.	
Yingkou Heping Samwha Minerals, Co., Ltd.	
Yingkou Heping Sanhua Materials Co., Ltd.	
The People's Republic of China: Narrow Woven Ribbons With Woven Selvedge, C–570–953	1/1/18–12/31/18
Yama Ribbons and Bows Co., Ltd.	
Turkey: Heavy Walled Rectangular Welded Carbon Steel Pipes, C–489–825	1/1/18–12/31/18

	Period to be reviewed
Agir Haddecilik A.S.	
Cag Celik Demir ve Celik Endiistri A.S.	
Cinar Boru Profil San Ve Tic. A.S.	
Mescier Dis Ticaret Ltd. Sti.	
MTS Lojistik ve Tasimacilik Hizmetleri TIC A.S. Istanbul	
Noksel Celik Boru Sanayi A	
Ozdemir Boru Profil San. ve Tic. Ltd. Sti.	
SEBA Dis Ticaret A.S	
Tosyali Toyo Celik A.S.	
Turkey: Oil Country Tubular Goods, C–489–817	1/1/18–12/31/18
Bakır Grup Makine İmalat Bakım Montaj Demontaj Sanayi ve Ticaret Ltd. Şti.	
Borusan Istikbal Ticaret	
Borusan Lojistik Dag. Deg. Tas Ve	
Borusan Mannesmann Boru Sanayi ve Ticaret A.Ş.	
Borusan Mannesmann Boru Yatirim Holding	
Cayirova Boru Sanayi ve Ticaret A.S.	
Hydra İnşaat Sanayi ve Ticaret Anonim Şirketi	
Kalibre Boru Sanayi ve Ticaret	
NETBORU San. ve Dış. Tic. Koll. Şti.	
Yılmaz Pipo	
Yucel Boru Ithalat-Ihracat ve Pazarlama A.S.	
Suspension Agreements	
None.	

Duty Absorption Reviews

During any administrative review covering all or part of a period falling between the first and second or third and fourth anniversary of the publication of an AD order under 19 CFR 351.211 or a determination under 19 CFR 351.218(f)(4) to continue an order or suspended investigation (after sunset review), Commerce, if requested by a domestic interested party within 30 days of the date of publication of the notice of initiation of the review, will determine whether AD duties have been absorbed by an exporter or producer subject to the review if the subject merchandise is sold in the United States through an importer that is affiliated with such exporter or producer. The request must include the name(s) of the exporter or producer for which the inquiry is requested.

Gap Period Liquidation

For the first administrative review of any order, there will be no assessment of antidumping or countervailing duties on entries of subject merchandise entered, or withdrawn from warehouse, for consumption during the relevant ''gap'' period of the order (*i.e.,* the period following the expiry of provisional measures and before definitive measures were put into place), if such a gap period is applicable to the POR.

Administrative Protective Orders and Letters of Appearance

Interested parties must submit applications for disclosure under administrative protective orders in accordance with the procedures outlined in Commerce's regulations at 19 CFR 351.305. Those procedures apply to administrative reviews included in this notice of initiation. Parties wishing to participate in any of these administrative reviews should ensure that they meet the requirements of these procedures (*e.g.,* the filing of separate letters of appearance as discussed at 19 CFR 351.103(d)).

Factual Information Requirements

Commerce's regulations identify five categories of factual information in 19 CFR 351.102(b)(21), which are summarized as follows: (i) Evidence submitted in response to questionnaires; (ii) evidence submitted in support of allegations; (iii) publicly available information to value factors under 19 CFR 351.408(c) or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2); (iv) evidence placed on the record by Commerce; and (v) evidence other than factual information described in (i)–(iv). These regulations require any party, when submitting factual information, to specify under which subsection of 19 CFR 351.102(b)(21) the information is being submitted and, if the information is submitted to rebut, clarify, or correct factual information already on the record, to provide an explanation identifying the information already on the record that the factual information seeks to rebut, clarify, or correct. The regulations, at 19 CFR 351.301, also provide specific time limits for such factual submissions based on the type of factual information being submitted. Please review the *Final Rule,*[6] available at *http://enforcement.trade.gov/frn/2013/1304frn/2013–08227.txt,* prior to submitting factual information in this segment.

Any party submitting factual information in an AD or CVD proceeding must certify to the accuracy and completeness of that information using the formats provided at the end of the *Final Rule.*[7] Commerce intends to reject factual submissions in any proceeding segments if the submitting party does not comply with applicable certification requirements.

Extension of Time Limits Regulation

Parties may request an extension of time limits before a time limit established under Part 351 expires, or as

[5] In the initiation notice that published on October 7, 2019 (84 FR 53411) Commerce inadvertently omitted ''Nippon Steel'' from the company name listed above. The correct company name is listed in this notice.

[6] *See Certification of Factual Information To Import Administration During Antidumping and Countervailing Duty Proceedings,* 78 FR 42678 (July 17, 2013) (*Final Rule*); *see also* the frequently asked questions regarding the *Final Rule,* available at *http://enforcement.trade.gov/tlei/notices/factual_info_final_rule_FAQ_07172013.pdf.*

[7] *See* section 782(b) of the Act; *see also Final Rule*; and the frequently asked questions regarding the *Final Rule,* available at *http://enforcement.trade.gov/tlei/notices/factual_info_final_rule_FAQ_07172013.pdf.*

otherwise specified by Commerce.[8] In general, an extension request will be considered untimely if it is filed after the time limit established under Part 351 expires. For submissions which are due from multiple parties simultaneously, an extension request will be considered untimely if it is filed after 10:00 a.m. on the due date. Examples include, but are not limited to: (1) Case and rebuttal briefs, filed pursuant to 19 CFR 351.309; (2) factual information to value factors under 19 CFR 351.408(c), or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2), filed pursuant to 19 CFR 351.301(c)(3) and rebuttal, clarification and correction filed pursuant to 19 CFR 351.301(c)(3)(iv); (3) comments concerning the selection of a surrogate country and surrogate values and rebuttal; (4) comments concerning CBP data; and (5) Q&V questionnaires. Under certain circumstances, Commerce may elect to specify a different time limit by which extension requests will be considered untimely for submissions which are due from multiple parties simultaneously. In such a case, Commerce will inform parties in the letter or memorandum setting forth the deadline (including a specified time) by which extension requests must be filed to be considered timely. This policy also requires that an extension request must be made in a separate, stand-alone submission, and clarifies the circumstances under which Commerce will grant untimely-filed requests for the extension of time limits. Please review the *Final Rule,* available at *http://www.gpo.gov/fdsys/pkg/FR-2013-09-;20/html/2013-22853.htm,* prior to submitting factual information in these segments.

These initiations and this notice are in accordance with section 751(a) of the Act (19 U.S.C. 1675(a)) and 19 CFR 351.221(c)(1)(i).

Dated: November 5, 2019.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2019–24461 Filed 11–8–19; 8:45 am]

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[8] *See* 19 CFR 351.302.

DEPARTMENT OF COMMERCE

International Trade Administration

[C–552–819]

Certain Steel Nails From the Socialist Republic of Vietnam: Rescission of Countervailing Duty Administrative Review; 2018

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

SUMMARY: The Department of Commerce (Commerce) is rescinding the administrative review of the countervailing duty order on certain steel nails (steel nails) from the Socialist Republic of Vietnam (Vietnam) for the period January 1, 2018, through December 31, 2018, based on the timely withdrawal of the request for review.

DATES: Applicable November 12, 2019.

FOR FURTHER INFORMATION CONTACT: Olatunbosun Leigh, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0506.

SUPPLEMENTARY INFORMATION:

Background

On July 1, 2019, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the countervailing duty order on steel nails from Vietnam for the period January 01, 2018, through December 31, 2018.[1] On July 31, 2019, Mid Continent Steel & Wire, Inc. (the petitioner), a domestic producer of steel nails, filed a timely request for review, in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.213(b).[2] Pursuant to this request, and in accordance with section 751(a) of the Act and 19 CFR 351.221(c)(1)(i), we initiated an administrative review of 16 companies.[3] On October 1, 2019, the petitioner filed a timely withdrawal of request for the administrative review with respect to all 16 companies.[4]

[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 84 FR 31295 (July 1, 2019).

[2] *See* Letter from the petitioner, ''Steel nails from Vietnam: Petitioner's Request for 2018 Administrative Review,'' dated July 31, 2019.

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 84 FR 47242 (September 9, 2019).

[4] *See* Letter from the petitioner, ''Certain Steel Nails from Vietnam: Withdrawal of Requests for Administrative Reviews,'' dated October 1, 2019.

Rescission of Review

Pursuant to 19 CFR 351.213(d)(1), the Secretary will rescind an administrative review, in whole or in part, if the party that requested the review withdraws the request within 90 days of the date of publication of the notice of initiation of the requested review. As noted above, the petitioner, the only party to file a request for review, withdrew its request by the 90-day deadline. Accordingly, we are rescinding the administrative review of the countervailing duty order on steel nails from Vietnam for the period January 1, 2018, through December 31, 2018, in its entirety.

Assessment

Commerce will instruct U.S. Customs and Border Protection (CBP) to assess antidumping duties on all appropriate entries of steel nails from Vietnam. Countervailing duties shall be assessed at rates equal to the cash deposit of estimated countervailing duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue appropriate assessment instructions to CBP 15 days after the date of publication of this notice in the **Federal Register**.

Notification to Importers

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

Notification Regarding Administrative Protective Orders

This notice also serves as a reminder to all 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. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213(d)(4).

Dated: November 5, 2019.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2019–24540 Filed 11–8–19; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–051]

Hardwood Plywood Products From the People's Republic of China: Rescission of Antidumping Duty New Shipper Review; 2019; Correction

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

DATES: Applicable November 12, 2019.

FOR FURTHER INFORMATION CONTACT: Jasun Moy, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–8194.

SUPPLEMENTARY INFORMATION:

Background

On September 27, 2019, the Department of Commerce (Commerce) published the *Rescission Notice* for the new shipper review of the antidumping duty order on hardwood plywood products (plywood) from the People's Republic of China (China).[1] In the *Rescission Notice,* we inadvertently stated that we would instruct U.S. Customs and Border Protection (CBP) to assess antidumping duties on entries of plywood from China during the period of review made by Xuzhou Constant Forest Industry Co., Ltd. (Constant Forest).

Correction to Rescission of Antidumping Duty New Shipper Review

Because the new shipper review of Constant Forest was not completed and Constant Forest's entries entered under a period for which parties will have an opportunity to request an administrative review, its entries should not be liquidated at this time. Once the opportunity to request an administrative review for the period January 1, 2019, through December 31, 2019, has passed, Commerce will assess duties on these entries consistent with either 19 CFR 351.212(b) (assessment as the result of a review) or 351.212(c) (automatic assessment if no review is requested). Commerce has deactivated the liquidation instructions issued to CBP's Automated Commercial Environment and intends to issue an informational message stating that these entries must remain suspended until further notice.

This notice is issued and published in accordance with sections 751 and 777(i)(l) of the Tariff Act of 1930, as amended, and 19 CFR 351.214(f)(3).

Dated: November 6, 2019.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2019–24538 Filed 11–8–19; 8:45 am]

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[1] *See Hardwood Plywood Products from the People's Republic of China: Rescission of Antidumping Duty New Shipper Review; 2019,* 84 FR 51111 (September 27, 2019) (*Rescission Notice*).

DEPARTMENT OF COMMERCE

International Trade Administration

[Application No. 19–00001]

Export Trade Certificate of Review

ACTION: Notice of issuance of an Export Trade Certificate of Review to National Pecan Shellers Association (''NPSA''), application number 19–00001.

SUMMARY: The Secretary of Commerce, through the Office of Trade and Economic Analysis (''OTEA''), issued an Export Trade Certificate of Review to NPSA on October 29, 2019.

FOR FURTHER INFORMATION CONTACT: Joseph Flynn, Director, OTEA, International Trade Administration, by telephone at (202) 482–5131 (this is not a toll-free number) or email at *etca@trade.gov.*

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of 1982 (15 U.S.C. Sections 4001–21) (''the Act'') authorizes the Secretary of Commerce to issue Export Trade Certificates of Review. An Export Trade Certificate of Review protects the holder and the members identified in the Certificate from State and Federal government antitrust actions and from private treble damage antitrust actions for the export conduct specified in the Certificate and carried out in compliance with its terms and conditions. The regulations implementing Title III are found at 15 CFR part 325. OTEA is issuing this notice pursuant to 15 CFR 325.6(b), which requires the Secretary of Commerce to publish a summary of the certification in the **Federal Register**. Under Section 305(a) of the Act and 15 CFR 325.11(a), any person aggrieved by the Secretary's determination may, within 30 days of the date of this notice, bring an action in any appropriate district court of the United States to set aside the determination on the ground that the determination is erroneous.

Description of Certified Conduct

A summary of the conduct covered by the Export Trade Certificate of Review follows.

Export Trade Activities and Methods of Operation

1. Establishment of Pecan Export Trade Council and Designation of Independent Third Party

a. NPSA will establish a specially-funded Pecan Export Trade Council (''PETC''), which will operate under the umbrella of NPSA. NPSA will contract with an Independent Third Party to manage and administer PETC. The Independent Third Party will not disclose information obtained from PETC or from a Member to another Member, an entity that is not a Member, and/or NPSA, except as described below and as limited by the Terms and Conditions in the Certificate of Review.

b. PETC will provide Export Trade Facilitation Services, including to the Members. PETC's charter members, and those certified to engage in Export Trade Activities, are the Members listed in Attachment A. An amendment to this Certificate is required to add members to PETC. PETC membership will be open to entities that are not NPSA members, but shall be limited to: (1) Exporting U.S. shellers (*i.e.,* entities with a commercial pecan shelling plant); (2) exporting U.S. pecan growers; and (3) exporting U.S. handlers of pecans. NPSA and PETC, once it is established, will not export Products, except as described below and as limited by the Terms and Conditions in the Certificate of Review.

2. Activities That Are Not Transaction-Specific

NPSA, acting through PETC, and including by use of Export Intermediaries, may:

a. Export Sales Prices. Discuss sales prices and other terms of sale prevailing in the Export Markets;

b. Marketing and Distribution. Conduct marketing and distribution of Products in the Export Markets;

c. Promotion. Conduct joint promotion of Products in the Export Markets;

d. Market and Customer Allocation. Allocate geographic areas or countries in the Export Markets and/or customers in the Export Markets among Members;

e. Refusals to Deal. Refuse to quote prices for Products, or to market or sell

Products, to or for any customers in the Export Markets, or any countries or geographical areas in the Export Markets;

f. Transportation Activities. Negotiate favorable transportation rates (volume discounts) and consolidate shipments to or within the Export Markets;

g. Exclusive and Nonexclusive Export Intermediaries. Enter into exclusive and nonexclusive agreements appointing one or more Export Intermediaries for the sale of Products with price, territorial, and/or customer restrictions as provided in this section.

3. Transaction-Specific Activities

a. For a given transaction or prospective transaction, any or all of the Members may join to bid for the sale of, and to sell, Products to the Export Markets, provided that each Member shall determine, independently of other Members, the quantity of Products the Member will make available for export. No Member shall be required to export any minimum quantity of Products.

b. For a given transaction or prospective transaction, and where individual Member commitments are required, for the purposes of allocating export quantities or determining price, the amount to be committed to the sale will be determined in the following manner:

i. The participating Member(s) will, without prior consultation, provide to the Independent Third Party the quantity of Products that it commits to the transaction and the price that it seeks.

ii. The Independent Third Party will independently incorporate such information into the joint sales or bid agreement. For the purposes of this provision, and to maintain the confidentiality of the data, ''independently'' means that the Independent Third Party will not disclose the information obtained from a Member to another Member, to an entity that is not a Member and/or to PETC, except as aggregated and will disclose the aggregated information only to the Members involved in the transaction. Information from individual Members shall not be disclosed by the Independent Third Party to the buyer.

4. Activities Involving Entities That Are Not Members

Individual Members may purchase Products from entities that are not Members to fulfill specific obligations in the Export Markets, provided that Members shall make such purchases only on a transaction-by-transaction basis and when the Members are unable to supply, in a timely manner, the requisite Products at a price competitive under the circumstances. In no event shall a supplier that is not a Member be included in any deliberations concerning any Export Trade Activities.

5. Information Exchange

Subject to section 1 of the Terms and Conditions in the Certificate, NPSA (acting through PETC) and Members may exchange and discuss the following information:

a. Information about sales and marketing efforts and prevailing market conditions for the Export Markets, including but not limited to activities and opportunities for sales of Products in the Export Markets, selling strategies for the Export Markets, sales for the Export Markets, contract and spot pricing in the Export Markets, projected demand in the Export Markets for Products, customary terms of sale in the Export Markets, prices and availability of Products from entities that are not Members for sale in the Export Markets, and specifications for Products by customers in the Export Markets;

b. Information about terms and conditions of contracts for sale in the Export Markets to be considered and/or bid on by NPSA acting through PETC;

c. Information about joint bidding or selling arrangements for the Export Markets;

d. Information about expenses specific to exporting to and within the Export Markets, including without limitation, expenses related to transportation, trans- or intermodal shipments, insurance, inland freight to port, port storage, commissions, export sales, documentation, financing, customs, duties, and taxes;

e. Information about U.S. and foreign legislation and regulations, including federal marketing order programs, affecting sales for the Export Markets;

f. Information about the export operations of PETC, including without limitation, information about sales and distribution networks established by NPSA acting through PETC or by Members in the Export Markets;

g. Information about export customer credit terms and credit history;

h. Information about completed and current export sales, provided that it is exchanged only when distributed by the Independent Third Party in aggregated and summary form to ensure confidentiality, and does not disclose, directly or by inference, information about completed and current sales by a specific Member.

6. Meetings

PETC and its Members, and where appropriate the Independent Third Party, may meet to engage in the activities described in sections 2–5 above.

The effective date of the Certificate is October 29, 2019.

Dated: November 6, 2019.

Joseph Flynn,

Director, Office of Trade and Economic Analysis, International Trade Administration, U.S. Department of Commerce.

[FR Doc. 2019–24586 Filed 11–8–19; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–943]

Oil Country Tubular Goods From the People's Republic of China: Rescission of Antidumping Duty Administrative Review; 2018–2019

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

SUMMARY: The Department of Commerce (Commerce) is rescinding the administrative review of the antidumping duty order on oil country tubular goods (OCTG) from the People's Republic of China (China) for the period May 1, 2018, through April 30, 2019, based on the timely withdrawal of the request for review.

DATES: Applicable November 12, 2019.

FOR FURTHER INFORMATION CONTACT: Olatunbosun Leigh or John Drury, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0506 or (202) 482–0195, respectively.

Background

On May 1, 2019, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the antidumping duty order on OCTG from China for the period May 1, 2018 through April 30, 2019.[1] On May 31, 2019, United States Steel Corporation, Maverick Tube Corporation, Tenaris Bay City, Inc., TMK IPSCO, Vallourec Star, L.P., and Welded Tube USA (the petitioners), filed a timely request for review, in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act),

[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 84 FR 18479 (May 1, 2019).

and 19 CFR 351.213(b).[2] Pursuant to this request, and in accordance with section 751(a) of the Act and 19 CFR 351.221(c)(1)(i), we initiated an administrative review of 130 companies.[3] On October 1, 2019, the petitioners filed a timely withdrawal of request for the administrative review with respect to all 130 companies.[4]

Rescission of Review

Pursuant to 19 CFR 351.213(d)(1), the Secretary will rescind an administrative review, in whole or in part, if the party that requested the review withdraws the request within 90 days of the date of publication of the notice of initiation of the requested review. As noted above, the petitioners, the only parties to file a request for review, withdrew their requests by the 90-day deadline. Accordingly, we are rescinding antidumping duty order on OCTG from China for the period May 1, 2018, through April 30, 2019, in its entirety.

Assessment

Commerce will instruct U.S. Customs and Border Protection (CBP) to assess antidumping duties on all appropriate entries of oil country tubular goods from China. Antidumping duties shall be assessed at rates equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue appropriate assessment instructions to CBP 15 days after the date of publication of this notice in the **Federal Register**.

Notification to Importers

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

[2] *See* Letter from the petitioners, ''Oil Country Tubular Goods from the People's Republic of China: Petitioners' Request for 2018/2019 Administrative Review,'' dated May 31, 2019.

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 84 FR 33739 (July 15, 2019).

[4] *See* Letter from the petitioners, ''Oil Country Tubular Goods from the People's Republic of China: Withdrawal of Request for Administrative Review,'' dated October 1, 2019.

Notification Regarding Administrative Protective Orders

This notice also serves as a reminder to all 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. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213(d)(4).

Dated: November 4, 2019.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2019–24460 Filed 11–8–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–113]

Certain Collated Steel Staples From the People's Republic of China: Preliminary Affirmative Countervailing Duty Determination, and Alignment of Final Determination With Final Antidumping Duty Determination

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

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that countervailable subsidies are being provided to producers and exporters of certain collated steel staples (collated staples) from the People's Republic of China (China) for the period of investigation (POI) January 1, 2018 through December 31, 2018. Interested parties are invited to comment on this preliminary determination.

DATES: Applicable November 12, 2019.

FOR FURTHER INFORMATION CONTACT: Bob Palmer or Joshua Simonidis, 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) 482–0608, respectively.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 703(b) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this investigation on July 3, 2019.[1]

On August 9, 2019, pursuant to a request from the Kyocera Senco Industrial Tools, Inc. (the petitioner),[2] Commerce postponed the preliminary determination of this investigation to November 4, 2019.[3] On October 24, 2019, Commerce issued its preliminary critical circumstances determination determining that critical circumstances exist for imports from all producers and exporters of the subject merchandise from China.[4]

For a complete description of the events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum.[5] A list of topics discussed in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov*, and is available to all parties in the Central Records Unit, Room B8024 of the main Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/*. The signed and electronic versions of the Preliminary Decision Memorandum are identical in content.

Scope of the Investigation

The product covered by this investigation is collated staples from China. For a complete description of the scope of this investigation, see

[1] *See Certain Collated Steel Staples from the People's Republic of China: Initiation of Countervailing Duty Investigation*, 84 FR 31840 (July 3, 2019) (*Initiation Notice*).

[2] *See* Petitioner's Letter, ''Certain Collated Steel Staples from the People's Republic of China: Petitioner's Request to Postpone the Deadline for the Preliminary Determination,'' dated August 5, 2019.

[3] *See Certain Collated Steel Staples from the People's Republic of China: Postponement of Preliminary Determination in the Countervailing Duty Investigation*, 84 FR 42896 (August 19, 2019).

[4] *See Certain Collated Steel Staples from the People's Republic of China: Preliminary Affirmative Determinations of Critical Circumstances in the Antidumping and Countervailing Duty Investigations, 84 FR 59353 (November 4, 2019) (signed October 24, 2019) (Preliminary Affirmative Critical Circumstances Determination).*

[5] *See* Memorandum, ''Decision Memorandum for the Preliminary Affirmative Determination: Countervailing Duty Investigation of Certain Collated Steel Staples from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

Appendix I and ''Scope Comments'' section below.

Scope Comments

In accordance with the Preamble to Commerce's regulations,[6] the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage (*i.e.*, scope).[7] Certain interested parties commented on the scope of the investigation as it appeared in the *Initiation Notice*.[8] Based on our preliminary analysis of these comments, we have not made any changes to the scope of the investigation. For a summary of the product coverage comments and responses submitted to the record for this preliminary determination, and accompanying discussion and analysis of all comments timely received, *see* the Preliminary Scope Decision Memorandum.[9]

Methodology

Commerce is conducting this investigation in accordance with section 701 of the Act. For each of the subsidy programs found countervailable, Commerce preliminarily determines that there is a subsidy, *i.e.*, a financial contribution by an ''authority'' that confers a benefit to the recipient, and that the subsidy is specific.[10] In making these findings, Commerce relied in part on facts available, and because Commerce found that certain respondents did not act to the best of their ability to respond to our requests for information, Commerce drew an adverse inference where appropriate in selecting from among the facts otherwise available.[11] For further information, *see* ''Use of Facts Otherwise Available and Adverse Inferences'' in the Preliminary Decision Memorandum. For a full description of the methodology underlying our preliminary conclusions, *see* the Preliminary Decision Memorandum.

Alignment

In accordance with section 705(a)(1) of the Act and 19 CFR 351.210(b)(4), Commerce is aligning the final determination in this countervailing duty investigation with the final determination in the companion antidumping duty investigation of collated staples from China, based on a request made by the petitioner.[12] Consequently, the final countervailing duty determination will be issued on the same date as the final antidumping duty determination, which is currently scheduled to be issued no later than March 17, 2020, unless postponed.

All-Others Rate

Sections 703(d)(1)(A)(i) and 705(c)(5)(A) of the Act provide that in the preliminary determination, Commerce shall determine an estimated all-others rate for companies not individually examined. This rate shall be an amount equal to the weighted average of the estimated subsidy rates established for those companies individually examined, excluding any zero and *de minimis* rates and any rates based entirely on facts otherwise available, as outlined under section 776 of the Act.

In this investigation, Commerce preliminarily assigned rates based entirely on facts available for Hai Sheng Xin Group Co., Ltd. and Ningbo Deli Stationery. Therefore, the only rate that is not zero, *de minimis*, or based entirely on facts otherwise available is the rate calculated for Zhejiang Best Nail Industrial Co., Ltd. (Best Nail). Consequently, the rate calculated for Best Nail is preliminarily assigned as the rate for all other producers and exporters.

Preliminary Determination

Commerce preliminarily determines that the following estimated countervailable subsidy rates exist:

Company	Subsidy rate (percent)
Zhejiang Best Nail Industrial Co., Ltd	12.38
Hai Sheng Xin Group Co., Ltd	156.99
Ningbo Deli Stationery	156.99
All Others	12.38

Suspension of Liquidation

In accordance with sections 703(d)(1)(B) and (d)(2) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise as described in the ''Scope of the Investigation'' section entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. Further, pursuant to 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit equal to the rates indicated above.

Section 703(e)(2) of the Act provides that, given an affirmative determination of critical circumstances,[13] any suspension of liquidation shall apply to unliquidated entries of merchandise entered, or withdrawn from warehouse, for consumption on or after the later of (a) the date which is 90 days before the date on which the suspension of liquidation was first ordered, or (b) the date on which the notice of initiation of the investigation was published. Commerce preliminarily found that critical circumstances exist for all imports of subject merchandise from China. In accordance with section 703(e)(2)(A) of the Act, the suspension of liquidation shall apply to unliquidated entries from all exporters and producers of the subject merchandise from China that were entered, or withdrawn from warehouse, for consumption on or after the date which is 90 days before the publication of this notice.

Disclosure

Commerce intends to disclose its calculations and analysis performed to interested parties in this preliminary determination within five days of its public announcement, or if there is no public announcement, within five days of the date of this notice in accordance with 19 CFR 351.224(b).

Verification

As provided in section 782(i)(1) of the Act, Commerce intends to verify the information relied upon in making its final determination.

[6] *See Antidumping Duties; Countervailing Duties, Final Rule*, 62 FR 27296, 27323 (May 19, 1997).

[7] *See Initiation Notice*, 84 FR at 31841.

[8] *See* Peace Industries Ltd.'s Letter, ''Certain Collated Steel Staples from Korea, the People's Republic of China, and Taiwan: Scope Comments,'' dated July 16, 2019; *see also* BeA Fasteners USA, Inc.'s (BeA) Letter, ''Antidumping and Countervailing Duty Investigations on Certain Collated Steel Staples from the People's Republic of China, the Republic of Korea, and Taiwan: Scope Comments,'' dated July 16, 2019; Petitioner's Letter, ''Certain Collated Steel Staples from the People's Republic of China: Response to Scope Comments,'' dated August 2, 2019; BeA's Letter, ''Antidumping and Countervailing Duty Investigations on Certain Collated Steel Staples From the People's Republic of China, the Republic of Korea, and Taiwan: Supplemental Scope Comments,'' dated October 11, 2019; and Petitioner's Letter, ''Certain Collated Steel Staples from the People's Republic of China: Response to BeA's Supplemental Scope Comments,'' dated October 17, 2019.

[9] *See* Memorandum, ''Less-Than-Fair-Value and Countervailing Duty Investigations of Certain Collated Steel Staples from the People's Republic of China: Preliminary Scope Decision Memorandum,'' dated concurrently with this notice (Preliminary Scope Decision Memorandum).

[10] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[11] *See* sections 776(a) and (b) of the Act.

[12] *See* Petitioner's Letter, ''Certain Collated Steel Staples from the People's Republic of China: Petitioner's Request for Alignment of Countervailing Duty Investigation Final Determination Deadline with Antidumping Investigation Final Determination Deadline,'' dated October 2, 2019.

[13] *See Preliminary Affirmative Critical Circumstances Determination*.

Public Comment

All interested parties will have the opportunity to submit case and rebuttal briefs on the preliminary scope determination. The deadline for these comments will be established in the **Federal Register** notice regarding the preliminary determination of the companion antidumping duty investigation of collated staples from China to be issued at a later date.

Case briefs or other written comments, not pertaining to scope issues, may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the last verification report is issued in this investigation. Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than five days after the deadline date for case briefs.[14] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this investigation are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at the U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Parties are reminded that briefs and hearing requests are to be filed electronically using ACCESS and that electronically filed documents must be received successfully in their entirety by 5 p.m. Eastern Time on the due date.

International Trade Commission Notification

In accordance with section 703(f) of the Act, Commerce will notify the International Trade Commission (ITC) of its determination. Pursuant to section 705(b)(2) of the Act, if the final determination is affirmative, the ITC will make its final injury determination before the later of 120 days after the date of this preliminary determination or 45 days after Commerce's final determination.

Notification to Interested Parties

This determination is issued and published pursuant to sections 703(f) and 777(i) of the Act and 19 CFR 351.205(c).

Dated: November 4, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The merchandise covered by the scope of this investigation is certain collated steel staples. Certain collated steel staples subject to this proceeding are made from steel wire having a nominal diameter from 0.0355 inch to 0.0830 inch, inclusive, and have a nominal leg length from 0.25 inch to 3.0 inches, inclusive, and a nominal crown width from 0.187 inch to 1.125 inch, inclusive.

Certain collated steel staples may be manufactured from any type of steel, and are included in the scope of the investigations regardless of whether they are uncoated or coated, and regardless of the type or number of coatings, including but not limited to coatings to inhibit corrosion.

Certain collated steel staples may be collated using any material or combination of materials, including but not limited to adhesive, glue, and adhesive film or adhesive or paper tape.

Certain collated steel staples are generally made to American Society for Testing and Materials (ASTM) specification ASTM F1667–18a, but can also be made to other specifications.

Excluded from the scope of these investigations are any carton-closing staples covered by the scope of the existing antidumping duty order on *Carton-Closing Staples from the People's Republic of China. See Carton-Closing Staples From the People's Republic of China: Antidumping Duty Order,* 83 FR 20792 (May 8, 2018).

Certain collated steel staples subject to these investigations are currently classifiable under subheading 8305.20.0000 of the Harmonized Tariff Schedule of the United States (HTSUS).

While the HTSUS subheading and ASTM specification are provided for convenience and for customs purposes, the written description of the subject merchandise is dispositive.

Appendix II

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Preliminary Determination of Critical Circumstances
IV. Alignment
V. Injury Test
VI. Diversification of China's Economy
VII. Use of Facts Otherwise Available and Adverse Inferences
VIII. Subsidies Valuation
IX. Benchmarks and Interest Rates
X. Analysis of Programs
XI. Recommendation

[FR Doc. 2019–24459 Filed 11–8–19; 8:45 am]

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[14] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–831]

Fresh Garlic From the People's Republic of China: Final Results of the Semiannual Antidumping Duty New Shipper Review of Jinxiang Infang Fruit & Vegetable Co., Ltd.

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

SUMMARY: The Department of Commerce (Commerce) has conducted a new shipper review (NSR) of Jinxiang Infang Fruit & Vegetable Co., Ltd. (Infang) regarding the antidumping duty order on fresh garlic from the People's Republic of China (China). The period of review (POR) is November 1, 2017 through May 31, 2018. Based on our analysis of the comments received, we continue to find that Infang's sale was a *bona fide* transaction, and that that sale was made below normal value (NV).

DATES: Applicable November 12, 2019.

FOR FURTHER INFORMATION CONTACT: Alex Cipolla, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4956.

SUPPLEMENTARY INFORMATION:

Background

On July 9, 2018, at the request of Infang, Commerce published a notice of initiation of a new shipper review of fresh garlic from China for the period November 1, 2017 through May 31, 2018.[1] On June 13, 2019, Commerce published the preliminary results of this new shipper review.[2] On August 29,

[1] *See Fresh Garlic from the People's Republic of China: Initiation of Semiannual Antidumping Duty New Shipper Review; 2017–2018,* 83 FR 31734 (July 9, 2018); *see also* Infang's Letter, ''Fresh Garlic from the People's Republic of China—Request for New Shipper Review,'' dated May 23, 2018.

[2] *See Fresh Garlic from the People's Republic of China: Preliminary Results of the Antidumping Duty New Shipper Review,* 84 FR 27585 (June 13, 2019) (*Preliminary Results*) and accompanying Preliminary Decision Memorandum.

2019, the deadline for the final results was extended to November 1, 2019.[3] On September 19, 2019, Commerce cancelled the planned verification of Infang's responses due to the petitioners'[4] withdrawal of their verification request.[5]

A summary of the events that occurred since Commerce published the *Preliminary Results,* as well as a full discussion of the issues raised by parties for this final determination, are found in the Issues and Decision Memorandum, hereby adopted by this notice.[6] The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov,* and it is available to all parties in the Central Records Unit, Room B8024 of the main Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* The signed and electronic versions of the Issues and Decision Memorandum are identical in content.

Scope of the Order

The merchandise covered by this order is all grades of garlic, whether whole or separated into constituent cloves. The subject merchandise is currently classifiable under the Harmonized Tariff Schedule of the United States (''HTSUS'') subheadings: 0703.20.0000, 0703.20.0005, 0703.20.0010, 0703.20.0015, 0703.20.0020, 0703.20.0090, 0710.80.7060, 0710.80.9750, 0711.90.6000, 0711.90.6500, 2005.90.9500, 2005.90.9700, and 2005.99.9700. A full description of the scope of the order is contained in the Issues and Decision Memorandum.[7] Although the HTSUS subheadings are provided for convenience and customs purposes, the written product description is dispositive.

Final Results of New Shipper Review

As explained in the Issues and Decision Memorandum, we continue to find that Infang's sale is *bona fide* within the meaning of section 751(a)(2)(B)(iv) of the Tariff Act of 1930, as amended (the Act). Commerce continues to find that the following weighted-average dumping margin exists for the period November 1, 2017 through May 31, 2018:

Producer/exporter	Weighted-average dumping margin (dollars per kg)
Producer: Jinxiang Excelink Foodstuffs Co., Ltd ..... Exporter: Jinxiang Infang Fruit & Vegetable Co., Ltd.	4.31

Analysis of Comments Received

All issues raised in the case and rebuttal briefs are addressed in the Issues and Decision Memorandum. A list of the issues that are raised in the briefs and addressed in the Issues and Decision Memorandum is in the Appendix to this notice.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of the NSR of Infang for shipments of subject merchandise from China entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by section 751(a)(2)(C) of the Act. Commerce will instruct U.S. Customs and Border Protection (CBP) to collect the following cash deposits: (1) For subject merchandise produced and exported by the producer and exporter combination listed in the ''Final Results of New Shipper Review'' section above, the cash deposit rate will be the rate listed above; (2) for subject merchandise exported by Infang, but not produced by Jinxiang Excelink Foodstuffs Co., Ltd., the cash deposit rate will be the rate for the China-wide entity; and (3) for subject merchandise produced by Jinxiang Excelink Foodstuffs Co., Ltd., but not exported by Infang, the cash deposit rate will be the rate applicable to the relevant exporter. These deposit requirements shall remain in effect until further notice.

Assessment Instructions

Pursuant to section 751(a)(2)(C) of the Act, and 19 CFR 351.212(b), 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. Commerce intends to issue assessment instructions directly to CBP 15 days after publication of this 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 POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Return or Destruction of Proprietary Information

This notice serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of business proprietary information disclosed under the APO in accordance with 19 CFR 351.305(a)(3). We request timely written notification of return or destruction of APO materials or conversion to judicial protective order. 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)(2)(B) and 777(i)(1) of the Act and 19 CFR 351.214.

Dated: November 1, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Discussion of the Issues
  Comment 1: Whether Romania or Mexico is a Significant Producer of Comparable Merchandise
  Comment 2: Whether the Garlic Market in Romania is Distorted
  Comment 3: Whether Garlic Grown in Romania or Mexico is of a Comparable Size to Garlic in China
  Comment 4: Whether Romania or Mexico Offer the Best Data
V. Recommendation

[FR Doc. 2019–24539 Filed 11–8–19; 8:45 am]

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[3] *See* Memorandum, ''Fresh Garlic from the People's Republic of China—2017–2018 Semiannual Antidumping Duty New Shipper Review: Extension of Deadline for the Final Results of the Review,'' dated August 29, 2019.

[4] The petitioners are the Fresh Garlic Producers Association (FGPA) and its individual members: Christopher Ranch L.L.C., the Garlic Company, and Valley Garlic.

[5] *See* Petitioners' Letter, ''27th New Shipper Review of the Antidumping Duty Order on Fresh Garlic from the People's Republic of China—Petitioners' Withdrawal of Request for Verification,'' dated August 23, 2019.

[6] *See* Memorandum, ''Decision Memorandum for the Final Results of the Semiannual 2017–2018 Antidumping Duty New Shipper Review: Fresh Garlic from the People's Republic of China,'' dated November 1, 2019 (Issues and Decision Memorandum).

[7] *See* the Issues and Decision Memorandum.

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XR046

Marine Mammals; File No. 23023

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

ACTION: Notice; receipt of application.

SUMMARY: Notice is hereby given that Robert Wayne, University of California Los Angeles, 610 Charles E. Young Drive East, Los Angeles, CA 90095, has applied in due form for a permit to receive, import, and export marine mammal parts for scientific research.

DATES: Written, telefaxed, or email comments must be received on or before December 12, 2019.

ADDRESSES: The application and related documents are available for review by selecting ''Records Open for Public Comment'' from the ''Features'' box on the Applications and Permits for Protected Species (APPS) home page, *https://apps.nmfs.noaa.gov,* and then selecting File No. 23023 from the list of available applications.

These documents are also available upon written request or by appointment in the Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376.

Written comments on this application should be submitted to the Chief, Permits and Conservation Division, at the address listed above. Comments may also be submitted by facsimile to (301) 713–0376, or by email to *NMFS.Pr1Comments@noaa.gov.* Please include the File No. in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request to the Chief, Permits and Conservation Division at the address listed above. The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Shasta McClenahan or Erin Markin, (301) 427–8401.

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

The applicant proposes to import biological samples for scientific research from up to 40 fin whales (*Balaenoptera physalus*) to perform a population genomics study that includes sequencing multiple complete fin whale genomes, with the objective of characterizing the genome-wide effects of population size reductions, isolation, and inbreeding in fin whale populations. The requested duration of the permit is 5 years.

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

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

Dated: November 5, 2019.

Julia Marie Harrison,

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

[FR Doc. 2019–24457 Filed 11–8–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XR064

Marine Mammals; File No. 23467

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

ACTION: Notice; receipt of application.

SUMMARY: Notice is hereby given that Sarah Conner, Wild Space Productions, St. Stephens House, Colston Avenue, Bristol, BS1 4ST, United Kingdom, has applied in due form for a permit to conduct commercial or educational photography on marine mammals.

DATES: Written, telefaxed, or email comments must be received on or before December 12, 2019.

ADDRESSES: These documents are available upon written request or by appointment in the Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376.

Written comments on this application should be submitted to the Chief, Permits and Conservation Division, at the address listed above. Comments may also be submitted by facsimile to (301) 713–0376, or by email to *NMFS.Pr1Comments@noaa.gov*. Please include the File No. in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request to the Chief, Permits and Conservation Division at the address listed above. The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Shasta McClenahan or Erin Markin, (301) 427–8401.

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216).

The applicant proposes to film pinnipeds in Monterey Bay National Marine Sanctuary to obtain footage for a wildlife documentary celebrating the world's greatest national parks and marine sanctuaries. Up to 1,520 Northern elephant seals (*Mirounga angustirostris*), 200 California sea lions (*Zalophus californianus*), 30 Steller sea lions (*Eumetopias jubatus;* Eastern Distinct Population Segment), and 30 harbor seals (*Phoca vitulina*) may be filmed from land or unmanned aircraft systems. The permit would expire on February 28, 2021.

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

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

Dated: November 5, 2019.

Julia Marie Harrison,

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

[FR Doc. 2019–24458 Filed 11–8–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XR053]

Endangered and Threatened Species; Take of Anadromous Fish

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

ACTION: Notice; extension of comment period.

SUMMARY: NMFS is extending the public comment period on the proposed Deschutes Basin Habitat Conservation Plan (DBHCP) developed by the Deschutes Basin Board of the Control and the City of Prineville (applicants) in support of their application for an incidental take permit from NMFS and the U.S. Fish and Wildlife Service (USFWS). The USFWS prepared a draft environmental impact statement (EIS) in compliance with the National Environmental Policy Act (NEPA). NMFS is a cooperating agency under NEPA for this action.

DATES: The original notice issued on October 4, 2019 (84 FR 53114), provided for a comment period to end on November 18, 2019. The comment period is now extended 15 days and will close on December 3, 2019. Comments must be received at the appropriate address (see **ADDRESSES**) no later than 11:59 p.m. Eastern time on December 3, 2019. Comments received after this date may not be accepted.

ADDRESSES: Copies of the proposed DBHCP are available for public inspection online at *https://www.fisheries.noaa.gov/action/proposed-deschutes-basin-habitat-conservatioin-plan.* The draft EIS (and the proposed DBHCP) can be viewed online at *http://www.regulations.gov,* Docket No. FWS–R1–ES–2019–0091.

You may submit comments by the following methods. You do not need to resubmit comments if they have already been submitted.

- *Electronic Submission: http://www.regulations.gov.* Follow instructions for submitting comments on Docket No. FWS–R1–ES–2019–0091.
- *Hard Copy:* Submit by U.S. mail or hand delivery to Public Comments Processing, Attn: Docket No. FWS–R1–ES–2019–0091, U.S. Fish and Wildlife Service, 5275 Leesburg Pike, MS: JAO/1N, Falls Church, VA 22041–3803.

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

FOR FURTHER INFORMATION CONTACT: Scott Carlon, NMFS (503) 231–2379 or by email at *scott.carlon@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Statutory Authority

Section 9 of the ESA prohibits the taking of any listed species. The definition of ''take'' under the ESA (16 U.S.C. 1532(19)) includes to harass, harm, hunt, shoot, wound, kill, trap, capture, collect, or attempt to engage in any such conduct. NMFS may issue permits, under limited circumstances to take listed species incidental to, and not the purpose of, otherwise lawful activity. Section 10(a) of the ESA and implementing regulations specify requirements for the issuance of incidental take permits (ITP) to non-Federal entities for the take of endangered and threatened species. NMFS regulations governing permits for threatened and endangered species are at 50 CFR 222.307. Any proposed take must be incidental to otherwise lawful activities, not appreciably reduce the likelihood of the survival and recovery of the species in the wild, and minimize and mitigate the impacts of such take to the maximum extent practicable. In addition, the applicant must prepare an habitat conservation plan describing the impact that will likely result from such taking, the strategy for minimizing and mitigating the take, the funding available to implement such steps, alternatives to such taking, and the reason such alternatives are not being implemented.

Background

The NMFS and USFWS received an incidental take permit application from the applicants on August 30, 2019. The eight DBBC-member districts are quasi-municipal organizations formed and operated according to Oregon state law to distribute water to irrigators within designated geographic boundaries. Collectively, the districts serve over 7,653 patrons and provide water for approximately 151,000 acres. The City of Prineville operates City-owned infrastructure and provides essential services to over 9,000 residents including municipal water supply, sewage treatment and public safety.

The application included the proposed DBHCP, which describes how impacts to steelhead, spring-run Chinook salmon, sockeye salmon, bull trout and Oregon spotted frog (hereafter covered species) would be minimized and mitigated. The proposed DBHCP also describes the estimated potential impact on covered species' populations, adaptive management, monitoring, and mitigation measures.

The various activities carried out by the applicants modify the quantity and quality of flow in the Deschutes River and its tributaries through the storage, release, diversion and return of irrigation water and the release of treated municipal sewage. The proposed DBHCP would modify covered activities to reduce the negative effects on the covered species aquatic habitat.

Dated: November 5, 2019.

Angela Somma,

Chief, Endangered Species Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2019–24486 Filed 11–8–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG910

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to the Sand Island Pile Dike System Test Piles Project Near the Mouth of the Columbia River

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 U.S. Army Corps of Engineers, Portland District (Corps) to incidentally harass, by Level A and Level B harassment only, marine mammals during construction activities associated with the Sand Island Pile Dike System Test Piles project near the Mouth of the Columbia River.

DATES: This Authorization is effective for one year from the date of issuance.

FOR FURTHER INFORMATION CONTACT: Rob Pauline, Office of Protected Resources, NMFS, (301) 427–8401. Electronic copies of the application and supporting documents, as well as the issued IHA, 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 such 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 such takings are set forth.

Summary of Request

On March 6, 2019, NMFS received a request from the Corps for an IHA to take marine mammals incidental to pile driving activities in the Columbia River Estuary. The application was deemed adequate and complete on June 20, 2019. The Corps' request is for take of a small number of harbor porpoises (*Phocoena phocoena*), Steller sea lions (*Eumetopias jubatus*), California sea lions (*Zalophus californianus*), and harbor seals (*Phoca vitulina richardii*) by Level B harassment and Level A harassment. Neither the Corps nor NMFS expect serious injury or mortality to result from this activity and, therefore, an IHA is appropriate.

Description of Activity

Overview

The Corps plans to drive test piles in order to investigate the feasibility of different construction methods at two of the four Sand Island pile dikes at the Mouth of the Columbia River (MCR) (Figure 1 in application). The Sand Island pile dikes are comprised of four pile dikes, which are named according to river mile (RM) location, at RMs 4.01, 4.47, 5.15, and 6.37 (the pile dike at RM 6.37 is also referred to as the Chinook pile dike). Three of the pile dikes are connected to West Sand Island and East Sand Island, and the fourth pile dike in open water runs parallel to the Chinook Channel on the upstream side (Figure 2 in application). The Sand Island pile dikes are part of the Columbia River pile dike system and were installed in the 1930's. The Corps intends to restore full functionality of pile dikes in the future but needs to drive test piles in order to inform possible design. The existing pile dikes have deteriorated greatly due to lack of maintenance. Impact and vibratory pile installation and vibratory pile removal would introduce underwater sounds at levels that may result in take, by Level A and Level B harassment, of marine mammals in the Columbia River Estuary. In-water construction activities are expected to last up to 41 days. The maximum 41 days of work includes the following estimates for various pile driving activities:

- Up to 20 days of impact driving only (steel piles);
- Up to 18 days of impact driving AND vibratory installation/removal of steel piles; and
- Up to 3 days for vibratory removal of timber piles only.

A detailed description of the planned test pile project is provided in the **Federal Register** notice for the proposed IHA (84 FR 38227; August 6, 2019). Since that time, no changes have been made to the planned pile driving activities. Therefore, a detailed description is not provided here. Please refer to that **Federal Register** notice for the description of the specific activity.

Comments and Responses

We published a notice of receipt of the Corps application and proposed IHA in the **Federal Register** on August 6, 2019 (84 FR 38227). We received one comment letter from the Marine Mammal Commission (Commission).

Comment 1: The Commission recommended that NMFS continue to prioritize the development of a methodology for determining the extent of the Level A harassment zones based on the associated permanent threshold shift (PTS) cumulative SEL (SELcum) thresholds for the various types of sound sources. The Commission also noted that NMFS should consider incorporating animat modeling into its user spreadsheet.

Response: The issue of accumulation time continues to be a priority for NMFS. The Working Group assembled by NMFS to specifically address this issue is exploring several options, including the use of animat modeling. Once the NMFS internal Working Group develops a proposal, it will be shared with Federal partners and other stakeholders.

Comment 2: The Commission questioned whether the public notice provision, for IHA renewals, including the 15-day comment period, fully satisfy the public notice and comment provision in the MMPA. The Commission also noted the potential burden on reviewers of reviewing key documents and developing comments quickly. Therefore the Commission recommended that NMFS refrain from using the proposed renewal process for the Corps' authorization. The Commission also recommended that NMFS use the IHA Renewal process sparingly and selectively for activities expected to have the lowest levels of impacts to marine mammals and that require less complex analysis. The Commission's final recommendation to NMFS was to provide the Commission and other reviewers the full 30-day comment period as set forth in section 101(a)(5)(D)(iii) of the MMPA

Response: The Commission has raised this concern before and NMFS refers readers to our full response, which may be found in the notice of issuance of an IHA to Ørsted Wind Power LLC (84 FR 52464, October 2, 2019.

Changes From Proposed to Final Authorization

Based on informal coordination with the Commission, NMFS has made several changes since the publication of the proposed IHA. The number of Level A and Level B harassment takes for both harbor porpoise and harbor seal were underestimated in the proposed IHA. Therefore, authorized take by Level A and Level B harassment for both species has increased and is described in detail in the ''Estimated Take'' section. In the monitoring report, NMFS will require that the Corps extrapolate observed takes across the entirety of the Level B harassment zone based on the area that is able to be monitored effectively. This

measure is described in the ''Monitoring'' section. Finally, the Corps will be required to provide marine mammal observational datasheets or raw data as part of the marine mammal monitoring report. These changes are described in the ''Reporting'' section.

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).*

Table 1 lists all species with expected potential for occurrence near the test piles project area 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 (2016). 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 Marine Mammal SARs (Carretta *et al.,* 2019) an Alaska Marine Mammal SARS (Muto *et al.,* 2019). All values presented in Table 1 are the most recent available at the time of publication.

TABLE 1—MARINE MAMMAL SPECIES LIKELY TO BE FOUND NEAR THE TEST PILES PROJECT AREA

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, 25849, 2016)	801	139
Family Balaenopteridae (rorquals):						
Humpback whale	*Megaptera novaeangliae*	California/ Oregon/ Washington	-, -, Y	2,900 (0.05, 2,784, 2014)	16.7	40.2
Superfamily Odontoceti (toothed whales, dolphins, and porpoises)						
Family Delphinidae:						
Killer whale	*Orcinus orca*	West Coast Transient	-, -, N	243 (N/A, 243, 2009)	2.4	0
Family Phocoenidae (porpoises):						
Harbor porpoise	*Phocoena phocoena*	Northern Oregon/ Washington Coast	-, -, N	21,487 (044, 15,123, 2011)	151	3.0
Order Carnivora—Superfamily Pinnipedia						
Family Otariidae (eared seals and sea lions):						
California sea lion	*Zalophus californianus*	U.S. Stock	-, -, N	257,606 (N/A, 233,515, 2014)	14,011	>320
Steller sea lion	*Eumetopias jubatus*	Eastern U.S	-, -, N	41,638 (See SAR, 41,638, 2015).	2,498	108
Family Phocidae (earless seals):						
Harbor seal	*Phoca vitulina richardii*	Oregon and Washington Coast	-, -, N	UNK (UNK, UNK, 1999)	UND	10.6

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

[2] NMFS marine mammal stock assessment reports online at: *www.nmfs.noaa.gov/pr/sars/.* CV is coefficient of variation; Nmin 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.

A detailed description of the of the species likely to be affected by the test pile 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 (84 FR 38227; August 6, 2019); 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. More general information about these species (*e.g.,* physical and behavioral descriptions) may be found on NMFS' website (*https://www.fisheries.noaa.gov/find-species*).

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

Underwater noise from impact and vibratory pile driving activities associated with the planned test piles project has the potential to result in harassment of marine mammals in the vicinity of the action area. The **Federal Register** notice for the proposed IHA (84 FR 38227; August 6, 2019) included a discussion of the potential effects of such disturbances on marine mammals and their habitat, therefore that information is not repeated in detail here; please refer to the **Federal Register** notice (84 FR 38227; August 6, 2019).

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 primarily be by Level B harassment, as impact and vibratory pile driving has the potential to result in disruption of behavioral patterns for individual marine mammals. There is also some potential for auditory injury (Level A harassment) to result, primarily for high frequency species and phocids because predicted auditory injury zones are larger than for low-frequency species, mid-frequency species and otariids. Auditory injury is unlikely to occur for low-frequency species, mid-frequency species and otariids. The mitigation and monitoring measures are expected to minimize the severity of such taking to the extent practicable.

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 take estimate.

Acoustic Thresholds

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

Level B Harassment 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 μPa (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.

The Corps' planned activity includes the use of continuous (vibratory pile driving) and impulsive (impact pile driving) sources, and therefore the 120 and 160 dB re 1 μPa (rms) are 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). The Corp's planned activity includes the use of impulsive (impact pile driving) and non-impulsive (vibratory pile driving) source.

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 1μPa²s. 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.

Sound Propagation

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:

$TL = B * \log_{10} (R_1/R_2)$,

Where:

B = transmission loss coefficient (assumed to be 15)

R_1 = the distance of the modeled SPL from the driven pile, and

R_2 = the distance from the driven pile of the initial measurement.

This formula neglects loss due to scattering and absorption, which is assumed to be zero here. The degree to which underwater sound propagates away from a sound source is dependent on a variety of factors, most notably the water bathymetry and presence or absence of reflective or absorptive conditions including in-water structures and sediments. Spherical spreading occurs in a perfectly unobstructed (free-field) environment not limited by depth or water surface, resulting in a 6 dB reduction in sound level for each doubling of distance from the source (20*log(range)). Cylindrical spreading occurs in an environment in which sound propagation is bounded by the water surface and sea bottom, resulting in a reduction of 3 dB in sound level for each doubling of distance from the source (10*log(range)). As is common practice in coastal waters, here we assume practical spreading loss (4.5 dB reduction in sound level for each doubling of distance). Practical spreading is a compromise that is often used under conditions where water depth increases as the receiver moves away from the shoreline, resulting in an expected propagation environment that would lie between spherical and cylindrical spreading loss conditions.

Sound Source Levels

The intensity of pile driving sounds is greatly influenced by factors such as the type of piles, hammers, and the physical environment in which the activity takes place. There are no source level measurements available the piles planned for installation at part of the test piles project. Sound pressure levels for impact driving of 24-in steel piles were taken from Caltrans 2015. Vibratory driving source levels for 24-in steel piles came from the United States Navy (2015). There was no data available pertaining to vibratory removal of 24-in timber piles. NMFS recommended that the Corps use data derived from Washington Department of Transportation Seattle Pier 62 project collected by the Greenbusch Group (2018) for vibratory removal of 14-in timber piles. NMFS reviewed the Greenbusch Group (2018) report and determined that the findings were incorrectly derived by pooling together all steel pile and timber pile measurements at various distances. Furthermore, the data was not normalized to the standard 10 m distance. NMFS analyzed source measurements at different distances for all 63 individual timber piles that were removed and normalized the values to 10 m. The results showed that the median is 152 dB SPLrms. This value was used as the proxy source level for vibratory removal of 24-in timber piles as shown in Table 5.

TABLE 5—ESTIMATED UNATTENUATED UNDERWATER SOUND PRESSURE LEVELS ASSOCIATED WITH PILE INSTALLATION AND REMOVAL

Pile type & activity	Sound source level at 10 m		
24-Inch Steel Pile Impact Installation [1]	203 dB_{PK}	190 dB_{RMS}	177 dB_{SEL}.
24-Inch Steel Piles Vibratory Installation/Removal [2]	Not Applicable	161 dB_{RMS}	Not Available.
24-Inch Timber Pile Vibratory Removal [3]	Not Applicable	152 dB_{RMS}	Not Available.

[1] From CalTrans 2015 Table I.2–1. Summary of Near-Source (10-Meter) Unattenuated Sound Pressure Levels for In-Water Pile Driving Using an Impact Hammer: 0.61-meter (24-inch) steel pipe pile in water ~5 meters deep.

[2] From United States Navy. 2015. Prepared by Michael Slater, Naval Surface Warfare Center, Carderock Division, and Sharon Rainsberry, Naval Facilities Engineering Command Northwest. Revised January 2015. Table 2–2.

[3] Due to the lack of information for vibratory removal of 24′ diameter timber piles, an estimate based on removal of 14-inch timber piles is used as a proxy (Greenbusch Group, 2018).

Level A Harassment

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 pile driving, NMFS User Spreadsheet predicts the closest distance at which, if a marine mammal remained at that distance the whole duration of the activity, it would not

incur PTS. Inputs used in the User Spreadsheet, and the resulting isopleths are reported below in Table 6.

TABLE 6—NMFS TECHNICAL GUIDANCE (2018) USER SPREADSHEET INPUT TO CALCULATE PTS ISOPLETHS

Inputs	24-in steel impact installation	24-in steel vibratory installation/removal	24-in timber pile removal
Spreadsheet Tab Used	E.1) Impact Pile Driving	A.1) Vibratory Pile Driving	A.1) Vibratory Pile Driving.
Source Level (Single Strike/shot SEL)	177 dB SEL/203 dB Peak	161 dB RMS	152 dB RMS.
Weighting Factor Adjustment (kHz)	2	2.5	2.5.
Number of strikes per pile	550		
Number of piles per day	6	6/9	9.
Duration to install/removal single pile (minutes)	60	30/5	5.
Propagation (xLogR)	15	15	15.
Distance of source level measurement (meters)	10	10	10.

TABLE 7—LEVEL A HARASSMENT (PTS) ISOPLETHS

Activity	PTS Isopleth distance (meters)				
	LF cetacean	MF cetacean	HF cetacean	Phocid pinniped	Otariid pinniped
24″ Steel Pipe Pile Impact Installation	881.2	31.3	1,049.7	471.6	34.3
24″ Steel Pipe Vibratory Installation	14.2	1.3	21.0	8.6	0.6
24″ Steel Pipe Vibratory Removal	5.6	0.5	8.3	3.4	0.2
24″ Timber Pile Removal Vibratory	1.4	0.1	2.1	0.9	0.1

Level B Harassment

Utilizing the practical spreading loss model, the Corps determined underwater noise will fall below the behavioral effects threshold of 160 dB and 120 dB rms for marine mammals at the distances shown in Table 8 with corresponding ensonified areas.

TABLE 8—LEVEL B HARASSMENT ISOPLETHS

Activity	Isopleth distance (m)	Isopleth area (km^2) *
24″ Steel Pipe Pile Impact Installation	1,000	3–4
24″ Steel Pipe Vibratory Installation	5,412	64–73
24″ Steel Pipe Vibratory Removal	5,412	64–73
24″ Timber Pile Removal Vibratory	1,359	0.6–0.7

* The lower limit represents the isopleth area for the pile dike at RM 4.01, which has a slightly smaller area due to land impedances. The upper limit of the range is the calculated isopleth area for the pile dike at RM 6.37.

Marine Mammal Occurrence and Take Calculation and Estimation

In this section we provide the information about the presence, density, or group dynamics of marine mammals that will inform the take calculations. Potential exposures to impact pile driving, vibratory pile driving and vibratory pile removal were estimated using group size estimates and local observational data. As previously stated, take by Level B harassment as well as small numbers of take by Level A harassment will be will be considered for this action. Take by Level B and Level A harassment are calculated differently for some species based on monthly or daily sightings data and average group sizes within the action area using the best available data. Take by Level A harassment is authorized for two species where the Level A harassment isopleths are very large during impact pile driving (harbor porpoise and harbor seal). Distances to Level A harassment thresholds for other project activities (vibratory pile driving/removal) are considerably smaller compared to impact pile driving, and mitigation is expected to avoid Level A harassment from these other activities.

Cetaceans

Harbor Porpoise

Harbor porpoises are regularly observed in the oceanward waters near the MCR and are known to occur there year-round. Porpoise abundance peaks when anchovy (*Engraulis mordax*) abundance in the river and nearshore are highest, which is usually between April and August (Litz *et al.* 2008). The 2016 monitoring report indicated that porpoises were sighted on 5 separate occasions (Grette Associates, 2016) while none were recorded as part of the 2017 LOA monitoring report. NMFS assumed a sighting rate of one animal per day in the proposed IHA for the Level B harassment. However, porpoises often occur in groups of 2–3. Therefore, to estimate take for days when there is vibratory pile driving and the Level B harassment zone is large (about five times the distance, and 20 times the area, of the Level B harassment zone for impact-only pile driving), NMFS has included consideration of a group size of 2 animals and will authorize take of two animals per driving day. With 21 days of vibratory driving (18 days of impact/vibratory and 3 days of timber pile vibratory removal), the number of authorized harbor porpoise takes by Level B harassment has been increased from 21 to 42 to account for this

increase in the estimated number of harbor porpoises likely to enter that zone per day.

For impact pile driving, the Level A harassment zone is slightly larger than the Level B harassment zone, and as noted above, about one twentieth of the area of the Level B harassment zone for vibratory pile driving. For the proposed IHA, NMFS assumed that due their cryptic behavior, it was plausible that during the 20 days of impact-only driving, some number of porpoises could enter into the Level A harassment zone without being detected by PSOs, and we initially proposed that 10 would be taken (approximately one fourth of the number currently projected for vibratory pile driving, which has a Level B harassment zone 20 times larger). No take by Level B harassment is proposed during impact only driving days (beyond that already counted within the Level A harassment zone) since the Level A harassment isopleth is greater than the Level B isopleth for HF cetaceans. However, in the proposed IHA we neglected to consider the Level A harassment that might occur in the 18 days that includes both vibratory and impact pile driving, and therefore we have increased the Level A harassment of harbor porpoises from 10 to 20.

Pinnipeds

Take calculations for Steller sea lions and California sea lions were estimated in the IHA using abundance estimates from the South Jetty recorded by the Washington Department of Fish and Wildlife (WDFW) between 2000 and 2014. The South Jetty is approximately four kilometers to the south of Sand Island. The Level B harassment area includes the entirety of the South Jetty where pinnipeds haul out. In order to estimate take, the average number of animals seen for the months of September, October, and November was used a basis for overall pinniped abundance as shown in Table 9. Since there was no data available for harbor seals during those three months, the December average was used to represent the average during the previous three months. NMFS assumed animals counted at the South Jetty comprised the majority of pinnipeds present in the Lower Columbia River west of Interstate 101 between September and November. This total area, including the jetties, was approximately 275 km^2. NMFS calculated the density of each pinniped species per km^2, then multiplied by the area of the harassment zone and number of workdays anticipated at each pile dike (Table 10).

NMFS used the methodology described above to estimate take of harbor seals in the proposed IHA resulting in estimated take of 3 seals by Level A harassment and 270 seals by Level B harassment. However, the Commission felt that the calculated harbor seal density underrepresents the number of seal that may occur at the project area. Harbor seals have been documented at two sites in Chinook/Baker Bay that are within the Level B harassment zone. These sites, however, are used only intermittently and feature less than 100 animals. There are an additional three haulouts at Desmond Sands, located southeast of the project area, including the main lower Columbia River seal haulout. Two of the haulouts are described as alternate sites to the main haulout and are used intermittently. Surveys resulted in counts of less than 100 seals at one site and 100–500 seals at the other. More than 500 seals have been recorded at the main river haulout at Desmond Sands. However, that location is approximately 10 km from the nearest test pile location (RM 6.37) or 5 km beyond the largest Level B harassment zone so may over represent seal numbers in the project area. NMFS opted to use WDFW abundance estimates from the South Jetty between 2000 and 2014 where the maximum daily number of observed seals was 57 as shown in Table 9. This daily take rate was multiplied by the number of driving days (41) resulting in 2,337 authorized takes by Level B harassment. This same daily take rate was used to estimate take of harbor seals for the recently expired IHA issued to the City of Astoria for a waterfront bridge replacement project (83 FR 19243; May 5, 2018).

Level A harassment takes for seals could when either an animal pops up in the 100-m shut-down zone before the operators are able to cease pile driving or when a seal occurs within the larger Level A harassment zone of 472-m for impact driving. NMFS has increased harbor seal authorized take by Level A harassment by assuming that two animals could be taken on each of the 38 days of impact driving. NMFS has increased authorized Level A harassment takes of harbor seals from 3 to 76 and the Level B harassment takes of harbor seals from 270 to 2,337.

TABLE 9—AVERAGE DAILY NUMBER OF PINNIPEDS PER MONTH ON SOUTH JETTY

[2000–2014]

Month	Average number of steller sea lions/month	Average number of California sea lions/month	Average number of harbor seals/month
September	209	249	.....
October	384	508	.....
November	1,663	1,214	.....
December	.....	.....	57
Construction Period Average	752	657	57

Source: Data from Washington Department of Fish and Wildlife 2014.

TABLE 10—ESTIMATED LEVEL B AND LEVEL A TAKE CALCULATIONS FOR PINNIPEDS AT RIVER MILE (RM) 4.01 AND 6.37

Species	Density (animals/km^2)	Activity type	Level B isopleth area RM 4.01	Level B isopleth area RM 6.37	Take/day RM 4.01	Take/day RM 6.37	Total take RM 4.01	Total take RM 6.37	Estimated total takes (Level B)
Stellar Sea lion	2.73	Impact Installation [1]	3	4	8.19	10.92	82	109	3,563
		Vibratory Installation/Removal [2].	64	73	174.72	199.29	1572	1794	
		Timber Vibratory Removal [3].	0.6	0.7	1.64	1.91	2	3	
							1657	1906	

TABLE 10—ESTIMATED LEVEL B AND LEVEL A TAKE CALCULATIONS FOR PINNIPEDS AT RIVER MILE (RM) 4.01 AND 6.37—Continued

Species	Density (animals/km²)	Activity type	Level B isopleth area RM 4.01	Level B isopleth area RM 6.37	Take/day RM 4.01	Take/day RM 6.37	Total take RM 4.01	Total take RM 6.37	Estimated total takes (Level B)
California Sea lion ..	2.39	Impact Installation ..	3	4	7.17	9.56	72	96	3,119
		Vibratory Installation/Removal.	64	73	152.96	174.47	1377	1570	
		Timber Vibratory Removal.	0.6	0.7	1.43	1.67	2	3	
							1450	1668	
		Impact Installation ..	0.8	0.9	0.15	0.11	2	1	

[1] Assumes 10 days each at RM 4.01 and RM 6.37 for all pinniped species.
[2] Assumes 9 days each at RM 4.01 and RM 6.37 for all pinniped species.
[3] Assumes 1.5 days each at RM 4.01 and RM 6.37 for all pinniped species.

Table 11 illustrates the stocks NMFS has authorize for take and the percentage of the stock taken.

TABLE 11—LEVEL A AND LEVEL B HARASSMENT TAKE ESTIMATES FOR THE SAND ISLAND PILE DIKES TEST PILES

Species	Level A take	Level B take	Stock abundance	Percentage of stock taken
Harbor porpoise	20	42	21,487	0.3
California Sea Lion	.....	3,119	296,750	1.1
Stellar Sea Lion	.....	3,563	61,746	5.8
Harbor Seal	76	2,337	24,732	9.7

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 such activity, and other means of effecting the least practicable impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such 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 such 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.

In addition to the measures described later in this section, the Corps must employ the following standard mitigation measures:

- Conduct briefings between construction supervisors and crews and the marine mammal monitoring team prior to the start of all pile driving activity, and when new personnel join the work, to explain responsibilities, communication procedures, marine mammal monitoring protocol, and operational procedures;
- For in-water heavy machinery work other than pile driving/removal (*e.g.,* standard barges, tug boats), if a marine mammal comes within 25 m, operations shall cease and vessels shall reduce speed to the minimum level required to maintain steerage and safe working conditions. This type of work could include the following activities: (1) Movement of the barge to the pile location; or (2) positioning of the pile on the substrate via a crane (*i.e.,* stabbing the pile);
- Work may only occur during daylight hours, when visual monitoring of marine mammals can be conducted;
- For any marine mammal species for which take by Level B harassment has not been requested or authorized, in-water pile installation/removal will shut down immediately when the animals are sighted;
- If take by Level B harassment reaches the authorized limit for an authorized species, pile installation will be stopped as these species approach the Level B harassment zone to avoid additional take of them.

Establishment of Shutdown Zones and Level A Harassment Zones—For all pile driving/removal and activities, the Corps establish a shutdown zone. 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 type of driving/removal activity type and by marine mammal hearing group, (See Table 10). Here, shutdown zones are larger than the calculated Level A harassment isopleth shown in Table 7, except for harbor seals during impact driving when a 100-

m shutdown zone and a 475-m Level A harassment zone will be visually monitored. The largest shutdown zones are generally for low frequency and high frequency cetaceans. The placement of (PSOs) during all pile driving/removal activities (described in detail in the Monitoring and Reporting Section) will ensure that the entirety of all shutdown zones are visible during pile installation.

TABLE 12—SHUTDOWN ZONES DURING PROJECT ACTIVITIES

Activity	Distance (meters)				
	LF cetacean	MF cetacean	HF cetacean	Phocid pinniped	Otariid pinniped
24″ Steel Pipe Pile Impact Installation	890	35	1050	100	35
24″ Steel Pipe Vibratory Installation	25	25	25	25	25
24″ Steel Pipe Vibratory Removal	25	25	25	25	25
24″ Timber Pile Removal Vibratory	25	25	25	25	25

Establishment of Monitoring Zones for Level B Harassment—The Corps will establish monitoring zones, based on the Level B harassment zones which are areas where SPLs are equal to or exceed the 160 dB rms threshold for impact driving and the 120 dB rms threshold during vibratory driving/removal. 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 cease of activity should the animal enter the shutdown zone. Due to the large size of the Level B harassment zones, it is impracticable for the PSOs to consistently view the entire harassment area. Therefore, takes by Level B harassment will be recorded and extrapolated based upon the number of observed takes and the percentage of the Level B harassment zone that was not visible. Distances to the Level B harassment zones are depicted in Table 13.

TABLE 13—DISTANCES TO LEVEL B HARASSMENT ZONES DURING PROJECT ACTIVITIES

Activity	Distance (m)
24″ Steel Pipe Pile Impact Installation	1,000
24″ Steel Pipe Vibratory Installation	5,420
24″ Steel Pipe Vibratory Removal	5,420
24″ Timber Pile Removal Vibratory	1,360

Soft Start—The use of a soft-start procedures is believed to provide additional protection to marine mammals by providing warning and/or giving marine mammals a chance to leave the area prior to the hammer operating at full capacity. For impact pile driving, contractors will be required to provide an initial set of strikes from the hammer at reduced percent energy, each strike followed by no less than a 30-second waiting period. This procedure will be conducted a total of three times before impact pile driving begins. Soft Start is not required during vibratory pile driving and removal activities. A soft start must be implemented at the start of each day's impact pile driving and at any time following cessation of impact pile driving for a period of thirty minutes or longer. If a marine mammal is present within the Level A harassment zone, soft start will be delayed until the animal leaves the Level A harassment zone. Soft start will begin only after the PSO has determined, through sighting, that the animal has moved outside the Level A harassment zone. If a marine mammal is present in the Level B harassment zone, soft start may begin and a Level B take will be recorded. Soft start up may occur when these species are in the Level B harassment zone, whether they enter the Level B zone from the Level A zone or from outside the monitoring area.

Pre-Activity Monitoring—Prior to the start of daily in-water construction activity, or whenever a break in pile driving of 30 minutes or longer occurs, PSOs will observe the shutdown and monitoring zones for a period of 30 minutes. The shutdown zone will be 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, a soft-start cannot proceed until the animal has left the zone or has not been observed for 15 minutes. If the Level B harassment zone has been observed for 30 minutes and marine mammals are not present within the zone, soft start procedures can commence and work can continue even if visibility becomes impaired within the Level B harassment zone. When a marine mammal permitted for take by Level B harassment is present in the Level B harassment zone, piling activities may begin and take by Level B will be recorded. As stated above, if the entire Level B harassment zone is not visible at the start of construction, pile driving/removal activities can begin. If work ceases for more than 30 minutes, the pre-activity monitoring of both the Level B harassment and shutdown zone will commence.

Based on our evaluation of the applicant's proposed measures, as well as other measures considered by NMFS, we have determined that the 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

Monitoring would 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 equipment is no more than thirty minutes.

There will be at least two PSOs employed during all pile driving/removal activities. PSO will not perform duties for more than 12 hours in a 24-hour period. One PSO would be positioned close to pile driving/removal activities at the best practical vantage point. A second PSO would be vessel-based to provide best coverage of the appropriate Level A and Level B harassment zones. If waters exceed a sea-state which restricts the observers' ability to make boat-based observations for the full Level A shutdown zone (*e.g.,* excessive wind, wave action, or fog), impact pile installation will cease until conditions allow monitoring to resume. Contractors should ensure compliance with NOAA advisories for safe boat operations based on the size of vessel to be used by the marine mammal observer.

As part of monitoring, PSOs would scan the waters using binoculars, and/or spotting scopes, and would use a handheld GPS or range-finder device to verify the distance to each sighting from the project site. All PSOs would be trained in marine mammal identification and behaviors and are required to have no other project-related tasks while conducting monitoring. In addition, monitoring will be conducted by qualified observers, who will be placed at the best vantage point(s) practicable to monitor for marine mammals and implement shutdown/delay procedures when applicable by calling for the shutdown to the hammer operator. Qualified observers are trained and/or experienced professionals, with the following minimum qualifications:

• Visual acuity in both eyes (correction is permissible) sufficient for discernment of moving targets at the water's surface with ability to estimate target size and distance; use of binoculars may be necessary to correctly identify the target;

• Independent observers (*i.e.,* not construction personnel);

• Observers must have their CVs/resumes submitted to and approved by NMFS;

• Advanced education in biological science or related field (*i.e.,* undergraduate degree or higher). Observers may substitute education or training for experience;

• Experience and ability to conduct field observations and collect data according to assigned protocols (this may include academic experience);

• At least one observer must have prior experience working as an observer;

• 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 and times when in-water construction activities were suspended to avoid potential incidental injury from construction sound of marine mammals observed within a defined shutdown zone; 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.

Reporting

A draft marine mammal monitoring report must be submitted to NMFS within 90 days after the completion of pile driving/removal activities. This reports will include an overall description of work completed, a narrative regarding marine mammal sightings, and associated PSO data sheets. Specifically, the reports must include:

• Date and time that monitored activity begins or ends;

• Construction activities occurring during each observation period;

• Weather parameters (*e.g.,* percent cover, visibility);

• Water conditions (*e.g.,* sea state, tide state);

• Species, numbers, and, if possible, sex and age class of marine mammals;

• Description of any observable marine mammal behavior patterns, including bearing and direction of travel and distance from pile driving activity;

• Distance from pile driving activities to marine mammals and distance from the marine mammals to the observation point;

• Locations of all marine mammal observations;

• An estimate of total take based on proportion of the monitoring zone that was observed;

• Other human activity in the area; and

• Marine mammal PSO observational datasheets or raw data.

If no comments are received from NMFS within 30 days, that phase's draft final report will constitute the final report. If comments are received, a final report for the given phase addressing NMFS comments must be submitted within 30 days after receipt of comments. In the unanticipated event that the specified activity clearly causes the take of a marine mammal in a manner prohibited by the IHA, such as an injury, serious injury or mortality, the Corps would immediately cease the specified activities and report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, and the West Coast Regional Stranding Coordinator. The report would include the following information:

• Description of the incident;

• Environmental conditions (*e.g.,* Beaufort sea state, visibility);

• Description of all marine mammal observations in the 24 hours preceding the incident;

• Species identification or description of the animal(s) involved;

- Fate of the animal(s); and
- Photographs or video footage of the animal(s) (if equipment is available).

Activities would not resume until NMFS is able to review the circumstances of the prohibited take. NMFS would work with the Corps to determine what is necessary to minimize the likelihood of further prohibited take and ensure MMPA compliance. The Corps would not be able to resume their activities until notified by NMFS via letter, email, or telephone.

In the event that the Corps discovers an injured or dead marine mammal, and the lead PSO determines that the cause of the injury or death is unknown and the death is relatively recent (*e.g.,* in less than a moderate state of decomposition as described in the next paragraph), the Corps would immediately report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, and the West Coast Regional Stranding Coordinator. The report would include the same information identified in the paragraph above. Activities would be able to continue while NMFS reviews the circumstances of the incident. NMFS would work with the Corps to determine whether modifications in the activities are appropriate.

In the event that the Corps discovers an injured or dead marine mammal and the lead PSO determines that the injury or death is not associated with or related to the activities authorized in these IHAs (*e.g.,* previously wounded animal, carcass with moderate to advanced decomposition, or scavenger damage), the Corps would report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, and the West Coast Regional Stranding Coordinator, within 24 hours of the discovery. The Corps would provide photographs, video footage (if available), or other documentation of the stranded animal sighting to NMFS and the Marine Mammal Stranding Network.

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 repetition, our analysis applies to all species listed in Table 11, given that NMFS expects the anticipated effects of the planned pile driving/removal to be similar in nature. Where there are meaningful differences between species or stocks, or groups of species, in anticipated individual responses to activities, impact of expected take on the population due to differences in population status, or impacts on habitat, NMFS has identified species-specific factors to inform the analysis.

NMFS does not anticipate that serious injury or mortality would occur as a result of the Corps' planned activity. As stated in the mitigation section, shutdown zones that equal or exceed Level A harassment isopleths shown in Table 12 will be implemented. Take by Level A harassment is authorized for some species (harbor seals, harbor porpoises) to account for the slight possibility that these species escape observation by the PSOs within the Level A harassment zone. Further, any take by Level A harassment is expected to arise from, at most, a small degree of PTS because animals would need to be exposed to higher levels and/or longer duration than are expected to occur here in order to incur any more than a small degree of PTS. Additionally, as noted previously, some subset of the individuals that are behaviorally harassed could also simultaneously incur some small degree of TTS for a short duration of time. Because of the small degree anticipated, though, any PTS or TTS potentially incurred here would not be expected to adversely impact individual fitness.

Behavioral responses of marine mammals to pile driving and removal at the planned test piles project sites are expected to be mild, short term, and temporary. Marine mammals within the Level B harassment zone may not show any visual cues they are disturbed by activities or they could become alert, avoid the area, leave the area, or display other mild responses that are not observable such as changes in vocalization patterns. Given the short duration of noise-generating activities (between 6–41 days over 3-month period), any harassment would be likely be intermittent and temporary. Furthermore, many of the species occurring near the MCR or in the Columbia River estuary would only be present temporarily based on seasonal patterns or during transit between other habitats. These temporarily present species would be exposed to even smaller periods of noise-generating activity, further decreasing the impacts.

In addition, for all species there are no known biologically important areas (BIAs) within the MCR or Columbia River estuary and there is no ESA-designated marine mammal critical habitat. The estuary represents a very small portion of the total available habitat to marine mammal species.

More generally, there are no known calving or rookery grounds within the project area, but anecdotal evidence from local experts shows that marine mammals are more prevalent during spring and summer associated with feeding on aggregations of fish. Because the Corps' activities would occur in the fall months, the project area represents a small portion of available foraging habitat, and the duration of noise-producing activities relatively is short, meaning impacts on marine mammal feeding for all species should be minimal.

Any impacts on marine mammal prey that would occur during the Corps' planned activity would have at most short-terms effects on foraging of individual marine mammals, and likely no effect on the populations of marine mammals as a whole. Therefore, indirect effects on marine mammal prey during the construction are not expected to be substantial, and these insubstantial effects would therefore be unlikely to cause substantial effects on marine mammals.

In summary and as described above, the following factors primarily support our 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;
- The Corps would implement mitigation measures including soft-starts for impact pile driving and shutdown zones that exceed Level A harassment zones for authorized species, except for harbor seals which will help to ensure that take by Level A harassment is at most a small degree of PTS;
- Anticipated incidents of Level B harassment consist of, at worst, temporary modifications in behavior;
- There are no BIAs within the MCR and Columbia River estuary or other known areas of particular biological importance to any of the affected stocks are impacted by the activity;
- The project area represents a very small portion of the available foraging area for all marine mammal species and anticipated habitat impacts are minimal; and
- The required mitigation measures (*e.g.* shutdown zones, soft-start) are expected to be effective in reducing the effects of the specified activity.

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. Additionally, other qualitative factors may be considered in the analysis, such as the temporal or spatial scale of the activities.

Table 11 in the *Marine Mammal Occurrence and Take Calculation and Estimation* section, present the number of animals that could be exposed to received noise levels that may result in take by Level A harassment or Level B harassment from the Corps' planned activities. Our analysis shows that 9.7 percent or less of the best population estimates of each affected stock could be taken. Additionally, the planned test piles project is located near the pinniped haulout at the South Jetty. Therefore, it is likely that many of these takes will be repeated takes of the same animals over multiple days. As such, the take estimate serves as a good estimate of instances of take, but is likely an overestimate of individuals taken, so actual percentage of stocks taken would be even lower.

Based on the analysis contained herein of the planned 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 proposed 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 (ESA)

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 the Corps for conducting test pile installation and removal at the Sand Island Pile Dike system near the MCR, for one year from the date of issuance, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated.

Dated: November 5, 2019.

Donna S. Wieting,

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

[FR Doc. 2019–24462 Filed 11–8–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XV126]

South Atlantic Fishery Management Council; Public Meetings

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

ACTION: Notice of public meetings.

SUMMARY: The South Atlantic Fishery Management Council (Council) will hold meetings of the following: Southeast Data, Assessment, and Review (SEDAR) Committee (Partially Closed Session); Executive Finance Committee; Shrimp Committee; Advisory Panel Selection Committee (Closed Session); Citizen Science Committee; Dolphin Wahoo Committee; Mackerel Cobia Committee; Snapper Grouper Committee; and Personnel Committee (Closed Session). The Council meeting week will include a formal public comment period and a meeting of the full Council.

DATES: The Council meeting will be held from 1:30 p.m. on Monday, December 2, 2019 until 1 p.m. on Friday, December 6, 2019.

ADDRESSES:

Meeting address: The meeting will be held at the Hotel Ballast, 301 North Water Street, Wilmington, NC 28401; phone: (910) 763–5900.

Council address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Kim Iverson, Public Information Officer, SAFMC; phone: (843) 302–8440 or toll free (866) SAFMC–10; fax: (843) 769–4520; email: *kim.iverson@safmc.net.* Meeting information is available from the Council's website at: *http://*

safmc.net/safmc-meetings/council-meetings/.

SUPPLEMENTARY INFORMATION:

Public comment: Written comments may be directed to Gregg Waugh, Executive Director, South Atlantic Fishery Management Council (see *Council address*) or electronically via the Council's website at *http://safmc.net/safmc-meetings/council-meetings/.* Comments received by close of business the Monday before the meeting (11/25/19) will be compiled, posted to the website as part of the meeting materials, and included in the administrative record; please use the Council's online form available from the website. For written comments received after the Monday before the meeting (after 11/25/19), individuals submitting a comment must use the Council's online form available from the website. Comments will automatically be posted to the website and available for Council consideration. Comments received prior to noon on Thursday, December 5, 2019 will be a part of the meeting administrative record.

The items of discussion in the individual meeting agendas are as follows:

SEDAR Committee (Partially Closed Session)—Monday, December 2, 2019, 1:30 p.m. Until 2:30 p.m.

1. *Closed Session:* The Committee will review appointments for upcoming assessments and provide recommendations for Council consideration. The Committee will also receive updates on the Council's Scientific and Statistical Committee (SSC) and advisory panel participation in the SEDAR process.

2. The meeting will continue in Open Session. The Committee will receive an update on SEDAR activities, a report from the Council's SSC, and approve the Terms of Reference and schedule for the SEDAR 71 stock assessment for South Atlantic gag grouper.

3. The Committee will also review and approve the SEDAR Scope of Work for 2022 Stock Assessments and provide recommendations for Council approval.

Executive Finance Committee—Monday, December 2, 2019, 2:30 p.m. Until 4 p.m.

1. The Committee will receive a report from the November 2019 meeting of the Council Coordination Committee (CCC), discuss and provide guidance to staff.

2. The Committee will receive a report from the October 2019 Executive Finance Committee meeting, review and take action as needed.

3. The Committee will review the Council's Follow-up document and Prioritization Schedule for work on amendments, discuss and provide guidance to staff.

4. The Committee will review documents from NOAA Fisheries currently open for review by the Council and take action as needed.

Shrimp Committee, Monday, December 2, 2019, 4 p.m. Until 5 p.m.

1. The Committee will review draft Amendment 11 to the Shrimp Fishery Management Plan (FMP) addressing transit provisions, discuss and consider approval for public hearings.

2. The Committee will also receive input from the Shrimp Advisory Panel on changes proposed for the Florida Keys National Marine Sanctuary.

Advisory Panel Selection Committee (Closed Session), Tuesday, December 3, 2019, 8 a.m. Until 10 a.m.

1. The Committee will review applications for open seats on the Councils advisory panels and provide recommendations for Council consideration.

Citizen Science Committee, Tuesday, December 3, 2019, 10 a.m. Until 12 p.m.

1. The Committee will receive program and project updates including 2019 activities and updates on the program's pilot projects, *SAFMC Scamp Release* and FISH story.

2. The Committee will also review updated Research Priorities for the Citizen Science Program, discuss and consider for adoption.

3. The Committee will receive an overview and presentation on program evaluation, discuss, and provide guidance and recommendations as needed. The Committee will also receive a presentation on the role of program infrastructure, discuss and take action as needed.

Dolphin Wahoo Committee, Tuesday, December 3, 2019, 1:30 p.m. Until 5:30 p.m. and Wednesday, December 4, 2019, 8:00 a.m. Until 12:00 p.m.

1. The Committee will receive updates from NOAA Fisheries on the status of commercial and recreational catches versus annual catch limits (ACLs).

2. The Committee will review the goals and objectives of the Dolphin Wahoo FMP and provide guidance to staff. The Committee will also review Amendment 10 to the Dolphin Wahoo FMP. Draft Amendment 10 currently includes 17 actions to address current needs in the fishery. These actions fall under four main areas of focus: (1) Actions to accommodate revised recreational data; (2) Actions that define Optimum Yield in the dolphin fishery; (3) Actions that accommodate adaptive management of sector ACLs and change accountability measures; and (4) Actions that implement miscellaneous management revisions in the dolphin and wahoo fisheries. The Committee will continue its review of actions in the draft amendment and consider approving for public scoping.

3. The Committee will review draft Amendment 12 to the Dolphin Wahoo FMP with measures to add bullet mackerel and frigate mackerel as Ecosystem Component species to the Dolphin Wahoo FMP, consider appropriate regulatory actions, and provide guidance to staff. The Committee will also receive input from the Advisory Panel on changes proposed for the Florida Keys National Marine Sanctuary.

Mackerel Cobia Committee, Wednesday, December 4, 2019, 1:30 p.m. Until 3:50 p.m.

1. The Committee will receive an update on the status of commercial and recreational catches versus ACLs and the status of amendments under formal Secretarial review.

2. The Committee will receive a report from the Mackerel Cobia Advisory Panel, discuss and provide recommendations as appropriate.

3. The Committee will receive an overview of Framework Amendment 8 to the Coastal Migratory Pelagic FMP addressing king mackerel commercial trip limits in Season 2 in the Atlantic Southern Zone, review public hearing comments, and provide recommendations for final approval.

4. The Committee will review draft Framework Amendment 9 with actions to revise accountability measures to address Spanish mackerel closures in the Atlantic Northern Zone. The Committee will review analyses, select preferred alternatives and consider approving for public hearings.

5. The Committee will also receive input from the Advisory Panel on changes proposed for the Florida Keys National Marine Sanctuary.

Formal Public Comment, Wednesday, December 4, 2019, 4 p.m.

Public comment will be accepted on items on the Council meeting agenda scheduled to be approved for Secretarial Review: Snapper Grouper Regulatory Amendment 33 (red snapper fishing seasons); Coastal Migratory Pelagics Framework Amendment 8 (king mackerel trip limits); and Snapper Grouper Abbreviated Framework 3 (blueline tilefish). Public comment will also be accepted on items for scoping/

public hearings and all other agenda items. The Council Chair, based on the number of individuals wishing to comment, will determine the amount of time provided to each commenter.

Snapper Grouper Committee, Thursday, December 5, 2019, 8 a.m. Until 12 p.m.

1. The Committee will receive updates from NOAA Fisheries on commercial and recreational catches for species under ACLs and the status of amendments under formal Secretarial review.
2. The Committee will receive a report from the SSC on issues relative to the management of snapper grouper species and a report from the Snapper Grouper Advisory Panel.
3. The Committee will receive an overview of Snapper Grouper Abbreviated Framework Amendment 3 addressing management of blueline tilefish and consider final approval for Secretarial review.
5. The Committee will receive an update on the Southeast Reef Fish Survey (SERFS) for red snapper that includes 2019 data.
6. The Committee will review Snapper Grouper Regulatory Amendment 33 addressing season modifications for red snapper and consider final approval.
7. The Committee will review draft Snapper Grouper Regulatory Amendment 31 addressing recreational accountability measures and provide guidance.
8. The Committee will receive a summary of outreach efforts for best fishing practices and take action as needed.
9. The Committee will receive a report from the System Management Plan Workgroup and an overview of input received from the Snapper Grouper Advisory Panel regarding proposed changes to the Florida Keys National Marine Sanctuary.

Personnel Committee, Thursday, December 5, 2019, 1:30 p.m. Until 3:30 p.m. (Closed Session)

1. The Committee will address the Executive Director's review and Council comments on documents, procedures, etc. and guidance for 2020.

Council Session: Thursday, December 5, 2019, 3:30 p.m. Until 5:30 p.m. and Friday, December 6, 2019, 8 a.m. Until 1 p.m.

The Full Council will begin with the Call to Order, adoption of the agenda, and approval of minutes.

The Council will receive a presentation on proposed changes to the Florida Keys National Marine Sanctuary. Staff will provide a summary of input received from the Council's advisory panels regarding the proposed changes and provide the Council with an overview of required actions.

The Council will receive staff reports including the Executive Director's Report and updates on the MyFishCount recreational reporting pilot program.

Updates will be provided by NOAA Fisheries including a report on the status of commercial and recreational catches versus ACLs for species not covered during an earlier committee meeting, data-related reports (for-hire amendment and bycatch), protected resources, and a presentation on the status of the of the Commercial Electronic Logbook Program. The Council will discuss and take action as necessary.

The Council will review any Exempted Fishing Permits received as necessary and review proposed changes to the Florida Keys National Marine Sanctuary and take action as appropriate.

The Council will receive reports from the following committees: Snapper Grouper; Mackerel Cobia; Dolphin Wahoo; Shrimp; SEDAR, Advisory Panel Selection; Citizen Science; Executive Finance; and Personnel. The Council will take action as appropriate.

The Council will receive agency and liaison reports; and discuss other business and upcoming meetings and take action as necessary.

Documents regarding these issues are available from the Council office (see **ADDRESSES**).

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

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for auxiliary aids should be directed to the Council office (see **ADDRESSES**) 5 days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

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

Dated: November 6, 2019.

Tracey L. Thompson,

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

[FR Doc. 2019–24592 Filed 11–8–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; Southeast Region Gulf of Mexico Mandatory Shrimp Vessel and Gear Characterization Survey

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

ACTION: Notice.

SUMMARY: The Department of Commerce, 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.

DATES: Written comments must be submitted by January 13, 2020.

ADDRESSES: Direct all written comments to Adrienne Thomas, PRA Officer, NOAA, 151 Patton Avenue, Room 159, Asheville, NC 28801 (or via the internet at *PRAcomments@doc.gov*). All comments received are part of the public record. Comments will generally be posted without change. All Personally Identifiable Information (for example, name and address) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Adam Bailey, National Marine Fisheries Service, Southeast Regional Office, Sustainable Fisheries Division, 263 13th Ave. S, St. Petersburg, FL 33701, telephone: 727–824–8305, email: *adam.bailey@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for the renewal of a current information collection.

The Magnuson-Stevens Fishery Conservation and Management Act

(Magnuson-Stevens Act) authorizes the Gulf of Mexico Fishery Management Council (Council) to prepare and amend fishery management plans (FMPs) for any fishery in Federal waters under its jurisdiction. NMFS and the Council manage the commercial shrimp fishery in Federal waters of the Gulf of Mexico (Gulf) under the FMP for the Shrimp Fishery of the Gulf.

Owners or operators of vessels applying for or renewing a commercial vessel permit for the Gulf shrimp fishery must complete an annual Gulf Shrimp Vessel and Gear Characterization Form. NMFS provides the form to each permit holder in January each year, and the form is due to NMFS prior to the submission of a permit application for renewal or transfer. Compliance with this reporting requirement is required for permit issuance and renewal. The regulations for the Gulf Shrimp Vessel and Gear Characterization Form may be found at 50 CFR 622.51(a)(3).

Through this form, NMFS collects census-level information on fishing vessel and gear characteristics in the Gulf shrimp fishery to conduct analyses that will improve management decision-making in this fishery. In addition, these analyses ensure that national goals, objectives, and requirements of the Magnuson-Stevens Act, National Environmental Policy Act, Regulatory Flexibility Act, Endangered Species Act, and Executive Order 12866 are met; and quantify achievement of the performance measures in the NMFS' Operating Plans. This information is vital in assessing the economic, social, and environmental effects of fishery management decisions and regulations on individual shrimp fishing enterprises, fishing communities, and the nation as a whole.

There have been minor adjustments to responses and burden. As of August 29, 2019, there are approximately 1,410 vessels with valid or renewable permits in the Gulf shrimp fishery. The slightly fewer number of vessels has resulted in adjusted estimates of total burden hours and costs as noted below in Section III.

II. Method of Collection

NMFS mails a paper copy of the form to respondents and also provides a pre-paid business reply envelope for permit applicants to submit the form. Permit applicants must complete and mail the form back to NMFS before a permit expires and before NMFS will issue or transfer a permit.

III. Data

OMB Control Number: 0648–0542.

Form Number(s): None.

Type of Review: Regular submission—extension of a current information collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 1,410.

Estimated Time per Response: 20 minutes.

Estimated Total Annual Burden Hours: 470.

Estimated Total Annual Cost to Public: $0 in recordkeeping or reporting costs.

IV. Request for Comments

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 shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (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 through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Sheleen Dumas,

Departmental Lead PRA Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2019–24582 Filed 11–8–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; South Pacific Tuna Act

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

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: To ensure consideration, written or on-line comments must be submitted on or before January 13, 2020.

ADDRESSES: Direct all written comments to Adrienne Thomas, PRA Officer, NOAA, 151 Patton Avenue, Room 159, Asheville, NC 28801 (or via the internet at *PRAcomments@doc.gov*). All comments received are part of the public record. Comments will generally be posted without change. All Personally Identifiable Information (for example, name and address) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Rini Ghosh, (808) 725–5033 or *rini.ghosh@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The National Oceanic and Atmospheric Administration (NOAA) collects vessel license, vessel registration, catch, and unloading information from operators of U.S. purse seine vessels fishing under the provisions of the Treaty on Fisheries between the Governments of Certain Pacific Island States and the Government of the United States of America (Treaty). The Treaty provides access for U.S. purse seine vessels to fish in the exclusive economic zones (EEZs) of Pacific Island Parties to the Treaty (PIPs). The PIPs include Australia, Cook Islands, Federated States of Micronesia, Fiji, Kiribati, Marshall Islands, Nauru, New Zealand, Niue, Palau, Papua New Guinea, Samoa, Solomon Islands, Tonga, Tuvalu, and Vanuatu. This collection of information is required to meet U.S. obligations under the Treaty.

The South Pacific Tuna Act of 1988 (16 U.S.C. 973–973r) and U.S. implementing regulations (50 CFR part 300, subpart D) authorize the collection of information from U.S. purse seine vessels fishing in the EEZs of PIPs under the Treaty. Vessel operators must submit annual vessel license and registration (including registration of vessel monitoring system (VMS) units) applications and periodic written reports of catch and unloading of fish from licensed vessels. They are also required to ensure the continued operation of VMS units on board licensed vessels, which is expected to require periodic maintenance of the units. The information collected is submitted to the Pacific Islands Forum Fisheries Agency (FFA) through the U.S.

government, NOAA's National Marine Fisheries Service (NMFS). The license and registration application information is used by the FFA to determine the operational capability and financial responsibility of a vessel operator interested in fishing under the Treaty. Information obtained from vessel catch and unloading reports is used by the FFA to assess fishing effort and fishery resources in the region and to track the amount of fish caught within each PIP's EEZ. Maintenance of VMS units is needed to ensure the continuous operation of the VMS units, which, as part of the VMS administered by the FFA, are used as an enforcement tool. If the information is not collected, the U.S. government will not meet its obligations under the Treaty, and the lack of fishing information will result in poor management of the fishery resources.

II. Method of Collection

All information are to be submitted in hard copy via mail or through electronic reporting.

III. Data

OMB Control Number: 0648–0218.

Form Number(s): None.

Type of Review: Regular submission extension of a current information collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 41.

Estimated Time per Response: License application, 15 minutes; VMS registration application, 45 minutes; catch report, 1 hour; and unloading logsheet, 30 minutes.

Estimated Total Annual Burden Hours: 402.

Estimated Total Annual Cost to Public: $153,081 in recordkeeping/reporting costs.

IV. Request for Comments

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 shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (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 through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Sheleen Dumas,

Departmental Lead PRA Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2019–24580 Filed 11–8–19; 8:45 am]

BILLING CODE 3510–22–P

CONSUMER PRODUCT SAFETY COMMISSION

Sunshine Act Meeting Notice

TIME AND DATE: Wednesday, November 13, 2019; 10:00 a.m.–12:00 p.m.

PLACE: Hearing Room 420, Bethesda Towers, 4330 East West Highway, Bethesda, MD 20814.

STATUS: Commission Meeting—Open to the Public.

MATTER TO BE CONSIDERED: Briefing Matter: Adjudicative Rules NPR.

CONTACT PERSON FOR MORE INFORMATION: Alberta E. Mills, Secretary, Division of the Secretariat, Office of the General Counsel, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814, (301) 504–7479.

Dated: November 6, 2019.

Alberta E. Mills,

Secretary.

[FR Doc. 2019–24603 Filed 11–7–19; 11:15 am]

BILLING CODE 6355–01–P

CONSUMER PRODUCT SAFETY COMMISSION

Sunshine Act Meeting Notice

TIME AND DATE: Wednesday, November 13, 2019; 1:30–2:30 p.m.*

PLACE: Hearing Room 420, Bethesda Towers, 4330 East West Highway, Bethesda, MD 20814.

STATUS: Commission Meeting—Closed to the Public.

MATTER TO BE CONSIDERED: Compliance Matters: Staff will brief the Commission on the status of compliance matters.

CONTACT PERSON FOR MORE INFORMATION: Alberta E. Mills, Secretary, Division of the Secretariat, Office of the General Counsel, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814, (301) 504–7479.

* The Commission unanimously determined by recorded vote that Agency business requires calling the meeting without seven calendar days advance public notice.

Dated: November 6, 2019.

Alberta E. Mills,

Secretary.

[FR Doc. 2019–24604 Filed 11–7–19; 11:15 am]

BILLING CODE 6355–01–P

DEPARTMENT OF DEFENSE

Department of the Air Force

[Docket ID: USAF–2019–HQ–0012]

Proposed Collection; Comment Request

AGENCY: Secretary of the Air Force, DoD.

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Secretary of the Air Force announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by January 13, 2020.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Chief Management Officer, Directorate for Oversight and Compliance, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to

obtain a copy of the proposal and associated collection instruments, please write to DoD Military Working Dog Program, 1030 Air Force Pentagon, Rm 5E762, Washington, DC 20330–1030, Dr. Richard Vargus, 703–545–9808.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Department of Defense Military Working Dog Adoption Application; DD Form 810–7, OMB Control Number 0701–XXXX.

Needs and Uses: This form will be used to assess the suitability of US citizens and local and state law enforcement agencies to adopt Department of Defense Military Working Dogs, as outlined in DoDI 5200.31E, Title 10 United States Code § 2583, and AFI 31–126. The information is needed to determine if individuals voluntarily submitting the adoption application are suitable adopters for Military Working Dogs, based on the best interests of the Military Working Dog. The information will be used to contact applicants and to interview, screen and select applicants for voluntary adoption.

Affected Public: Individuals or Households; State, Local or Tribal Government.

Annual Burden Hours: 1.

Number of Respondents: 200.

Responses per Respondent: 1.

Annual Responses: 200.

Average Burden per Response: 1 hour.

Frequency: 1.

Dated: November 6, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2019–24524 Filed 11–8–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Army

Board of Visitors, United States Military Academy (USMA); Meeting Cancellation

AGENCY: Department of the Army, DoD.

ACTION: Meeting cancellation notice.

SUMMARY: Under the provisions of the Federal Advisory Committee Act of 1972, the Government in the Sunshine Act of 1976, the Department of Defense announces that the following Federal advisory committee meeting will not take place.

FOR FURTHER INFORMATION CONTACT: The Committee's Designated Federal Officer or Point of Contact is Ms. Deadra Ghostlaw, (845) 938–4200, *Deadra.Ghostlaw@westpoint.edu.*

SUPPLEMENTARY INFORMATION: Due to circumstances beyond the control of the Department of Defense (DoD) and the Designated Federal Officer, the U.S. Military Academy Board of Visitors was unable to provide sufficient public notification required by 41 CFR 102–3.150(a) concerning the cancellation of its previously noticed October 22, 2019 meeting. Accordingly, the Advisory Committee Management Officer for the Department of Defense, pursuant to 41 CFR 102–3.150(b), waives the 15-calendar day notification requirement.

1. *Name of Committee:* United States Military Academy Board of Visitors.

2. *Date:* Tuesday, October 22, 2019.

3. *Time:* 1:30 p.m.–4:30 p.m.

4. *Location:* Room LJ–119, Library of Congress, Thomas Jefferson Building, 10 First Street SE, Washington, DC.

5. *Reason for Cancellation:* Due to circumstances surrounding a missing Cadet at West Point and the need for senior USMA leadership to remain at USMA during the search, the USMA Board of Visitors meeting originally scheduled for Tuesday, October 22, 2019, is postponed until a date to be determined.

6. *Committee's Designated Federal Officer or Point of Contact:* Ms. Deadra Ghostlaw, (845) 938–4200, *Deadra.Ghostlaw@westpoint.edu.*

Brenda S. Bowen,

Army Federal Register Liaison Officer.

[FR Doc. 2019–24547 Filed 11–8–19; 8:45 am]

BILLING CODE 5001–03–P

DEPARTMENT OF DEFENSE

Department of the Army

Board of Visitors, United States Military Academy (USMA)

AGENCY: Department of the Army, DoD.

ACTION: Notice of committee meeting.

SUMMARY: Under the provisions of the Federal Advisory Committee Act of 1972, the Government in the Sunshine Act of 1976, the Department of Defense announces that the following Federal advisory committee meeting will take place.

DATES: The meeting will be held on Wednesday, November 13, 2019, Time 10:00 a.m.–1:00 p.m. Members of the public wishing to attend the meeting will be required to show a government photo ID upon entering in order to gain access to the meeting location. All members of the public are subject to security screening.

ADDRESSES: The meeting will be held in Room 303 Cannon House Office Building, New Jersey and Independence Avenues SE, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mrs. Deadra K. Ghostlaw, the Designated Federal Officer for the committee, in writing at: Secretary of the General Staff, ATTN: Deadra K. Ghostlaw, 646 Swift Road, West Point, NY 10996; by email at: *deadra.ghostlaw@westpoint.edu* or *BoV@westpoint.edu;* or by telephone at (845) 938–4200.

SUPPLEMENTARY INFORMATION: The committee meeting is being held under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.150. The USMA BoV provides independent advice and recommendations to the President of the United States on matters related to morale, discipline, curriculum, instruction, physical equipment, fiscal affairs, academic methods, and any other matters relating to the Academy that the Board decides to consider.

Purpose of the Meeting: This is the 2019 Annual Meeting of the USMA BoV. Members of the Board will be provided updates on Academy issues. Agenda: Introduction; Board Business: Approval of the Minutes from May's Meeting, vote on tentative dates for Winter and Summer meetings; Superintendent's Remarks; Academy Topics: Cultivate a Culture of Character, Develop Leaders of Character; Upcoming Events; Closing Comments.

Public's Accessibility to the Meeting: Pursuant to 5 U.S.C. 552b and 41 CFR 102–3.140 through 102–3.165 and subject to the availability of space, this meeting is open to the public. Seating is on a first to arrive basis. Attendees are requested to submit their name, affiliation, and daytime phone number seven business days prior to the meeting to Mrs. Ghostlaw, via electronic mail, the preferred mode of submission, at the address listed in the **FOR FURTHER INFORMATION CONTACT** section. Pursuant to 41 CFR 102–3.140d, the committee is not obligated to allow a member of the public to speak or otherwise address the committee during the meeting, and members of the public attending the committee meeting will not be permitted to present questions from the floor or speak to any issue under consideration by the committee. Because the committee meeting will be held in a Federal Government facility security screening is required. A government photo ID is required to enter the building. The Cannon House Office Building is fully handicapped accessible. Wheelchair access is

available at the intersection of C Street and First Street SE, Washington, DC.

For additional information about public access procedures, contact Mrs. Ghostlaw, the committee's Designated Federal Officer, at the email address or telephone number listed in the **FOR FURTHER INFORMATION CONTACT** section.

Written Comments or Statements: Pursuant to 41 CFR 102–3.105(j) and 102–3.140 and section 10(a)(3) of the Federal Advisory Committee Act, the public or interested organizations may submit written comments or statements to the committee, in response to the stated agenda of the open meeting or in regard to the committee's mission in general. Written comments or statements should be submitted to Mrs. Ghostlaw, the committee Designated Federal Officer, via electronic mail, the preferred mode of submission, at the address listed in the **FOR FURTHER INFORMATION CONTACT** section. Each page of the comment or statement must include the author's name, title or affiliation, address, and daytime phone number. Written comments or statements should be submitted to Mrs. Ghostlaw, the committee Designated Federal Officer, via electronic mail, the preferred mode of submission, at the address listed in the **FOR FURTHER INFORMATION CONTACT** section. Written comments or statements being submitted in response to the agenda set forth in this notice must be received by the Designated Federal Official at least seven business days prior to the meeting to be considered by the committee. The Designated Federal Official will review all timely submitted written comments or statements with the committee Chairperson and ensure the comments are provided to all members of the committee before the meeting. Written comments or statements received after this date may not be provided to the committee until its next meeting.

Pursuant to 41 CFR 102–3.140d, the committee is not obligated to allow a member of the public to speak or otherwise address the committee during the meeting. However, the committee Designated Federal Official and Chairperson may choose to invite certain submitters to present their comments verbally during the open portion of this meeting or at a future meeting. The Designated Federal Officer, in consultation with the committee Chairperson, may allot a specific amount of time for submitters to present their comments verbally.

Due to circumstances beyond the control of the Department of Defense (DoD) and the Designated Federal Officer, the U.S. Military Academy Board of Visitors was unable to provide public notification required by 41 CFR 102–3.150(a) concerning the meeting on November 13, 2019 of the U.S. Military Academy Board of Visitors. Accordingly, the Advisory Committee Management Officer for the Department of Defense, pursuant to 41 CFR 102–3.150(b), waives the 15-calendar day notification requirement.''

Brenda S. Bowen,

Army Federal Register Liaison Officer.

[FR Doc. 2019–24546 Filed 11–8–19; 8:45 am]

BILLING CODE 5001–03–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DoD–2019–OS–0124]

Proposed Collection; Comment Request

AGENCY: Department of Defense Education Activity, DoD.

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Department of Defense Education Activity announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by January 13, 2020.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Department of Defense, Office of the Chief Management Officer, Directorate for Oversight and Compliance, 4800 Mark Center Drive, Mailbox #24, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

Any associated form(s) for this collection may be located within this same electronic docket and downloaded for review/testing. Follow the instructions at *http://www.regulations.gov* for submitting comments. Please submit comments on any given form identified by docket number, form number, and title.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Department of Defense Education Activity, ATTN: Kathleen Facon, 4800 Mark Center Dr., Alexandria, VA 22350–1400 Tel: (571) 372–5834 DSN: (312) 372–5834.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Application for DoD Impact Aid for Children with Severe Disabilities; SD Form 816 and SD 816c; OMB Control Number 0704–0425.

Needs and Uses: The information collection requirement is necessary to authorize DoD funds for local educational agencies (LEAs) that educate military dependent students with severe disabilities that meet certain criteria. This application will be requested of military-impacted LEAs to determine if they meet the DoD criteria to receive compensation for the cost of educating military dependent students with severe disabilities.

Affected Public: State, Local, or Tribal governments.

Annual Burden Hours: 400.

Number of Respondents: 50.

Responses per Respondent: 1.

Annual Responses: 50.

Average Burden per Response: 8 hours.

Frequency: Annually.

The data collection consists of an application and signature sheet that must be submitted by email or fax with the original signature clearly visible on the document. The application is identified as Secretary of Defense Form 816 (SD 816), with SD Form 816C to be used as a continuation page if necessary. In order for DoD to compute the maximum payment amount, the LEA will need to determine and provide the following information in its application. First, the LEA must provide the special education costs of individual military dependent children who have severe disabilities and meet the threshold for

payments (at least two military dependents with severe disabilities and the cost per student must be at least five times the national average or three times the state average for students with disabilities, whichever is lower). These averages are provided to the LEAs by DoD in the application guidelines and acknowledged by the LEA in the application. Second, LEAs are required to identify the number of eligible children who were residing on-base or off-base during the previous school year. Third, the LEA must provide its banking information to receive payment.

Dated: November 6, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2019–24579 Filed 11–8–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2019–OS–0104]

Submission for OMB Review; Comment Request

AGENCY: Office of the Under Secretary of Defense for Research and Engineering, DoD.

ACTION: 30-Day information collection notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by December 12, 2019.

ADDRESSES: Comments and recommendations on the proposed information collection should be emailed to Ms. Jasmeet Seehra, DoD Desk Officer, at *oira_submission@omb.eop.gov.* Please identify the proposed information collection by DoD Desk Officer, Docket ID number, and title of the information collection.

FOR FURTHER INFORMATION CONTACT: Angela James, 571–372–7574, or *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Customer Satisfaction Surveys Generic Clearance; OMB Control Number 0704–0403.

Type of Request: Extension.

Number of Respondents: 6,400

Responses per Respondent: 1.

Annual Responses: 6,400.

Average burden per Response: 8 minutes.

Annual Burden Hours: 853.3.

Needs and Uses: The information collection requirement is necessary to assess the level of service the DTIC provides to its current customers. The surveys will provide information on the level of overall customer satisfaction as well as on customer satisfaction with several attributes of service that impact the level of overall satisfaction. These customer satisfaction surveys are required to implement Executive Order 12862, ''Setting Customer Service Standards.'' Respondents are DTIC registered users who are components of the DoD, military services, other Federal Government Agencies, U.S. Government contractors, and universities involved in federally funded research. The information obtained by these surveys will be used to assist agency senior management in determining agency business policies and processes that should be selected for examination, modification, and reengineering from the customer's perspective. These surveys will also provide statistical and demographic basis for the design of follow-on surveys. Future surveys will be used to assist monitoring of changes in the level of customer satisfaction overtime.

Affected Public: Business or other for-profit; individuals or households; Federal Government.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Ms. Angela James.

Requests for copies of the information collection proposal should be sent to Ms. James at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: November 5, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2019–24471 Filed 11–8–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2019–OS–0125]

Proposed Collection; Comment Request

AGENCY: Office of the Assistant to the Secretary of Defense for Public Affairs, DoD.

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Office of the Assistant to the Secretary of Defense for Public Affairs, announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by January 13, 2020.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Chief Management Officer, Directorate for Oversight and Compliance, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to David O'Connor, Office of the Assistant to the Secretary of Defense (Public Affairs), Community and Public Outreach, Room 2D982, 1400 Defense Pentagon, Washington, DC 20301–1400 or call 703–695–2036.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Joint Civilian Orientation Conference Program (JCOC) Eligibility of Nominators and Candidates; JCOC Nomination Form, JCOC Registration Form; OMB Control Number 0704–0562.

Needs and Uses: The information collection requirement is necessary to administer the JCOC Program; to verify the eligibility of nominators and candidates; and to select those nominated individuals for participation in JCOC.

Affected Public: Individuals or households.

Annual Burden Hours: 25.

Number of Respondents: 100.

Responses per Respondent: 1.

Annual Responses: 100.

Average Burden per Response: 15 minutes.

Frequency: Annually.

Respondents are individuals authorized to nominate candidates for participation in JCOC, and candidates nominated for and selected to participate in JCOC. The JCOC Nomination Form and Registration Form each record the nominator's credentials and contact information and the candidate's credentials and contact information. The completed forms are used to administer the JCOC program, verify the eligibility of nominators and candidates, and to select those nominated individuals for participation in JCOC, which is impossible to do without this information. Ensuring the credentials of nominators and candidates is vital to the integrity and accountability of the JCOC program.

Dated: November 6, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2019–24584 Filed 11–8–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2019–OS–0097]

Submission for OMB Review; Comment Request

AGENCY: The Office of the Under Secretary of Defense, DoD.

ACTION: 30-Day information collection notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by December 12, 2019.

ADDRESSES: Comments and recommendations on the proposed information collection should be emailed to Ms. Jasmeet Seehra, DoD Desk Officer, at *oira_submission@omb.eop.gov.* Please identify the proposed information collection by DoD Desk Officer, Docket ID number, and title of the information collection.

FOR FURTHER INFORMATION CONTACT: Angela James, 571–372–7574, or *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Application for Trusteeship; DD Form 2827; OMB Control Number 0730–0013.

Type of Request: Revision.

Number of Respondents: 75.

Responses per Respondent: 1.

Annual Responses: 75

Average Burden per Response: 15 minutes.

Annual Burden Hours: 19 hours.

Needs and Uses: The information collection is needed to identify the prospective trustees for active duty military and retirees. The information is required in order for the Defense Finance and Accounting Service (DFAS) to make payments on behalf of incompetent military members or retirees. DFAS is representing all services as the functional proponent for Retired and Annuitant Pay.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Ms. Angela James.

Requests for copies of the information collection proposal should be sent to Ms. James at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: November 5, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2019–24480 Filed 11–8–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Navy

Certificate of Alternate Compliance for USS ST LOUIS (LCS 19)

AGENCY: Department of the Navy, DoD.

ACTION: Notice of issuance of Certificate of Alternate Compliance.

SUMMARY: The U.S. Navy hereby announces that a Certificate of Alternate Compliance has been issued for USS ST LOUIS (LCS 19). Due to the special construction and purpose of this vessel, the Deputy Assistant Judge Advocate General (DAJAG)(Admiralty and Maritime Law) has determined it is a vessel of the Navy which, due to its special construction and purpose, cannot comply fully with the navigation lights provisions of the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS) without interfering with its special function as a naval ship. The intended effect of this notice is to warn mariners in waters where 72 COLREGS apply.

DATES: This action takes effect November 12, 2019 and is applicable beginning November 5, 2019.

FOR FURTHER INFORMATION CONTACT: Lieutenant Tom Bright, JAGC, U.S. Navy, Admiralty Attorney, Office of the Judge Advocate General, Admiralty and Maritime Law Division (Code 11), 1322 Patterson Ave. SE, Suite 3000, Washington Navy Yard, DC 20374–

5066, 202–685–5040, or *admiralty@navy.mil.*

SUPPLEMENTARY INFORMATION: Background and Purpose. Executive Order 11964 of January 19, 1977 and 33 U.S.C. 1605 provide that the requirements of the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), as to the number, position, range, or arc of visibility of lights or shapes, as well as to the disposition and characteristics of sound-signaling appliances, shall not apply to a vessel or class of vessels of the Navy where the Secretary of the Navy shall find and certify that, by reason of special construction or purpose, it is not possible for such vessel(s) to comply fully with the provisions without interfering with the special function of the vessel(s). Notice of issuance of a Certificate of Alternate Compliance must be made in the **Federal Register**.

In accordance with 33 U.S.C. 1605, the DAJAG (Admiralty and Maritime Law), under authority delegated by the Secretary of the Navy, hereby finds and certifies that USS ST LOUIS (LCS 19) is a vessel of special construction or purpose, and that, with respect to the position of the following navigational lights, it is not possible to comply fully with the requirements of the provisions enumerated in the 72 COLREGS without interfering with the special function of the vessel:

Annex I, paragraph 2(a)(i), pertaining to the vertical placement of the masthead light; Annex I, paragraph 3(a), pertaining to the horizontal position of the forward masthead light; and Annex I, paragraph 3(a), pertaining to the horizontal separation between the forward and aft masthead lights.

The DAJAG (Admiralty and Maritime Law) further finds and certifies that these navigational lights are in closest possible compliance with the applicable provision of the 72 COLREGS.

Authority: 33 U.S.C. 1605(c), E.O. 11964.

Approved: November 5, 2019.

D.J. Antenucci,

Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 2019–24479 Filed 11–8–19; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF DEFENSE

Department of the Navy

[Docket ID USN–2019–HQ–0023]

Proposed Collection; Comment Request

AGENCY: The Office of the Secretary of the Navy, DoD.

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Office of the Secretary of the Navy announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by January 13, 2020.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Chief Management Officer, Directorate for Oversight and Compliance, 4800 Mark Center Drive, Mailbox #24 Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Naval Research Laboratory, 4555 Overlook Ave SW, Washington DC 20375, Mail Code 5580 or call Mark A. Livingston at 202–767–0380.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Graphicacy in Interactive Dashboards; OMB Control Number 0703–XXXX.

Needs and Uses: Many modern jobs, including military duties, rely heavily on reading and interpreting simple data displays such as bar graphs, line graphs, and pie charts. However, there is no method for determining the ''reading level'' of a graph, as may be done for prose through multiple methods. We adapted a methodology for generating queries for a reading comprehension test to generate queries for graph comprehension. We seek to determine how well this methodology works by asking example queries of participants, and simultaneously measuring the difficulty associated with certain graph styles (*e.g.* multiple axes).

Affected Public: Individuals and households.

Annual Burden Hours: 125.

Number of Respondents: 100.

Responses per Respondent: 1.

Annual Responses: 100.

Average Burden per Response: 75 minutes.

Frequency: As required.

Dated: November 6, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2019–24563 Filed 11–8–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF ENERGY

[OE Docket No. EA–284–F]

Application to Export Electric Energy; Calpine Energy Solutions, LLC

AGENCY: Office of Electricity, Department of Energy.

ACTION: Notice of application.

SUMMARY: Calpine Energy Solutions, LLC (Applicant or Calpine Solutions) (formerly known as Noble Americas Energy Solutions LLC) has applied to renew its authorization to transmit electric energy from the United States to Mexico pursuant to the Federal Power Act.

DATES: Comments, protests, or motions to intervene must be submitted on or before December 12, 2019.

ADDRESSES: Comments, protests, motions to intervene, or requests for more information should be addressed to: Office of Electricity, Mail Code: OE–20, U.S. Department of Energy, 1000 Independence Avenue SW, Washington, DC 20585–0350. Because of delays in

handling conventional mail, it is recommended that documents be transmitted by overnight mail, by electronic mail to *Electricity.Exports@hq.doe.gov,* or by facsimile to (202) 586–8008.

SUPPLEMENTARY INFORMATION: The Department of Energy (DOE) regulates exports of electric energy from the United States to a foreign country, pursuant to sections 301(b) and 402(f) of the Department of Energy Organization Act (42 U.S.C. 7151(b) and 7172(f)). Such exports require authorization under section 202(e) of the Federal Power Act (16 U.S.C. 824a(e)).

On January 27, 2015, DOE issued Order No. EA–284–D, which renewed the authorization of Noble Americas Solutions LLC (Noble Americas) to transmit electric energy from the United States to Mexico as a power marketer for a five-year term using existing international transmission facilities. On January 11, 2017, DOE issued Order No. EA–284–E, recognizing that Noble Americas changed its name to Calpine Energy Solutions, LLC (Calpine Solutions). The authorization issued to Calpine Solutions f/k/a Noble Americas expires on January 29, 2020. On October 16, 2019, Calpine Solutions filed an application with DOE (Application or App.) for renewal of the export authorization contained in Order No. EA–284–D (as amended in Order No. EA–284–E) for an additional five-year term.

The Application states that ''Calpine Solutions does not have a franchised utility service area'' and that ''Calpine Solutions proposes to continue to export electric power through the existing facilities of [San Diego Gas & Electric Company] and [Comisión Federal de Electricidad].'' App. at 3. The electric energy that the Applicant proposes to export to Mexico would be purchased from ''electric utilities, merchant generators, energy brokers, and federal power marketing agencies.'' *Id.* The existing international transmission facilities to be utilized by the Applicant have previously been authorized by Presidential permits issued pursuant to Executive Order 10485, as amended, and are appropriate for open access transmission by third parties.

Procedural Matters: Any person desiring to be heard in this proceeding should file a comment or protest to the Application at the address provided above. Protests should be filed in accordance with Rule 211 of the Federal Energy Regulatory Commission's (FERC) Rules of Practice and Procedure (18 CFR 385.211). Any person desiring to become a party to this proceeding should file a motion to intervene at the above address in accordance with FERC Rule 214 (18 CFR 385.214). Five (5) copies of such comments, protests, or motions to intervene should be sent to the address provided above on or before the date listed above.

Comments and other filings concerning the Application should be clearly marked with OE Docket No. EA–284–F. An additional copy is to be provided directly to Sarah Novosel, Calpine Corporation, 875 15th Street NW, Suite 700, Washington, DC 20005, and Greg Bass, Calpine Energy Solutions, LLC, 401 West A Street, Suite 500, San Diego, CA 92101.

A final decision will be made on the Application after the environmental impacts have been evaluated pursuant to DOE's National Environmental Policy Act Implementing Procedures (10 CFR part 1021) and after DOE determines that the proposed action will not have an adverse impact on the sufficiency of supply or reliability of the U.S. electric power supply system.

Copies of the Application will be made available, upon request, for public inspection and copying at the address provided above, by accessing the program website at *http://energy.gov/node/11845,* or by emailing Angela Troy at *Angela.Troy@hq.doe.gov.*

Signed in Washington, DC, on November 5, 2019.

Christopher Lawrence,

Management and Program Analyst, Transmission Permitting and Technical Assistance, Office of Electricity.

[FR Doc. 2019–24533 Filed 11–8–19; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP20–200–000.
Applicants: ConocoPhillips Company,W&T Offshore, Inc.
Description: Joint Petition for Temporary Waiver of Commission Capacity Release Regulations and Policies, et al. of ConocoPhillips Company, et al under RP20–200.
Filed Date: 11/4/19.
Accession Number: 20191104–5062.
Comments Due: 5 p.m. ET 11/12/19.

Docket Numbers: RP20–201–000.
Applicants: Enable Mississippi River Transmission, LLC.
Description: § 4(d) Rate Filing: Negotiated Rate Filing—Spire RP18–923 Settlement to be effective 1/1/2019.
Filed Date: 11/4/19.
Accession Number: 20191104–5072.
Comments Due: 5 p.m. ET 11/18/19.

Docket Numbers: RP20–202–000.
Applicants: Transcontinental Gas Pipe Line Company, LLC.
Description: § 4(d) Rate Filing: Non-Conforming—Gateway to be effective 12/1/2019.
Filed Date: 11/4/19.
Accession Number: 20191104–5102.
Comments Due: 5 p.m. ET 11/18/19.

Docket Numbers: RP20–203–000.
Applicants: Equitrans, L.P.
Description: § 4(d) Rate Filing: Negotiated Capacity Release Agreements—11/4/2019 to be effective 11/1/2019.
Filed Date: 11/4/19.
Accession Number: 20191104–5105.
Comments Due: 5 p.m. ET 11/18/19.

The filings are accessible in the Commission's eLibrary system by clicking on the links or 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: November 5, 2019.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2019–24557 Filed 11–8–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2814–025]

Great Falls Hydroelectric Company; City of Paterson, New Jersey; Notice Extending Scoping Comment Period

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

a. *Type of Application:* New Major License.

b. *Project No.:* 2814–025.

c. *Date Filed:* February 28, 2019.

d. *Applicants:* Great Falls Hydroelectric Company and the City of Paterson, New Jersey, as co-licensees.

e. *Name of Project:* Great Falls Hydroelectric Project.

f. *Location:* On the Passaic River, near the City of Paterson, Passaic County, New Jersey. The project does not occupy federal land.

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

h. *Applicant Contact:* Mr. Robert Gates, Senior Vice President of Operations, Eagle Creek Renewable Energy, 65 Madison Avenue, Suite 500, Morristown, NJ 07960; (973) 998–8400; email—*bob.gates@eaglecreekre.com* and/or Ben-David Seligman, 2nd Assistant Corp. Counsel, City of Paterson, 155 Market Street, Paterson, NJ; (973) 321–1366; email—*bseligman@patersonnj.gov*.

i. *FERC Contact:* Christopher Millard at (202) 502–8256; or email at *christopher.millard@ferc.gov.*

j. *Deadline for filing scoping comments:* December 23, 2019.

The Commission strongly encourages electronic filing. Please file scoping 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, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. The first page of any filing should include docket number P–2814–025.

k. This application is not ready for environmental analysis at this time.

l. The existing project works consist of: (1) The Society for the Establishment of Useful Manufactures dam, an overflow granite stone gravity structure about 315 feet long, with a maximum height of 15 feet and having a crest elevation of 114.6 feet mean sea level (msl); (2) a reservoir with a surface area of 202 acres and a storage capacity of 1,415 acre-feet at elevation 114.6 feet msl; (3) a forebay inlet structure; (4) a headgate control structure containing three trashracks and three steel gates; (5) three penstocks, each 8.5 feet in diameter and approximately 55 feet long; (6) a powerhouse containing three turbine-generator units with a total rated capacity of 10.95 megawatts; (7) a 37-foot-long, 4.16-kilovolt (kV) underground transmission line connecting the powerhouse to a 4.16/26.4-kV step-up transformer which in turn is connected to a 26.4-kV transmission grid via an approximately 30-foot-long, 26.4-kV underground transmission line; (8) and appurtenant facilities.

The Great Falls Project is operated in a run-of-river mode. For the period 2010 through 2018, the average annual generation at the Great Falls Project was 17,484 megawatt-hours.

m. A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's website at *http://www.ferc.gov* using the eLibrary link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support. A copy is also available for inspection and reproduction at the address in item h above.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

n. Scoping Process

The Commission staff intends to prepare an environmental assessment (EA) for the Great Falls Project in accordance with the National Environmental Policy Act. The EA will consider both site-specific and cumulative environmental impacts and reasonable alternatives to the proposed action.

Scoping meetings were held on October 23 and 24, 2019, near the project site in Paterson, New Jersey to receive input on the scope of the EA. The meetings were noticed in the **Federal Register**; however, it has come to our attention that the meetings were not noticed in a local newspaper. Thus, we are extending the comment period to December 23, 2019.

Copies of the scoping document (SD1) outlining the subject areas to be addressed in the EA were distributed to the parties on the Commission's mailing list and the co-licensee's distribution list. Copies of SD1 may be viewed on the web at *http://www.ferc.gov* using the eLibrary link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, call 1–866–208–3676 or for TTY, (202) 502–8659.

Dated: November 5, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–24569 Filed 11–8–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. OR20–3–000]

Tallgrass Pony Express Pipeline, LLC; Notice of Petition for Declaratory Order

Take notice that on November 4, 2019, pursuant to Rule 207(a)(2) of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.207(a)(2) (2019), Tallgrass Pony Express Pipeline, LLC, filed a declaratory order petition seeking approval of the proposed rate structure and terms of service for its crude oil expansion project's transportation services agreements and the terms for the conversion of existing committed shipper volume commitments into new volume commitments under a new open season, all as more fully explained in the petition.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Petitioner.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the eFiling link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the eLibrary link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance

with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern time on December 4, 2019.

Dated: November 5, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–24567 Filed 11–8–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 10624–026]

French Paper Company; Notice of Application Accepted for Filing, Soliciting Motions To Intervene and Protests, Ready for Environmental Analysis, and Soliciting Comments, Recommendations, Preliminary Terms and Conditions, and Preliminary Fishway Prescriptions

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

a. *Type of Application:* Subsequent Minor License.

b. *Project No.:* 10624–026.

c. *Date filed:* February 27, 2019.

d. *Applicant:* French Paper Company (French Paper).

e. *Name of Project:* French Paper Company Hydroelectric Project (French Paper Project).

f. *Location:* The French Paper Project is located on the St. Joseph River in the City of Niles, Berrien County, Michigan. No federal lands are occupied by the project works or located within the project boundary.

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

h. *Applicant Contact:* Mr. Shane Fenske, President, French Paper Company, P.O. Box 398, 100 French Street, Niles, MI 49120; (269) 683–1100 or *fenske@frenchpaper.com.*

i. *FERC Contact:* Jay Summers, (202) 502–8764 or *jay.summers@ferc.gov.*

j. *Deadline for filing motions to intervene and protests, comments, recommendations, preliminary terms and conditions, and preliminary prescriptions:* 60 days from the issuance date of this notice; reply comments are due 105 days from the issuance date of this notice.

The Commission strongly encourages electronic filing. Please file motions to intervene, protests, comments, recommendations, preliminary terms and conditions, and preliminary fishway prescriptions 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, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. The first page of any filing should include docket number P–10624–026.

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

k. This application has been accepted for filing and is now ready for environmental analysis.

l. The French Paper Project consists of the following existing facilities: (1) An 112 acre reservoir with a storage capacity of 864 acre-feet at a water surface elevation of 653.75 feet mean sea level; (2) a 321-foot-long, 13-foot-high concrete spillway structure, topped by 2.3-foot-high flashboards; (3) a 100-foot-wide, 600-foot-long intake channel; (4) a 115-foot-wide, 55-foot-long, 56-foot-high powerhouse with an operating head of 14 feet; (5) a floating debris boom at the entrance to the intake channel and two separate trash racks at the entrance to the powerhouse; (6) two vertical shaft propeller turbines each coupled to a 400-kilowatt (kW) generator, one vertical shaft propeller turbine coupled to a 300-kW generator, and one vertical shaft Francis turbine coupled to a 200-kW generator, for a total installed capacity of 1.3 megawatts; (7) a 6-foot-wide, 220-foot-long reinforced concrete fish ladder; (8) a 480-volt to 12-kilovolt (kV) transformer adjacent to the powerhouse; (9) a 0.16-mile-long, 3-phase, 3 wire 12-kV overhead interconnection line, tying into Indiana Michigan Power Company's transmission line adjacent to French Paper's property; and (10) appurtenant facilities.

The French Paper Project is operated in a run-of-river mode with an estimated annual energy production of approximately 8,442.8 megawatt-hours. French Paper proposes to continue operating the project in a run-of-river mode and does not propose any new construction or modifications to the project.

m. A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's website at *http://www.ferc.gov* using the eLibrary link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support. A copy is also available for inspection and reproduction at the address in item h above.

Register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

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

All filings must (1) bear in all capital letters the title PROTEST, MOTION TO INTERVENE, COMMENTS, REPLY COMMENTS, RECOMMENDATIONS, PRELIMINARY TERMS AND CONDITIONS, or PRELIMINARY FISHWAY PRESCRIPTIONS; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, recommendations, terms and conditions or prescriptions must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. 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 4.34(b) and 385.2010.

o. *Procedural Schedule:* The application will be processed according to the following revised Hydro Licensing Schedule. Revisions to the schedule may be made as appropriate.

Milestone	Target date
Filing of recommendations, preliminary terms and conditions, and preliminary fishway prescriptions.	January 2019.
Commission issues EA	June 2020.
Comments on EA	July 2020.
Modified terms and conditions.	September 2020.

p. Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of this notice.

q. A license applicant must file no later than 60 days following the date of issuance of the notice of acceptance and ready for environmental analysis provided for in 5.22: (1) A copy of the water quality certification; (2) a copy of the request for certification, including proof of the date on which the certifying agency received the request; or (3) evidence of waiver of water quality certification.

Dated: November 5, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–24564 Filed 11–8–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC19–40–000]

Commission Information Collection Activities (FERC–516a); Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of 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 currently approved information collection FERC–516A (Standardization of Small Generator Interconnection Agreements and Procedures) and submitting the information collection 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. On September 4, 2019, the Commission published a Notice in the **Federal Register** (84 FR 46506) in Docket No. IC19–40–000 requesting public comments. The Commission received no public comments.

DATES: Comments on the collection of information are due December 12, 2019.

ADDRESSES: Comments filed with OMB, identified by OMB Control No. 1902–0203, should be sent via email to the Office of Information and Regulatory Affairs: *oira_submission@omb.gov.* Attention: Federal Energy Regulatory Commission Desk Officer.

A copy of the comments should also be sent to the Commission, in Docket No. IC19–40–000, by either of the following methods:

- *eFiling at Commission's Website: http://www.ferc.gov/docs-filing/efiling.asp.*
- *Mail/Hand Delivery/Courier:* Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426.

Instructions: All submissions must be formatted and filed in accordance with submission guidelines at: *http://www.ferc.gov/help/submission-guide.asp.* For user assistance, contact FERC Online Support by email at *ferconlinesupport@ferc.gov,* or by phone at: (866) 208–3676 (toll-free), or (202) 502–8659 for TTY.

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/docs-filing/docs-filing.asp.*

FOR FURTHER INFORMATION CONTACT: Ellen Brown may be reached by email at *DataClearance@FERC.gov,* telephone at (202) 502–8663, and fax at (202) 273–0873.

SUPPLEMENTARY INFORMATION:

Title: FERC–516A, Standardization of Small Generator Interconnection Agreements and Procedures.

OMB Control No.: 1902–0203.

Type of Request: Three-year extension of the FERC–516A information collection requirements with no changes to the current requirements.

Abstract: Under Sections 205 and 206 of the Federal Power Act (FPA), the Commission is charged with ensuring just and reasonable electric transmission rates and charges as well as ensuring that jurisdictional providers do not subject any person to any undue prejudice or disadvantage.

The lack of consistent and readily accessible terms and conditions for connecting resources to the grid led to a large number of disputes between jurisdictional transmission providers and small generators in the late 1990s and early 2000s. In response, the Commission directed transmission providers to include Commission-approved, standard, pro-forma interconnection procedures (small generator interconnection procedures or SGIP) and a single uniformly applicable interconnection agreement (small generator interconnection agreement or SGIA) in their open-access transmission tariffs (OATTs). The requirement to create and file these documents was instituted in August 2005 by Commission Order No. 2006 and is codified in 18 CFR 35.28(f). This requirement set and maintained a standard in OATTs for consistent consideration and processing of interconnection requests by transmission providers.

Since the issuance of Order No. 2006, many aspects of the energy industry have changed including the growth of small generator interconnection requests and the growth in solar photovoltaic (PV) installations. These changes have been driven, in part, by state renewable energy goals and policies. For example, approximately 3,300 MW of grid-connected PV capacity were installed in the U.S. in 2012, compared to 79 MW in 2005, the year Order No. 2006 was issued.

In February 2012, pursuant to Sections 205 and 206 of the FPA and Rule 207 of the Commission's Rules of Practice and Procedures,[1] and noting that the Commission encouraged stakeholders to submit proposed revisions to the regulations set forth in Order No. 2006, the Solar Energy Industries Association (SEIA) filed a Petition to Initiate Rulemaking (Petition).[2] The Petition requested the Commission revise the pro forma SGIA and SGIP set forth in Order No. 2006. SEIA asserted that the pro forma SGIP and SGIA as applied to small solar generation were no longer just and reasonable, had become unduly discriminatory, and presented unreasonable barriers to market entry. SEIA noted that its Petition would apply exclusively to solar electric generation due to its unique characteristics.

In 2012 the Commission issued a Notice of Petition for Rulemaking in Docket No. RM12–10–000 and began a public process to explore SEIA's

[1] 18 CFR 385.207.

[2] SEIA Petition at 4 (citing Order No. 2006, FERC Stats. & Regs. 31,180 at P 118). Docket No. RM12–10–000, *https://elibrary.ferc.gov/idmws/common/opennat.asp?fileID=12895647.*

Petition through the Commission's formal notice and comment process as well as technical conferences.

In November 2013, the Commission issued Order No. 792 to amend the pro forma Small Generator Interconnection Procedures and pro forma Small Generator Interconnection Agreement. Order No. 792:

(1) Incorporated provisions that provided an Interconnection Customer with the option of requesting from the Transmission Provider a pre-application report providing existing information about system conditions at a possible Point of Interconnection;

(2) revised the 2 megawatt (MW) threshold for participation in the Fast Track Process included in section 2 of the pro forma SGIP;

(3) revised the customer options meeting and the supplemental review following failure of the Fast Track screens so that the supplemental review is performed at the discretion of the Interconnection Customer and includes minimum load and other screens to determine if a Small Generating Facility may be interconnected safely and reliably;

(4) revised the pro forma SGIP Facilities Study Agreement to allow the Interconnection Customer the opportunity to provide written comments to the Transmission Provider on the upgrades required for interconnection;

(5) revised the pro forma SGIP and the pro forma SGIA to specifically include energy storage devices; and

(6) clarified certain sections of the pro forma SGIP and the pro forma SGIA.

With these modifications, the Commission concluded that the package of reforms adopted in Order No. 792 would reduce the time and cost to process small generator interconnection requests for Interconnection Customers and Transmission Providers, maintain reliability, increase energy supply, and remove barriers to the development of new energy resources.

Type of Respondents: Jurisdictional transmission service providers.

Estimate of Annual Burden: [3] The Commission estimates the following burden and cost.[4]

FERC–516A

Requirements [5]	Number of respondents annually (1)	Annual number of responses per respondent (2)	Total number of responses (rounded) (1) * (2) = (3)	Average burden & cost ($) per response (4)	Total annual burden hours & total annual cost ($) (rounded) (3) * (4) = (5)	Cost per respondent ($) (5) ÷ (1)
Maintenance of Documents—Transmission Providers.	46	1	46	1 hr.; $84.38	46 hrs.; $3,881	$84.38
Filing of Agreements—Transmission Providers.	95	1	95	25 hrs.; $2,109.50	2,375 hrs.; $200,403	2,109.50
Pre-Application Report—Interconnection Customers [6].	800	1	800	1 hr.; $84.38	800 hrs.; $67,504	84.38
Pre-Application Report—Transmission Providers.	142	5.63	800	2.5 hrs.; $210.95	2,000 hrs.; $168,760	1,188.45
Supplemental Review—Interconnection Customers.	500	1	500	0.5 hr.; $42.19	250 hrs.; $21,095	42.19
Supplemental Review—Transmission Providers.	142	3.52	500	20 hrs.; $1,687.60	10,000 hrs.; $843,800	5,942.25
Review of Required Upgrades—Interconnection Customers.	250	1	250	1 hr.; $84.38	250 hrs.; $21,095	84.38
Review of Required Upgrades—Transmission Providers.	142	1.76	250	2 hrs.; $168.76	500 hrs.; $42,190	297.11
Total			3,241		16,221 hrs.; $1,368,728	

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 collection techniques or other forms of information technology.

Dated: November 5, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–24565 Filed 11–8–19; 8:45 am]

BILLING CODE 6717–01–P

[3] 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 Title 5 Code of Federal Regulations Part 1320.

[4] The hourly estimates for wages plus benefits are derived from the Bureau of Labor Statistics (at *http://bls.gov/oes/current/naics3_221000.htm* and *http://www.bls.gov/news.release/ecec.nr0.htm*). For wages plus benefits, we are using $84.38 per hour, which is the average for an attorney (occupation code 23–0000, $142.86/hour), an electrical engineer (occupation code 17–2071, $68.17/hour), and administrative staff (occupation code 43–0000, $42.11/hour).

[5] All requirements for transmission providers are mandatory. All requirements for interconnection customers are voluntary.

[6] We assume each request for a pre-application report corresponds with one Interconnection Customer.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

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

Docket Numbers: ER19–465–001.
Applicants: Midcontinent Independent System Operator, Inc.
Description: Report Filing: 2019–11–01_Order 841 extension request to be effective N/A.
Filed Date: 11/1/19.
Accession Number: 20191101–5279.
Comments Due: 5 p.m. ET 11/8/19.

Docket Numbers: ER19–2818–001.
Applicants: Upper Missouri G. & T. Electric Cooperative, Inc.
Description: Tariff Amendment: Supplement to Initial Formula Rate Filing to be effective 11/15/2019.
Filed Date: 11/5/19.
Accession Number: 20191105–5069.
Comments Due: 5 p.m. ET 11/26/19.

Docket Numbers: ER19–2820–000.
Applicants: Upper Missouri G. & T. Electric Cooperative, Inc.
Description: Supplement to September 16, 2019 Upper Missouri G. & T. Electric Cooperative, Inc. tariff filing.
Filed Date: 11/5/19.
Accession Number: 20191105–5100.
Comments Due: 5 p.m. ET 11/26/19.

Docket Numbers: ER19–2823–000.
Applicants: Isabella Wind, LLC.
Description: Second Supplement to September 17, 2019 Isabella Wind, LLC tariff filing.
Filed Date: 11/1/19.
Accession Number: 20191101–5293.
Comments Due: 5 p.m. ET 11/15/19.

Docket Numbers: ER20–301–000.
Applicants: PJM Interconnection, L.L.C.
Description: Tariff Cancellation: Notice of Cancellation of WMPA/SA No. 4377; Queue No. AB1–040 to be effective 11/12/2019.
Filed Date: 11/4/19.
Accession Number: 20191104–5096.
Comments Due: 5 p.m. ET 11/25/19.

Docket Numbers: ER20–302–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: First Revised ISA, SA No. 2255, Queue AC1–100 to be effective 10/4/2019.
Filed Date: 11/4/19.
Accession Number: 20191104–5099.
Comments Due: 5 p.m. ET 11/25/19.

Docket Numbers: ER20–303–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2019–11–04_CTA Continuous Improvement Filing to be effective 2/2/2020.
Filed Date: 11/4/19.
Accession Number: 20191104–5100.
Comments Due: 5 p.m. ET 11/25/19.

Docket Numbers: ER20–304–000.
Applicants: PPL Electric Utilities Corporation.
Description: § 205(d) Rate Filing: Service Agreement 941 between MAIT and PPL EU to be effective 11/4/2019.
Filed Date: 11/4/19.
Accession Number: 20191104–5103.
Comments Due: 5 p.m. ET 11/25/19.

Docket Numbers: ER20–305–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2019–11–04_CTA Project Cost Definition Filing to be effective 2/2/2020.
Filed Date: 11/4/19.
Accession Number: 20191104–5101.
Comments Due: 5 p.m. ET 11/25/19.

Docket Numbers: ER20–306–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Amendment to Original WMPA, SA No. 4951; Queue No. AD1–054 to be effective 2/20/2018.
Filed Date: 11/4/19.
Accession Number: 20191104–5104.
Comments Due: 5 p.m. ET 11/25/19.

Docket Numbers: ER20–307–000.
Applicants: C.P. Crane LLC.
Description: Tariff Cancellation: cancellation tariff to be effective 1/5/2020.
Filed Date: 11/5/19.
Accession Number: 20191105–5066.
Comments Due: 5 p.m. ET 11/26/19.

Docket Numbers: ER20–308–000.
Applicants: ISO New England Inc.
Description: ISO New England Inc. submits Informational filing for Qualification in the Forward Capacity Market.
Filed Date: 11/5/19.
Accession Number: 20191105–5086.
Comments Due: 5 p.m. ET 11/20/19.

Docket Numbers: ER20–310–000.
Applicants: Tampa Electric Company.
Description: Compliance filing: Compliance Filing Changes to Market-Based Rate Tariff to be effective 1/1/2020.
Filed Date: 11/5/19.
Accession Number: 20191105–5089.
Comments Due: 5 p.m. ET 11/26/19.

Docket Numbers: ER20–311–000.
Applicants: ISO New England Inc.
Description: ISO New England Inc. submits Installed Capacity Requirement, Hydro Quebec Interconnection Capability Credits and Related Values for the 2023/2024 Capacity Commitment Period.
Filed Date: 11/5/19.
Accession Number: 20191105–5112.
Comments Due: 5 p.m. ET 11/26/19.

Docket Numbers: ER20–312–000.
Applicants: PJM Interconnection, L.L.C.
Description: Tariff Cancellation: Notice of Cancellation of WMPA/SA No. 4378; Queue No. AB1–041 to be effective 11/12/2019.
Filed Date: 11/5/19.
Accession Number: 20191105–5114.
Comments Due: 5 p.m. ET 11/26/19.

Docket Numbers: ER20–313–000.
Applicants: Sun Streams 2, LLC.
Description: Baseline eTariff Filing: Certificate of Concurrence for Shared Facilities Common Ownership Agreement to be effective 11/6/2019.
Filed Date: 11/5/19.
Accession Number: 20191105–5115.
Comments Due: 5 p.m. ET 11/26/19.

Docket Numbers: ER20–314–000.
Applicants: Sun Streams 4, LLC.
Description: Baseline eTariff Filing: Certificate of Concurrence for Shared Facilities Common Ownership Agreement to be effective 11/6/2019.
Filed Date: 11/5/19.
Accession Number: 20191105–5116.
Comments Due: 5 p.m. ET 11/26/19.

Docket Numbers: ER20–315–000.
Applicants: PJM Interconnection, L.L.C.
Description: Tariff Cancellation: Notice of Cancellation of WMPA/SA No. 4379; Queue No. AB1–042 to be effective 11/12/2019.
Filed Date: 11/5/19.
Accession Number: 20191105–5128.
Comments Due: 5 p.m. ET 11/26/19.

Docket Numbers: ER20–316–000.
Applicants: Sun Streams PVS, LLC.
Description: Baseline eTariff Filing: Certificate of Concurrence for Shared Facilities Common Ownership Agreement to be effective 11/6/2019.
Filed Date: 11/5/19.
Accession Number: 20191105–5132.
Comments Due: 5 p.m. ET 11/26/19.

Docket Numbers: ER20–317–000.
Applicants: Sun Streams Expansion, LLC.
Description: Baseline eTariff Filing: Certificate of Concurrence for Shared Facilities Common Ownership Agreement to be effective 11/6/2019.
Filed Date: 11/5/19.
Accession Number: 20191105–5133.
Comments Due: 5 p.m. ET 11/26/19.

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

Docket Numbers: ES19–25–001.

Applicants: NSTAR Electric Company.

Description: Supplement to April 24, 2019 Application under Section 204 of the Federal Power Act for Authorization to Issue Securities of NSTAR Electric Company.

Filed Date: 11/1/19.

Accession Number: 20191101–5316.

Comments Due: 5 p.m. ET 11/22/19.

The filings are accessible in the Commission's eLibrary system by clicking on the links or 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 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: November 5, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–24566 Filed 11–8–19; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2019–0588; FRL–10001–99–OAR]

Alternative Methods for Calculating Off-Cycle Credits Under the Light-Duty Vehicle Greenhouse Gas Emissions Program: Applications From Nissan North America, Inc.

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is requesting comment on applications from Nissan North America, Inc. (''Nissan'') for off-cycle carbon dioxide (CO_2) credits under EPA's light-duty vehicle greenhouse gas emissions standards. ''Off-cycle'' emission reductions can be achieved by employing technologies that result in real-world benefits, but where that benefit is not adequately captured on the test procedures used by manufacturers to demonstrate compliance with emission standards. EPA's light-duty vehicle greenhouse gas program acknowledges these benefits by giving automobile manufacturers several options for generating ''off-cycle'' CO_2 credits. Under the regulations, a manufacturer may apply for CO_2 credits for off-cycle technologies that result in off-cycle benefits. In these cases, a manufacturer must provide EPA with a proposed methodology for determining the real-world off-cycle benefit. Nissan has submitted applications that describe methodologies for determining off-cycle credits from technologies described in their application. Pursuant to applicable regulations, EPA is making Nissan's off-cycle credit calculation methodologies available for public comment.

DATES: Comments must be received on or before December 12, 2019.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2019–0588, to the Federal eRulemaking Portal: *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 (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets*.

FOR FURTHER INFORMATION CONTACT: Roberts French, Environmental Protection Specialist, Office of Transportation and Air Quality, Compliance Division, U.S. Environmental Protection Agency, 2000 Traverwood Drive, Ann Arbor, MI 48105. Telephone: (734) 214–4380. Fax: (734) 214–4869. Email address: *french.roberts@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

EPA's light-duty vehicle greenhouse gas (GHG) program provides three pathways by which a manufacturer may accrue off-cycle carbon dioxide (CO_2) credits for those technologies that achieve CO_2 reductions in the real world but where those reductions are not adequately captured on the test used to determine compliance with the CO_2 standards, and which are not otherwise reflected in the standards' stringency. The first pathway is a predetermined list of credit values for specific off-cycle technologies that may be used beginning in model year 2014.[1] This pathway allows manufacturers to use conservative credit values established by EPA for a wide range of technologies, with minimal data submittal or testing requirements, if the technologies meet EPA regulatory definitions. In cases where the off-cycle technology is not on the menu but additional laboratory testing can demonstrate emission benefits, a second pathway allows manufacturers to use a broader array of emission tests (known as ''5-cycle'' testing because the methodology uses five different testing procedures) to demonstrate and justify off-cycle CO_2 credits.[2] The additional emission tests allow emission benefits to be demonstrated over some elements of real-world driving not adequately captured by the GHG compliance tests, including high speeds, hard accelerations, and cold temperatures. These first two methodologies were completely defined through notice and comment rulemaking and therefore no additional process is necessary for manufacturers to use these methods. The third and last pathway allows manufacturers to seek EPA approval to use an alternative methodology for determining the off-cycle CO_2 credits.[3] This option is only available if the benefit of the technology cannot be adequately demonstrated using the 5-cycle methodology. Manufacturers may also use this option for model years prior to 2014 to demonstrate off-cycle CO_2 reductions for technologies that are on the predetermined list, or to demonstrate reductions that exceed those available via use of the predetermined list.

Under the regulations, a manufacturer seeking to demonstrate off-cycle credits with an alternative methodology (*i.e.,* under the third pathway described above) must describe a methodology that meets the following criteria:

- Use modeling, on-road testing, on-road data collection, or other approved analytical or engineering methods;
- Be robust, verifiable, and capable of demonstrating the real-world emissions benefit with strong statistical significance;

[1] See 40 CFR 86.1869–12(b).

[2] See 40 CFR 86.1869–12(c).

[3] See 40 CFR 86.1869–12(d).

• Result in a demonstration of baseline and controlled emissions over a wide range of driving conditions and number of vehicles such that issues of data uncertainty are minimized;

• Result in data on a model type basis unless the manufacturer demonstrates that another basis is appropriate and adequate.

Further, the regulations specify the following requirements regarding an application for off-cycle CO_2 credits:

• A manufacturer requesting off-cycle credits must develop a methodology for demonstrating and determining the benefit of the off-cycle technology and carry out any necessary testing and analysis required to support that methodology.

• A manufacturer requesting off-cycle credits must conduct testing and/or prepare engineering analyses that demonstrate the in-use durability of the technology for the full useful life of the vehicle.

• The application must contain a detailed description of the off-cycle technology and how it functions to reduce CO_2 emissions under conditions not represented on the compliance tests.

• The application must contain a list of the vehicle model(s) which will be equipped with the technology.

• The application must contain a detailed description of the test vehicles selected and an engineering analysis that supports the selection of those vehicles for testing.

• The application must contain all testing and/or simulation data required under the regulations, plus any other data the manufacturer has considered in the analysis.

Finally, the alternative methodology must be approved by EPA prior to the manufacturer using it to generate credits. As part of the review process defined by regulation, the alternative methodology submitted to EPA for consideration must be made available for public comment.[4] EPA will consider public comments as part of its final decision to approve or deny the request for off-cycle credits.

II. Off-Cycle Credit Applications

A. Variable Crankcase Suction Valve Technology in Denso AC Compressors

Using the alternative methodology approach discussed above, Nissan is applying for credits for an air conditioning compressor manufactured by Denso that results in air conditioning efficiency credits beyond those provided in the regulations. This request is for the 2017 and subsequent model years. This compressor, known as the Denso SAS compressor, improves the internal valve system within the compressor to reduce the internal refrigerant flow necessary throughout the range of displacements that the compressor may use during its operating cycle. The addition of a variable crankcase suction valve allows a larger mass flow under maximum capacity and compressor start-up conditions (when high flow is ideal), and then it can reduce to smaller openings with reduced mass flow in mid- or low-capacity conditions. The refrigerant exiting the crankcase is thus optimized across the range of operating conditions, reducing the overall energy consumption of the air conditioning system. EPA first approved credits for General Motors (GM) for the use of the Denso SAS compressor in 2015,[5] and has subsequently approved such credits for BMW, Ford, and Hyundai.[6]

The credits calculated for the Denso SAS compressor would be in addition to the credits of 1.7 grams/mile for variable-displacement A/C compressors already allowed under EPA regulations.[7] However, it is important to note that EPA regulations place a limit on the cumulative credits that can be claimed for improving the efficiency of A/C systems. The rationale for this limit is that the additional fuel consumption of A/C systems can never be reduced to zero, and the limits established by regulation reflect the maximum possible reduction in fuel consumption projected by EPA. These limits, or caps, on credits for A/C efficiency, must also be applied to A/C efficiency credits granted under the off-cycle credit approval process. In other words, cumulative A/C efficiency credits for an A/C system—from the A/C efficiency regulations and those granted via the off-cycle regulations—must comply with the stated limits.

Nissan is requesting an off-cycle GHG credit of 1.1 grams CO_2 per mile for the Denso SAS compressor. Nissan cited the bench test modeling analysis referenced in the original GM application, which demonstrated a benefit of 1.1 grams/mile. Like other manufacturers, Nissan also ran vehicle tests using the AC17 test to confirm the credit amount. Seven tests were conducted, resulting in a calculated benefit of 4.4 grams/mile, thus substantiating the bench test results. Based on these results, Nissan is requesting a credit of 1.1 grams/mile for all Nissan vehicles equipped with the Denso SAS compressor with variable crankcase suction valve technology, starting with 2017 model year vehicles. Details of the testing and analysis can be found in the manufacturer's application.

B. Off-Cycle GHG Credits for Calsonic Kansei A/C Compressor Incorporating Flowpath Resistance Reduction Technology

Using the alternative methodology approach discussed above, Nissan is applying for credits for an air conditioning compressor manufactured by Calsonic Kansei that results in air conditioning efficiency credits beyond those provided in the regulations. This request is for the 2018 and subsequent model years. This compressor (the ''Calsonic Kansei CR-Phase 4 compressor''), improves the efficiency of the compressor by changing the contours of the refrigerant flow path, reducing the pressure loss and improving the efficiency relative to previous versions of the system.

The credits calculated for the Calsonic Kansei compressor would be in addition to the credits of 1.7 grams/mile for variable-displacement A/C compressors already allowed under EPA regulations.[8] However, it is important to note that EPA regulations place a limit on the cumulative credits that can be claimed for improving the efficiency of A/C systems. The rationale for this limit is that the additional fuel consumption of A/C systems can never be reduced to zero, and the limits established by regulation reflect the maximum possible reduction in fuel consumption projected by EPA. These limits, or caps, on credits for A/C efficiency, must also be applied to A/C efficiency credits granted under the off-cycle credit approval process. In other words, cumulative A/C efficiency credits for an A/C system—from the A/C efficiency regulations and those granted via the off-cycle regulations—must comply with the stated limits.

Nissan is requesting an off-cycle GHG credit of 1.1 grams CO_2 per mile for the Calsonic Kansei compressor. Nissan cited the bench test modeling analysis conducted by Calsonic Kansei, using the procedures contained in SAE standard J2765, which characterize a system's coefficient of performance. Nissan also ran six vehicle tests comparing compressors on the AC17 test protocol; these tests demonstrated a 1.7 gram/

[4] See 40 CFR 86.1869–12(d)(2).

[5] ''EPA Decision Document: Off-cycle Credits for Fiat Chrysler Automobiles, Ford Motor Company, and General Motors Corporation.'' Compliance Division, Office of Transportation and Air Quality, U.S. Environmental Protection Agency. EPA–420–R–15–014, September 2015.

[6] EPA Decision Document: Off-cycle Credits for BMW Group, Ford Motor Company, and Hyundai Motor Company.'' Compliance Division, Office of Transportation and Air Quality, U.S. Environmental Protection Agency. EPA–420–R–17–010, December 2017.

[7] See 40 CFR 86.1868–12.

[8] See 40 CFR 86.1868–12.

mile benefit. Finally, Calsonic Kansei used the LCCP model to estimate the benefits of the technology, and this modeling also supported a credit value of 1.1 grams/mile. Details of the bench testing, vehicle testing, and modeling are available in Nissan's application.

III. EPA Decision Process

EPA has reviewed the applications for completeness and is now making the applications available for public review and comment as required by the regulations. The off-cycle credit applications submitted by the manufacturer (with confidential business information redacted) have been placed in the public docket (see **ADDRESSES** section above) and on EPA's website at *https://www.epa.gov/vehicle-and-engine-certification/compliance-information-light-duty-greenhouse-gas-ghg-standards.*

EPA is providing a 30-day comment period on the applications for off-cycle credits described in this notice, as specified by the regulations. The manufacturers may submit a written rebuttal of comments for EPA's consideration, or may revise an application in response to comments. After reviewing any public comments and any rebuttal of comments submitted by manufacturers, EPA will make a final decision regarding the credit requests. EPA will make its decision available to the public by placing a decision document (or multiple decision documents) in the docket and on EPA's website at the same manufacturer-specific pages shown above. While the broad methodologies used by these manufacturers could potentially be used for other vehicles and by other manufacturers, the vehicle specific data needed to demonstrate the off-cycle emissions reductions would likely be different. In such cases, a new application would be required, including an opportunity for public comment.

Dated: November 1, 2019.

Byron J. Bunker,

Director, Compliance Division, Office of Transportation and Air Quality, Office of Air and Radiation.

[FR Doc. 2019–24572 Filed 11–8–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2017–0750; FRL–10001–71]

Pesticide Registration Review; Proposed Interim Decisions for Several Pyrethroids; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the availability of EPA's proposed interim registration review decisions and opens a 60-day public comment period on the proposed interim decisions for the following pesticides: cyphenothrin, flumethrin, imiprothrin, momfluorothrin, and tetramethrin. The Agency is also announcing the availability of the *Pyrethroids and Pyrethrins Ecological Risk Mitigation Proposal for 23 Chemicals,* which summarizes proposed labeling intended to address ecological risks for all the pyrethroids.

DATES: Comments must be received on or before January 13, 2020.

ADDRESSES: Submit your comments, identified by the docket identification (ID) number for the specific pesticide of interest provided in the Table in Unit IV., by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

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

FOR FURTHER INFORMATION CONTACT: *For pesticide specific information, contact:* The Chemical Review Manager for the pesticide of interest identified in the Table in Unit IV.

For general information on the registration review program, contact: Melanie Biscoe, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (703) 305–7106; email address: *biscoe.melanie@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, farm worker, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the Chemical Review Manager for the pesticide of interest identified in the Table in Unit IV.

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

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

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

II. Background

Registration review is EPA's periodic review of pesticide registrations to ensure that each pesticide continues to satisfy the statutory standard for registration, that is, the pesticide can perform its intended function without unreasonable adverse effects on human health or the environment. As part of the registration review process, the Agency has completed proposed interim decisions for all pesticides listed in the Table in Unit IV. Through this program, EPA is ensuring that each pesticide's registration is based on current scientific and other knowledge,

including its effects on human health and the environment.

III. Authority

EPA is conducting its registration review of the chemicals listed in the Table in Unit IV pursuant to section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Procedural Regulations for Registration Review at 40 CFR part 155, subpart C. Section 3(g) of FIFRA provides, among other things, that the registrations of pesticides are to be reviewed every 15 years. Under FIFRA, a pesticide product may be registered or remain registered only if it meets the statutory standard for registration given in FIFRA section 3(c)(5) (7 U.S.C. 136a(c)(5)). When used in accordance with widespread and commonly recognized practice, the pesticide product must perform its intended function without unreasonable adverse effects on the environment; that is, without any unreasonable risk to man or the environment, or a human dietary risk from residues that result from the use of a pesticide in or on food.

IV. What action is the Agency taking?

Pursuant to 40 CFR 155.58, this notice announces the availability of EPA's proposed interim registration review decisions for the pesticides shown in Table 1, and opens a 60-day public comment period on the proposed interim registration review decisions.

The Agency is also announcing the availability of the *Pyrethroids and Pyrethrins Ecological Risk Mitigation Proposal for 23 Chemicals,* which summarizes proposed labeling intended to address potential ecological risks for the 23 chemicals noted in Table 2. The *Pyrethroids and Pyrethrins Ecological Risk Mitigation Proposal for 23 Chemicals* and all supporting documents that pertain to the pyrethroids/pyrethrins as a group will be posted in the Special Docket for the Pyrethroids, Pyrethrins, and Synergists, EPA–HQ–OPP–2008–0331. Public comments concerning the *Pyrethroids and Pyrethrins Ecological Risk Mitigation Proposal for 23 Chemicals* and those comments concerning the 23 affected chemicals as a group should be submitted to the same Special Docket for the Pyrethroids, Pyrethrins, and Synergists, EPA–HQ–OPP–2008–0331.

TABLE 1—PROPOSED INTERIM DECISIONS

Registration review case name and No.	Docket ID No.	Chemical review manager and contact information
Cyphenothrin, Case 7412	EPA–HQ–OPP–2009–0842	Jonathan Williams, *williams.jonathanr@epa.gov,* 703–347–0670.
Flumethrin, Case 7456	EPA–HQ–OPP–2016–0031	Rachel Fletcher, *fletcher.rachel@epa.gov,* 703–347–0512.
Imiprothrin, Case 7426	EPA–HQ–OPP–2011–0692	Michelle Nolan, *nolan.michelle@epa.gov,* 703–347–0258.
Momfluorothrin, Case 7457	EPA–HQ–OPP–2015–0752	Andy Muench, *muench.andrew@epa.gov,* 703–347–8263.
Tetramethrin, Case 2660	EPA–HQ–OPP–2011–0907	Nathan Sell, *sell.nathan@epa.gov,* 703–347–8020.

TABLE 2—CHEMICALS AND DOCKETS AFFECTED BY THE PYRETHROIDS AND PYRETHRINS ECOLOGICAL RISK MITIGATION PROPOSAL FOR 23 CHEMICALS

[All supporting documents that pertain to the pyrethroids/pyrethrins as a group will be posted in the Special Docket EPA–HQ–OPP–2008–0331]

Chemical	Docket ID No.	Chemical review manager and contact information
Special Docket for Pyrethroids, Pyrethrins, and Synergists.	EPA–HQ–OPP–2008–0331	Moana Appleyard, 703–308–8175, *appleyard.moana@epa.gov.*
Bifenthrin	EPA–HQ–OPP–2010–0384	Moana Appleyard, 703–308–8175, *appleyard.moana@epa.gov.*
Cyfluthrin, beta-cyfluthrin	EPA–HQ–OPP–2010–0684	Michelle Nolan, 703–347–0258, *nolan.michelle@epa.gov.*
Gamma-cyhalothrin	EPA–HQ–OPP–2010–0479	Wilhelmena Livingston, 703–308–8025, *livingston.wilhelmena@epa.gov.*
Lambda-cyhalothrin	EPA–HQ–OPP–2010–0480	Wilhelmena Livingston, 703–308–8025, *livingston.wilhelmena@epa.gov.*
Cypermethrin, alpha-cypermethrin, zeta-cypermethrin.	EPA–HQ–OPP–2012–0167	Susan Bartow, 703–603–0065, *bartow.susan@epa.gov.*
Cyphenothrin	EPA–HQ–OPP–2009–0842	Jonathan Williams, 703–347–0670, *williams.jonathanr@epa.gov.*
Deltamethrin	EPA–HQ–OPP–2009–0637	Rachel Fletcher, 703–347–0512, *fletcher.rachel@epa.gov.*
D-phenothrin	EPA–HQ–OPP–2011–0539	Patricia Biggio, 703–347–0547, *biggio.patricia@epa.gov.*
Esfenvalerate	EPA–HQ–OPP–2009–0301	Marianne Mannix, 703–347–0275, *mannix.marianne@epa.gov.*
Etofenprox	EPA–HQ–OPP–2007–0804	Wilhelmena Livingston, 703–308–8025, *livingston.wilhelmena@epa.gov.*
Fenpropathrin	EPA–HQ–OPP–2010–0422	Tiffany Green, 703–347–0314, *green.tiffany@epa.gov.*
Flumethrin	EPA–HQ–OPP–2011–0013	Rachel Fletcher, 703–347–0512, *fletcher.rachel@epa.gov.*
Imiprothrin	EPA–HQ–OPP–2011–0692	Michelle Nolan, 703–347–0258, *nolan.michelle@epa.gov.*
Momfluorothrin	EPA–HQ–OPP–2015–0752	Andy Muench, 703–347–8263, *muench.andy@epa.gov.*
Permethrin	EPA–HQ–OPP–2011–0039	Ana Pinto, 703–347–8421, *pinto.ana@epa.gov.*
Prallethrin	EPA–HQ–OPP–2011–1009	Wilhelmena Livingston, 703–308–8025, *livingston.wilhelmena@epa.gov.*
Pyrethrins	EPA–HQ–OPP–2011–0885	Jordan Page, 703–347–0467, *page.jordan@epa.gov.*
Tau-fluvalinate	EPA–HQ–OPP–2010–0915	Linsey Walsh, 703–347–8030, *walsh.linsey@epa.gov.*
Tefluthrin	EPA–HQ–OPP–2012–0501	Carolyn Smith, 703–347–8325, *smith.carolyn@epa.gov.*
Tetramethrin	EPA–HQ–OPP–2011–0907	Nathan Sell, 703–347–8020, *sell.nathan@epa.gov.*

The registration review docket for a pesticide includes earlier documents related to the registration review case. For example, the review opened with a Preliminary Work Plan, for public comment. A Final Work Plan was placed in the docket following public comment on the Preliminary Work Plan.

The documents in the dockets describe EPA's rationales for conducting additional risk assessments for the registration review of the pesticides included in the tables in Unit IV, as well as the Agency's subsequent risk findings and consideration of possible risk

mitigation measures. These proposed interim registration review decisions are supported by the rationales included in those documents. Following public comment, the Agency will issue interim or final registration review decisions for the pesticides listed in Table 1 in Unit IV.

The registration review final rule at 40 CFR 155.58(a) provides for a minimum 60-day public comment period on all proposed interim registration review decisions. This comment period is intended to provide an opportunity for public input and a mechanism for initiating any necessary amendments to the proposed interim decision. All comments should be submitted using the methods in **ADDRESSES** and must be received by EPA on or before the closing date. These comments will become part of the docket for the pesticides included in the Tables in Unit IV. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments.

The Agency will carefully consider all comments received by the closing date and may provide a ''Response to Comments Memorandum'' in the docket. The interim registration review decision will explain the effect that any comments had on the interim decision and provide the Agency's response to significant comments.

Background on the registration review program is provided at: *http://www.epa.gov/pesticide-reevaluation.*

Authority: 7 U.S.C. 136 *et seq.*

Dated: October 29, 2019.

Mary Reaves,

Acting Director, Pesticide Re-Evaluation Division, Office of Pesticide Programs.

[FR Doc. 2019–24514 Filed 11–8–19; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[CDC–2019–0093; NIOSH–156–E]

Request for Information for Six Chemicals To Develop Immediately Dangerous to Life or Health (IDLH) Values.

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Request for information.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) intends to evaluate the scientific data for 6 chemicals—allyl alcohol, bromine chloride, hydrogen bromide, hydrogen iodide, lewisite (a chemical warfare agent), and propylene imine—to develop new or updated Immediately Dangerous to Life or Health (IDLH) values.

DATES: Electronic or written comments must be received by January 13, 2020.

ADDRESSES: You may submit comments, identified by CDC–2019–0093 and Docket Number NIOSH–156–E, by either of the two following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* NIOSH Docket Office, Robert A. Taft Laboratories, MS–C34, 1090 Tusculum Avenue, Cincinnati, OH 45226.

Instructions: All information received in response to this notice must include the agency name and docket number (CDC–2019–0093; NIOSH–156–E). All relevant comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. All electronic comments should be formatted in Microsoft Word. Please make reference to CDC–2019–0093 and Docket Number NIOSH–156–E.

FOR FURTHER INFORMATION CONTACT: R. Todd Niemeier, MS, NIOSH, MS–C32, 1090 Tusculum Avenue, Cincinnati, OH 45226, telephone (513) 533–8166.

SUPPLEMENTARY INFORMATION: In 2013, NIOSH published Current Intelligence Bulletin (CIB) 66—Derivation of Immediately Dangerous to Life or Health (IDLH) Values [*http://www.cdc.gov/niosh/docs/2014-100/pdfs/2014-100.pdf*] [NIOSH 2013]. The information presented in this CIB represents the most recent update of the scientific rationale and the methodology (hereby referred to as the IDLH methodology) used to derive IDLH values. Since the establishment of the IDLH values in the 1970s, NIOSH has continued to review available scientific data to improve the protocol used to derive acute exposure guidelines, in addition to the chemical-specific IDLH values.

IDLH values are based on health effects considerations determined through a critical assessment of the toxicology and human health effects data. This approach ensures that the IDLH values reflect an airborne concentration of a substance that represents a high-risk situation that may endanger workers' lives or health.

The primary steps applied in the establishment of an IDLH value include the following:

1. Critical review of human and animal toxicity data to identify potentially relevant studies and characterize the various lines of evidence that can support the derivation of the IDLH value;
2. Determination of a chemical's mode of action (MOA) or description of how a chemical exerts its toxic effects;
3. Application of duration adjustments (time scaling) to determine 30-minute-equivalent exposure concentrations and the conduct of other dosimetry adjustments, as needed;
4. Experimental or other data to establish a point of departure (POD) such as lethal concentrations (*e.g.,* LC50), lowest observed adverse effect level (LOAEL), or no observed adverse effect level (NOAEL);
5. Selection and application of an uncertainty factor (UF) for POD or critical adverse effect concentration, identified from the available studies to account for issues associated with interspecies and intraspecies differences, severity of the observed effects, data quality, or data insufficiencies; and
6. Development of the final recommendation for the IDLH value from the various alternative lines of evidence, with use of a weight-of-evidence approach to all of the data.

NIOSH seeks to obtain materials, including published and unpublished reports and research findings, to evaluate the possible acute health risks of occupational exposure to the following six chemicals:

1. Allyl Alcohol (CAS# 107–18–6)
2. Bromine Chloride (CAS# 13863–41–7)
3. Hydrogen Bromide (CAS# 10035–10–6)
4. Hydrogen Iodide (CAS# 10034–85–2)
5. Lewisite (a chemical warfare agent) (CAS#s 541–25–3, 40334–69–8, 40334–70–1)
6. Propylene Imine (CAS# 75–55–8)

Materials also include reports of acute animal toxicity studies, acute human toxicology studies, mode of action studies, and other information about a chemical's toxic effects such as studies on sensory or respiratory irritation, nervous system effects (*e.g.,* dizziness, central nervous system excitability, autonomic effects, muscle tone/equilibrium effects, sensorimotor reactivity, nervous system histopathology), metabolic toxicants, target organ toxicants, gastrointestinal effects, cardiovascular changes, and asphyxiants.

In a subsequent notice, Draft IDLH Value profiles for these chemicals will be made available for public comment.

Reference

NIOSH [2013]. Current intelligence bulletin 66: derivation of immediately dangerous to life or health (IDLH) values. Cincinnati, OH: US Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication 2014–100.

John J. Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2019–24465 Filed 11–8–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–6089–N]

Medicare, Medicaid, and Children's Health Insurance Programs; Provider Enrollment Application Fee Amount for Calendar Year 2020

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

ACTION: Notice.

SUMMARY: This notice announces a $595.00 calendar year (CY) 2020 application fee for institutional providers that are initially enrolling in the Medicare or Medicaid program or the Children's Health Insurance Program (CHIP); revalidating their Medicare, Medicaid, or CHIP enrollment; or adding a new Medicare practice location. This fee is required with any enrollment application submitted on or after January 1, 2020 and on or before December 31, 2020.

DATES: The application fee announced in this notice is effective on January 1, 2020.

FOR FURTHER INFORMATION CONTACT: Melissa Singer, (410) 786–0365.

SUPPLEMENTARY INFORMATION:

I. Background

In the February 2, 2011 **Federal Register** (76 FR 5862), we published a final rule with comment period titled ''Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers.'' This rule finalized, among other things, provisions related to the submission of application fees as part of the Medicare, Medicaid, and CHIP provider enrollment processes. As provided in section 1866(j)(2)(C)(i) of the Social Security Act (the Act) and in 42 CFR 424.514, ''institutional providers'' that are initially enrolling in the Medicare or Medicaid programs or CHIP, revalidating their enrollment, or adding a new Medicare practice location are required to submit a fee with their enrollment application. An ''institutional provider'' for purposes of Medicare is defined at § 424.502 as (a)ny provider or supplier that submits a paper Medicare enrollment application using the CMS–855A, CMS–855B (not including physician and non-physician practitioner organizations), CMS–855S, CMS–20134, or associated internet-based PECOS enrollment application. As we explained in the February 2, 2011 final rule (76 FR 5914), in addition to the providers and suppliers subject to the application fee under Medicare, Medicaid-only and CHIP-only institutional providers would include nursing facilities, intermediate care facilities for persons with intellectual disabilities (ICF/IID), psychiatric residential treatment facilities, and may include other institutional provider types designated by a state in accordance with their approved state plan.

As indicated in §§ 424.514 and 455.460, the application fee is not required for either of the following:

- A Medicare physician or non-physician practitioner submitting a CMS–855I.
- A prospective or revalidating Medicaid or CHIP provider—

++ Who is an individual physician or non-physician practitioner; or

++ That is enrolled in Title XVIII of the Act or another state's Title XIX or XXI plan and has paid the application fee to a Medicare contractor or another state.

II. Provisions of the Notice

Section 1866(j)(2)(C)(i)(I) of the Act established a $500 application fee for institutional providers in calendar year (CY) 2010. Consistent with section 1866(j)(2)(C)(i)(II) of the Act, § 424.514(d)(2) states that for CY 2011 and subsequent years, the preceding year's fee will be adjusted by the percentage change in the consumer price index (CPI) for all urban consumers (all items; United States city average, CPI U) for the 12 month period ending on June 30 of the previous year. Each year since 2011, accordingly, we have published in the **Federal Register** an announcement of the application fee amount for the forthcoming CY based on the above formula. Most recently, in the November 19, 2018 **Federal Register** (83 FR 58255), we published a notice announcing a fee amount for the period of January 1, 2019 through December 31, 2019 of $586.00. The $586.00 fee amount for CY 2019 was used to calculate the fee amount for CY 2020 as specified in § 424.514(d)(2).

According to Bureau of Labor Statistics (BLS) data, the CPU–U increase for the period of July 1, 2018 through June 30, 2019 was 1.6 percent. As required by § 424.514(d)(2), the preceding year's fee of $586 will be adjusted by the CPI–U of 1.6 percent. This results in a CY 2020 application fee amount of $595.376 ($586 × 1.016). As we must round this to the nearest whole dollar amount, the resultant application fee amount for CY 2020 is $595.00.

III. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995. However, it does reference previously approved information collections. The Forms CMS–855A, CMS–855B, and CMS–855I are approved under OMB control number 0938–0685; the Form CMS–855S is approved under OMB control number 0938–1056.

IV. Regulatory Impact Statement

A. Background

We have examined the impact of this notice as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

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. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). As explained in this section of the notice, we estimate that the total cost of the increase in the application fee will not exceed $100 million. Therefore, this notice does not reach the $100 million economic threshold and is not considered a major notice.

B. Estimated Costs

The costs associated with this notice involve the increase in the application fee amount that certain providers and suppliers must pay in CY 2020. The CY 2020 cost estimates are as follows:

1. Medicare

Based on CMS data, we estimate that in CY 2020 approximately—

- 14,852 newly enrolling institutional providers will be subject to and pay an application fee; and
- 41,747 revalidating institutional providers will be subject to and pay an application fee.

Using a figure of 56,599 (14,852 newly enrolling + 41,747 revalidating) institutional providers, we estimate an increase in the cost of the Medicare application fee requirement in CY 2020 of $509,391 (or 56,599 × $9 (or $595 minus $586)) from our CY 2019 projections.

2. Medicaid and CHIP

Based on CMS and state statistics, we estimate that approximately 30,000 (9,000 newly enrolling + 21,000 revalidating) Medicaid and CHIP institutional providers will be subject to an application fee in CY 2020. Using this figure, we project an increase in the cost of the Medicaid and CHIP application fee requirement in CY 2020 of $270,000 (or 30,000 × $9 (or $595 minus $586)) from our CY 2019 projections.

3. Total

Based on the foregoing, we estimate the total increase in the cost of the application fee requirement for Medicare, Medicaid, and CHIP providers and suppliers in CY 2020 to be $779,391 ($509,391 + $270,000) from our CY 2019 projections.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.5 million to $38.5 million in any 1 year. Individuals and states are not included in the definition of a small entity. As we stated in the RIA for the February 2, 2011 final rule with comment period (76 FR 5952), we do not believe that the application fee will have a significant impact on 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 for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this notice would not have a significant impact on the operations of a substantial number of small rural hospitals.

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. In 2019, that threshold is approximately $154 million. The Agency has determined that there will be minimal impact from the costs of this notice, as the threshold is not met under the UMRA.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. Since this notice does not impose substantial direct costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

Executive Order 13771, titled ''Reducing Regulation and Controlling Regulatory Costs,'' was issued on January 30, 2017 (82 FR 9339, February 3, 2017). It has been determined that this notice is a transfer notice that does not impose more than de minimis costs and thus is not a regulatory action for the purposes of E.O. 13771.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

Dated: September 26, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2019–24443 Filed 11–8–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Proposed Collection; Comment Request; Development Disabilities State Plan Information Collection; OMB #0985–0029

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) is announcing an opportunity for the public to comment on the proposed collection of information listed above. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish a notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the Proposed Extension without Change and solicits comments on the information collection requirements related to Development Disabilities State Plan.

DATES: Comments on the collection of information must be submitted electronically by 11:59 p.m. (EST) or postmarked by January 13, 2020.

ADDRESSES: Submit electronic comments on the collection of information to Sara Newell-Perez. Submit written comments on the collection of information to Administration for Community Living, Washington, DC 20201, Attention: Sara Newell-Perez.

FOR FURTHER INFORMATION CONTACT: Sara Newell-Perez, Administration for Community Living, Washington, DC 20201, 202–795–7413 *sara.newell-perez@acl.hhs.gov*.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the

public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, ACL is publishing a notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, ACL invites comments on our burden estimates or any other aspect of this collection of information, including:

(1) Whether the proposed collection of information is necessary for the proper performance of ACL's functions, including whether the information will have practical utility;

(2) the accuracy of ACL's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used to determine burden estimates;

(3) ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

The State Councils on Developmental Disabilities (Councils) are authorized in Subtitle B, of the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (DD Act), as amended, [42 U.S.C. 15001 *et seq.*] (The DD Act). They are required to submit a five-year State plan. Section 124(a) [42 U.S.C. 15024(a)], states any State desiring to receive assistance under this subtitle shall submit to the Secretary, and obtain approval of, a 5-year strategic State plan under this section. The requirement for a State plan is also further emphasized in the regulations in 45 CFR part 1326.30: (a) In order to receive Federal financial assistance under this subpart, each State Developmental Disabilities Council must prepare and submit to the Secretary, and have in effect, a State Plan which meets the requirements of sections 122 and 124 of the Act (42 U.S.C. 6022 and 6024) and these regulations.

Additionally, data is collected in the State Plan and submitted to Administration on Intellectual and Developmental Disabilities (AIDD) for compliance with the GPRA Modernization Act of 2010 (GPRAMA). In the State Plans, the Councils provide to AIDD future year targets for outcome performance measures. These targets are reported to Congress under GPRAMA.

As required by the statute, the Council is responsible for the development and submission of the State plan, and is then responsible for implementation of the activities described in the plan. Further, the Council updates the Plan annually during the five years. The State plan provides information on individuals with developmental disabilities in the State, and a description of the services available to them and their families. The plan further sets forth the goals and specific objectives to be achieved by the State in pursuing systems change and capacity building in order to more effectively meet the service needs of this population. It describes State priorities, strategies, and actions, and the allocation of funds to meet these goals and objectives.

The State Plan is used in three ways. First, it is used by the individual Council as a planning document to guide it's planning and execution processes. Secondly, it provides a mechanism in the State whereby individual citizens, as well as the State government, are made aware of the goals and objectives of the Council and have an opportunity to provide comments on them during its development. Finally, the State plan provides to the Department a stewardship tool; the staff of the Department provides some technical assistance to Councils and monitor compliance with Subtitle B of the DD Act, as an adjunct to on-site monitoring. The stewardship role of the State plan is useful both for providing technical assistance during the planning process, during the execution process, and also during program site visits.

The proposed data collection tools may be found on the ACL website for review at *https://www.acl.gov/about-acl/public-input.*

Estimated Program Burden

ACL estimates the burden associated with this collection of information as follows.

Number of states	Number of responses per state	Average burden hours per state	Total hours
56	1	367	20,522

Dated: October 30, 2019.

Mary Lazare,

Principal Deputy Administrator.

[FR Doc. 2019–24523 Filed 11–8–19; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Proposed Collection; Comment Request; The National Adult Maltreatment Reporting System; OMB #0985–0054

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) is announcing an opportunity for the public to comment on the proposed collection of information listed above. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish a notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the Proposed Extension without Change and solicits comments on the information collection requirements related to the National Maltreatment Reporting System (NAMRS).

DATES: Comments on the collection of information must be submitted

electronically by 11:59 p.m. (EST) or postmarked by January 13, 2020.

ADDRESSES: Submit electronic comments on the collection of information to Stephanie Whittier Eliason, Administration for Community Living, Washington, DC 20201, at *Stephanie.WhittierEliason@acl.hhs.gov*.

FOR FURTHER INFORMATION CONTACT: Stephanie Whittier Eliason, Administration for Community Living, Washington, DC 20201, at 202.795.7467 and *Stephanie.WhittierEliason@acl.hhs.gov*.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party the PRA requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, ACL is publishing a notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, ACL invites comments on our burden estimates or any other aspect of this collection of information, including:

(1) Whether the proposed collection of information is necessary for the proper performance of ACL's functions, including whether the information will have practical utility;

(2) the accuracy of ACL's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used to determine burden estimates;

(3) ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

This data collection effort is in response to the Elder Justice Act of 2009, which amended title XX of the Social Security Act [42.U.S.C. 13976 *et seq.*]. These provisions require that the Secretary of HHS ''collects and disseminates data annually relating to the abuse, exploitation, and neglect of elders in coordination with the Department of Justice'' [Sec. 2041(a)(1)(B)], and ''conducts research related to the provision of adult protective services'' [Sec. 2041(a)(1)(D)]. Furthermore, the Elder Justice Coordinating Council (EJCC) included as its third recommendation for increasing federal involvement in addressing elder abuse, neglect, and exploitation: Develop a national adult protective services (APS) system based upon standardized data collection and a core set of service provision standards and best practices. NAMRS is a voluntary system that since FFY2016 has been collecting on an annual basis both summary and de-identified case-level data on APS investigations submitted by states. NAMRS consists of three components:

(1) ACL proposes to collect descriptive data on state agency and practices from all states through the ''Agency Component,'' and

(2) Case-level, non-identifiable data on persons who receive an investigation by APS in response to an allegation of abuse, neglect, or exploitation through ''Case Component''

(3) For states that are unable to submit a case-level file through the ''Case Component,'' a ''Key Indicators Component'' will be available for them to submit data on a smaller set of core items.

ACL provides technical assistance to states to assist in the preparation of their data submissions. Respondents are state APS agencies and APS agencies in the District of Columbia, Puerto Rico, Guam, Northern Mariana Islands, Virgin Islands, and American Samoa (states, hereafter). No personally identifiable information is collected.

The proposed data collection tools may be found on the ACL website for review at *https://www.acl.gov/about-acl/public-input.*

Estimated Program Burden

ACL estimates the burden associated with this collection of information as follows: 56 states will respond every year. It will take approximately 7 hours to respond to the Agency Component, 32 hours to respond to the Key Indicator Component, and 125 hours to respond and jointly complete the Case Component and the development of NAMRS for a total of approximately 5,436 hours. The estimates are based on the amount of time States have previously reported in completing the data collection instruments; continued increase in the number of states reporting on Case Component and Key Indicator Component data; and assumption of modest incremental efficiencies by States in reporting data to NAMRS every year, including, most significantly, minimal need to recode to extract data after the initial year.

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
Agency Component	56	1	4	224
Key Indicators Component	17	1	20	340
Case Component	36	1	100	3,600
Total				4,164

Dated: November 1, 2019.

Mary Lazare,

Principal Deputy Administrator.

[FR Doc. 2019–24521 Filed 11–8–19; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Proposed Collection; Comment Request; State Program Report; OMB #0985–0008

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) is announcing that the proposed collection of information listed above has been submitted to the Office of Management and Budget (OMB) for review and clearance as required under section 506(c)(2)(A) of the Paperwork Reduction Act of 1995. This 30-Day notice collects comments on the information collection requirements related to Proposed Revision for the information collection requirements related to the State Program Report.

DATES: Submit written comments on the collection of information by December 12, 2019.

ADDRESSES: Submit electronic comments on the collection of information by:

(a) Email to: *OIRA_submission@omb.eop.gov,* Attn: OMB Desk Officer for ACL;

(b) fax to 202.395.5806, Attn: OMB Desk Officer for ACL; or

(c) by mail to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW, Rm. 10235, Washington, DC 20503, Attn: OMB Desk Officer for ACL.

FOR FURTHER INFORMATION CONTACT: Susan Jenkins, Director, Office of Performance and Evaluation, Administration for Community Living, Washington, DC 20201, Phone: (202) 795–7369, Email: *Susan.Jenkins@acl.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, ACL has submitted the following proposed collection of information to OMB for review and clearance.

The Older Americans Act (OAA) requires annual program performance reports from States, the District of Columbia, and Territories. In compliance with this OAA provision, ACL developed a SPR in 1996 as part of its National Aging Program Information System (NAPIS). The SPR collects information about how State Agencies on Aging expend their OAA funds as well as funding from other sources for OAA authorized supportive services. The SPR also collects information on the demographic and functional status of the recipients, and is a key source for ACL performance measurement.

ACL is requesting approval from OMB to continue collecting data after expiration on 12/31/2019. This is a revision request to the 2016 approved version of the Reporting Requirements for Title III and VII State Program Report Definitions. The currently approved version of the State Program Report (SPR) includes language intended for usage in FY 2023. Since these data elements are not required for usage until FY 2023, under the Paperwork Reduction Act ACL is required to update the information collection (IC) to contain only the language and requirements for collection years 2020–2023. Removing the proposed FY 2023 language from the currently approved SPR causes a revision to OMB 0985–0008. ACL intends to seek OMB approval under a new OMB control number for the FY 2023–2026 data elements allowing usage of 0985–0008 until the new IC is approved and ready for usage.

Comments in Response to the 60–Day Federal Register Notice

A 60-Day Notice was published in the **Federal Register** on August 30, 2019, Vol. 84, No. 169, pp. 45768–45769. No comments were received. The proposed FY 2020 version posts on the ACL website link entitled *Proposed State Program Report (SPR) Form 2020 Revision* available at *https://acl.gov/programs/performance-older-americans-act-programs.* For review and comment on this proposed information collection request, please visit the ACL website *https://www.acl.gov/about-acl/public-input.*

Estimated Program Burden:

ACL estimates the burden associated with this collection of information as follows: 2,750 annual burden hours.

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
SPR	55	1	50	2,750
Total	55	1	50	2,750

Dated: November 1, 2019.

Mary Lazare,

Principal Deputy Administrator.

[FR Doc. 2019–24522 Filed 11–8–19; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1592]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Controlled Correspondence Related to Generic Drug Development

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

DATES: Fax written comments on the collection of information by December 12, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0797. Also include the FDA docket number found

in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Controlled Correspondence Related to Generic Drug Development

OMB Control No. 0910–0797—Revision

This information collection supports implementation of the Generic Drug User Fee Amendments (GDUFA) of the FDA Reauthorization Act of 2017 (Pub. L. 115–52, Title III). As established in the ''Reauthorization Performance Goals And Program Enhancements Fiscal Years 2018–2022 Letter'' (''The GDUFA II Commitment Letter'') under GDUFA, certain goals have been identified with regard to controlled correspondence relating to generic drug development. The GDUFA II Commitment Letter includes details of our commitment to respond to questions submitted as controlled correspondence within certain timeframes. The GDUFA II Commitment Letter also includes details regarding our commitment to respond to requests to clarify FDA ambiguities in a controlled correspondence response within certain timeframes.

To support these program goals, we developed the associated guidance entitled ''Controlled Correspondence Related to Generic Drug Development.'' The guidance is intended to facilitate our prompt consideration of controlled correspondence and to assist in meeting the prescribed GDUFA II performance goals and timeframes. Specifically, the guidance provides procedural instruction, including recommendations that the following information be included in controlled correspondence submitted to FDA and requests to clarify FDA response to controlled correspondence:

- Name, title, address, phone number, and entity of the person submitting the inquiry;
- a letter of authorization, if applicable;
- the FDA-assigned control number and submission date of any previous, related controlled correspondence that was accepted for substantial review and response, if any, as well as a copy of that previous controlled correspondence and FDA's response, if any;
- the relevant reference listed drug(s), as applicable, including the application number, proprietary (brand) name, manufacturer, active ingredient, dosage form, and strength(s);
- a statement that the controlled correspondence is related to a potential abbreviated new drug application (ANDA) submission to the Office of Generic Drugs and the ANDA number, if applicable;
- a concise statement of the inquiry;
- a recommendation of the appropriate FDA review discipline;
- relevant prior research and supporting materials; and
- the clarifying questions and the corresponding section(s) of FDA's controlled correspondence response on which the requestor is seeking clarification.

In the **Federal Register** of May 22, 2018 (83 FR 23692), we published a 60-day notice under the PRA requesting public comment on the proposed collection of information. No comments were received in response to the PRA notice. Separately, in the **Federal Register** of November 3, 2017 (82 FR 51277), we announced the availability of a revised draft version of the associated guidance. Because the guidance is currently being revised to reflect 2018 through 2022 GDUFA reauthorization goals, we are revising the supporting information collection request.

The guidance is being issued consistent with FDA's good guidance practice regulation (21 CFR part 10.115), we intend no changes to the information collection elements recommended, and have not modified the burden estimate we ascribe to the related activities.

We therefore estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Submission of controlled correspondence	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Generic drug manufacturers, related industry, and representatives	390	3.8	1,496	5	7,480

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We base our estimate on a review of Agency data of fiscal year submissions for 2014, 2015, and 2016, which reflects an increase in submissions that we attribute to an increase in generic drug development. Accordingly, we estimate 390 generic drug manufacturers and related industry (*e.g.,* contract research organizations conducting bioanalytical or bioequivalence clinical trials) or their representatives will each submit an average of 3.8 inquiries annually for a total of 1,496 inquiries [1,496 ÷ 390 = 3.8]. Information submitted with each inquiry varies widely in content, depending on the complexity of the request. Inquiries that are defined as controlled correspondence may range from a simple inquiry on generic drug labeling to a more complex inquiry for a formulation assessment for a specific proposed generic drug product. As a result, these inquiries can vary between 1 and 10 burden hours.

Because the content of inquiries considered controlled correspondence is widely varied, we are providing an average burden hour for each inquiry. We estimate that it will take an average of 5 hours per inquiry for industry to gather necessary information, prepare the request, and submit the request to FDA. As a result, we estimate that it will take an average of 7,480 hours annually for industry to prepare and submit inquiries considered controlled correspondence.

Dated: November 5, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–24562 Filed 11–8–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0380]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Product Jurisdiction: Assignment of Agency Component for Review of Premarket Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by December 12, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0523. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Product Jurisdiction: Assignment of Agency Component for Review of Premarket Applications—21 CFR Part 3

OMB Control Number 0910–0523—Extension

This regulation relates to Agency management and organization and has two purposes. The first is to implement section 503(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)), as added by the Safe Medical Devices Act of 1990 (Pub. L. 101–629), and amended by the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107–250), by specifying how FDA will determine the organizational component within FDA assigned to have primary jurisdiction for the premarket review and regulation of products that are comprised of any combination of: (1) A drug and a device; (2) a device and a biological product; (3) a biological product and a drug; or (4) a drug, a device, and a biological product. The second purpose of this regulation is to enhance the efficiency of Agency management and operations by providing procedures for classifying and determining which Agency component is designated to have primary jurisdiction for any drug, device, or biological product where such jurisdiction is unclear or in dispute.

The regulation establishes a procedure by which an applicant may obtain an assignment or designation determination. The regulation requires that the request include the identity of the applicant, a comprehensive description of the product and its proposed use, and the applicant's recommendation as to which Agency component should have primary jurisdiction, with an accompanying statement of reasons. The information submitted would be used by FDA as the basis for making the assignment or designation decision. Most information required by the regulation is already required for premarket applications affecting drugs, devices, biological products and combination products. The respondents will be businesses or other for-profit organizations.

In the **Federal Register** of July 17, 2019 (84 FR 34188), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR part	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
3	61	1	61	24	1,464

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden for the information collection reflects an overall decrease of 552 hours and a corresponding decrease of 23 responses/records. This adjustment is based on the number of submissions we received since the last OMB approval.

Dated: October 29, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–24513 Filed 11–8–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0823]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Format and Content Requirements for Over-the-Counter Drug Product Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

DATES: Fax written comments on the collection of information by December 12, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the

OMB control number 0910–0340. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Format and Content Requirements for Over-the-Counter Drug Product Labeling—21 CFR Part 201

OMB Control Number 0910–0340—Extension

This information collection supports FDA regulations at § 201.66 (21 CFR 201.66), which establish standardized content and format requirements for the labeling of all marketed over-the-counter (OTC) drug products. The regulations set forth the content and format requirements for the Drug Facts portion of labels on OTC drug products. These regulations require OTC drug product labeling to include uniform headings and subheadings, presented in a standardized order, with minimum standards for type size and other graphical features.

Currently marketed OTC drug products are already required to comply with these labeling requirements and will incur no further burden to comply with Drug Facts labeling requirements in § 201.66. Labeling modifications already required to be in Drug Facts format are ''usual and customary'' as part of routine redesign practice, thus they do not create additional burden within the meaning of the PRA.

Therefore, burden for this information collection is that which is necessary to comply with the labeling requirements in § 201.66, applicable to new OTC drug products and OTC sunscreen drug products introduced to the marketplace under new drug applications, abbreviated new drug applications, or an OTC drug monograph. New OTC drug products must comply with the labeling requirements in § 201.66 as they are introduced to the marketplace.

Based on our electronic drug registration and listing database, we estimate that approximately 10,463 new OTC drug product stock keeping units (SKUs) are introduced to the marketplace each year. We estimate that these SKUs are marketed by 1,416 manufacturers. We estimate that the preparation of labeling for new OTC drug products requires 12 hours to prepare, complete, and review prior to submitting the new labeling to us. Based on this estimate, the annual reporting burden for this type of labeling is 94,296 hours.

All currently marketed sunscreen products are required to comply with the Drug Facts labeling requirements in § 201.66, so they will incur no further burden under the information collection provisions in the regulation. However, a new OTC sunscreen drug product, like any new OTC drug product, will be subject to a one-time burden to comply with Drug Facts labeling requirements in § 201.66. We estimate, based on our electronic drug registration and listing database, that 5,253 new SKUs of OTC sunscreen drug products will be marketed each year. We estimate that these 5,253 SKUs will be marketed by 294 manufacturers. We estimate that 12 hours will be spent on each label. This is reflected in table 1, row 1.

When determining the burden for § 201.66, it is also important to consider exemptions or deferrals of the regulation allowed products under § 201.66(e). We receive very few requests for exemptions or deferrals. We also estimate that a request for deferral or exemption requires 24 hours to complete. This is reflected in table 1, row 2.

In the **Federal Register** of June 19, 2019 (84 FR 28555), we published a 60-day notice requesting public comment on the proposed collection of information. One comment was received from a trade organization representing nurse practitioners. The comment advocated revising FDA regulations to provide for provider-neutral language in Agency regulations but acknowledged its use in current Agency guidance. We appreciate this comment, but we decline to adopt the suggestion at this time.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
§ 201.66(c) and (d) for new OTC drug products	855	9.19	7,858	12	94,296
§ 201.66(e)	1	1	1	24	24
Total					94,320

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden for the information collection reflects an overall increase of 82,797 hours and a corresponding increase of 6,898 disclosures. This increase corresponds with data obtained from our database.

Dated: October 30, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–24509 Filed 11–8–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–4777]

Haemonetics Manufacturing, Inc.; Withdrawal of Approval of Abbreviated New Drug Application of Anticoagulant Citrate Dextrose Solution A, USP

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of abbreviated new drug application (ANDA) BA 710497/0 for Anticoagulant Citrate Dextrose Solution A, USP (ACD–A), In Plastic Bags, held by Haemonetics Manufacturing, Inc. Haemonetics Manufacturing, Inc., requested in writing that the Agency's approval of the application be withdrawn because the drug is no longer being marketed and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of December 12, 2019.

FOR FURTHER INFORMATION CONTACT: Sana F. Hussain, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION: Haemonetics Manufacturing, Inc., 400 Wood Rd., Braintree, MA 02184, has requested that FDA withdraw approval of ANDA BA 710497/0, pursuant to § 314.150(c) (21 CFR 314.150(c)), because the drug is no longer being marketed. By its request, Haemonetics Manufacturing, Inc., has also waived its opportunity for a hearing. Withdrawal of approval of an application under § 314.150(c) is without prejudice to refiling.

Application No.	Proprietary name
ANDA BA 710497/0 ...	Anticoagulant Citrate Dextrose Solution A, USP (ACD–A) In Plastic Bags.

Therefore, approval of the application listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of December 12, 2019. Introduction or delivery for introduction into interstate commerce for products without an approved new drug application or ANDA violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). The drug product that is listed in the table above that is in inventory on December 12, 2019 may continue to be dispensed until the inventory has been depleted or the drug product has reached its expiration date or otherwise becomes violative, whichever occurs first.

Dated: October 29, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–24527 Filed 11–8–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health Center for Scientific Review; 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 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: Center for Scientific Review Special Emphasis Panel; Member Conflicts: Interventions and Mechanisms for Addiction.

Date: December 2, 2019.

Time: 10:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Marc Boulay, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3110, MSC 7808, Bethesda, MD 20892, (301) 300–6541, *boulaymg@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Interactive Digital Media STEM Resources for Pre-College and Informal Science Education Audiences (SBIR/STTR).

Date: December 3, 2019.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Marie-Jose Belanger, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm. 6188, MSC 7804, Bethesda, MD 20892, 301–435–1267, *belangerm@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Lasker Clinical Research Scholars Program (Si2/R00 Clinical Trial Optional).

Date: December 3, 2019.

Time: 12:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Abdelouahab Aitouche, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4222, MSC 7814, Bethesda, MD 20892, 301–435–2365, *aitouchea@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Neurodevelopmental and Neurodegenerative Disorders.

Date: December 3, 2019.

Time: 12:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Seetha Bhagavan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5194, MSC 7846, Bethesda, MD 20892, (301) 237–9838, *bhagavas@csr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 4, 2019.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–24466 Filed 11–8–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[Docket No. USCBP–2019–0042]

Commercial Customs Operations Advisory Committee (COAC)

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security (DHS).

ACTION: Committee Management; Notice of Federal Advisory Committee Meeting.

SUMMARY: The Commercial Customs Operations Advisory Committee (COAC) will hold its quarterly meeting on Wednesday, December 4, 2019, in Washington, DC. The meeting will be open to the public to attend either in person or via webinar.

DATES: The COAC will meet on Wednesday, December 4, 2019, from 1:00 p.m. to 5:00 p.m. EST. Please note that the meeting may close early if the committee has completed its business. Comments must be submitted in writing no later than December 3, 2019.

ADDRESSES: The meeting will be held at the Ronald Reagan Building, International Trade Center-Horizon Ballroom, 1300 Pennsylvania Ave. NW, Washington, DC 20229. For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact Ms. Florence Constant-Gibson, Office of Trade Relations, U.S. Customs and Border Protection (CBP), at (202) 344–1440 as soon as possible.

FOR FURTHER INFORMATION CONTACT: Ms. Florence Constant-Gibson, Office of Trade Relations, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Room 3.5A, Washington, DC 20229; telephone (202) 344–1440; facsimile (202) 325–4290; or Ms. Valarie M. Neuhart, Acting Executive Director

and Designated Federal Officer at (202) 344–1440.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. Appendix. The Commercial Customs Operations Advisory Committee (COAC) provides advice to the Secretary of Homeland Security, the Secretary of the Treasury, and the Commissioner of U.S. Customs and Border Protection (CBP) on matters pertaining to the commercial operations of CBP and related functions within the Department of Homeland Security and the Department of the Treasury.

Pre-Registration: Meeting participants may attend either in person or via webinar after pre-registering using one of the methods indicated below:

For members of the public who plan to attend the meeting in person, please register by 5:00 p.m. EST on December 3, 2019, either: online at *https://teregistration.cbp.gov/index.asp?w=169;* by email to *tradeevents@cbp.dhs.gov;* or by fax to (202) 325–4290. You must register prior to the meeting in order to attend the meeting in person.

For CBP personnel who plan to attend in-person, please register online by 5:00 p.m. EST December 3, 2019, at *https://teregistration.cbp.gov/index.asp?w=171.*

For members of the public who plan to participate via webinar, please register online at *https://teregistration.cbp.gov/index.asp?w=170* by 5:00 p.m. EST on December 3, 2019.

Please feel free to share this information with other interested members of your organization or association.

Members of the public who are pre-registered to attend and later need to cancel, please do so by December 3, 2019, utilizing the following links: *https://teregistration.cbp.gov/cancel.asp?w=169* to cancel an in-person registration; or *https://teregistration.cbp.gov/cancel.asp?w=170* to cancel a webinar registration. For CBP personnel who are registered to attend in-peron and later need to cancel, please do so by utilizing the following link: *https://teregistration.cbp.gov/cancel.asp?w=171.*

To facilitate public participation, we are inviting public comment on the issues the committee will consider prior to the formulation of recommendations as listed in the Agenda section below.

Comments must be submitted in writing no later than December 3, 2019, and must be identified by Docket No. USCBP–2019–0042, and may be submitted by one (1) of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: tradeevents@cbp.dhs.gov.* Include the docket number in the subject line of the message.
- *Fax:* (202) 325–4290, Attention Florence Constant-Gibson.
- *Mail:* Ms. Florence Constant-Gibson, Office of Trade Relations, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Room 3.5A, Washington, DC 20229.

Instructions: All submissions received must include the words ''Department of Homeland Security'' and the docket number (USCBP–2019–0042) for this action. Comments received will be posted without alteration at *http://www.regulations.gov.* Please do not submit personal information to this docket.

Docket: For access to the docket or to read background documents or comments, go to *http://www.regulations.gov* and search for Docket Number USCBP–2019–0042. To submit a comment, click the ''Comment Now!'' button located on the top-right hand side of the docket page.

There will be multiple public comment periods held during the meeting on December 4, 2019. Speakers are requested to limit their comments to two (2) minutes or less to facilitate greater participation. Contact the individual listed below to register as a speaker. Please note that the public comment period for speakers may end before the time indicated on the schedule that is posted on the CBP web page, *http://www.cbp.gov/trade/stakeholder-engagement/coac.*

Agenda

The COAC will hear from the current subcommittees on the topics listed below and then will review, deliberate, provide observations, and formulate recommendations on how to proceed:

1. The Next Generation Facilitation Subcommittee will provide an update on the One U.S. Government Working Group's progress and an overview of the recent two-day meeting, during which the working group discussed the Global Business Identifier and working group priorities. There will be a subcommittee update on the progress of the Unified Entry Processes Working Group's development of an operational framework and the mapping of deficiencies in the current entry process. The subcommittee will discuss progress on the Emerging Technologies Working Group's various initiatives, including the recent completion of the Intellectual Property Rights Blockchain Proof of Concept testing and follow-up assessment. Finally, the subcommittee will provide an update on the efforts of the E-Commerce Working Group's projects and pilots.

2. The Secure Trade Lanes Subcommittee will provide updates on the Trusted Trader Working Group's activites. They will also provide an analysis of the In-Bond processes with a view to areas that are being developed for greater efficiency. The newly launched Export Modernization Working Group will provide updates regarding categorizing issues with export handling and identification of export data elements and opportunities for export process efficiencies. The Export Modernization Working Group may also submit recommendations for COAC's consideration. The subcommittee will report on the planned scope of work to be addressed by the newly formed Remote and Autonomous Cargo Processing Working Group.

3. The Rapid Response Subcommittee will provide an update regarding the newly formed Broker Continuing Education Taskforce and their goal to evaluate a continuing education framework for licensed customs brokers.

4. The Intelligent Enforcement Subcommittee will discuss their progress and activities, and they may also submit recommendations from the working groups under their jurisdiction for COAC's consideration. There will be updates from the following: the recently launched Intellectual Property Rights Working Group, which encompasses the visions of the 21st Century Customs Framework; the Anti-Dumping and Countervailing Duties (AD/CVD) Working Group (reporting on its efforts to discuss the AD/CVD Redesign and Date of Duty Calculation); the Bond Working Group (reporting on risk-based bonding and bond sufficiency); and, the Forced Labor Working Group, which was previously on hiatus (reporting on new topics).

Meeting materials will be available by December 2, 2019, at: *http://www.cbp.gov/trade/stakeholder-engagement/coac/coac-public-meetings.*

Dated: November 5, 2019.

Valarie M. Neuhart,

Acting Executive Director, Office of Trade Relations.

[FR Doc. 2019–24478 Filed 11–8–19; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R8–ES–2019–N087; FXES11140800000–XXX–FF08EVEN00]

Habitat Conservation Plan for the Smith's Blue Butterfly, Monterey Spineflower, and Monterey Gilia; Categorical Exclusion for the South of Tioga Project; Monterey County, California

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), have received an application for an incidental take permit for the federally endangered Smith's blue butterfly under the Endangered Species Act. DBO Development #30, LLC, submitted an application for a permit, which, if issued, would authorize take incidental to otherwise lawful activities associated with the South of Tioga Project draft habitat conservation plan. We invite public comments.

DATES: Written comments should be received on or before December 12, 2019.

ADDRESSES:

To obtain documents: You may download a copy of the draft habitat conservation plan and categorical exclusion screening form which includes the environmental action statement at *http://www.fws.gov/ventura/,* or you may request copies of the documents by U.S. mail (below) or by phone (see **FOR FURTHER INFORMATION CONTACT**).

To submit written comments: Please send us your written comments using one of the following methods:

- *U.S. mail:* Send your comments to Stephen P. Henry, Field Supervisor, Ventura Fish and Wildlife Office, U.S. Fish and Wildlife Service, 2493 Portola Road, Suite B, Ventura, CA 93003.
- *Facsimile:* Fax your comments to 805–644–3958.
- *Electronic mail:* Send your comments to *karen_sinclair@fws.gov.*

FOR FURTHER INFORMATION CONTACT: Karen Sinclair, Fish and Wildlife Biologist, 805–677–3315 (by phone), or at the Ventura Fish and Wildlife office (by mail; see **ADDRESSES**).

SUPPLEMENTARY INFORMATION: We have received an application for an incidental take permit under the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*). The applicant has developed a draft habitat conservation plan (HCP) for the project, which includes measures to mitigate and avoid/minimize impacts to the federally threatened Monterey spineflower (*Chorizanthe pungens* var. *pungens*) and federally endangered Smith's blue butterfly (*Euphilotes enoptes smithi*) and Monterey gilia (*Gilia tenuiflora* ssp. *arenaria*). The permit would authorize take of the listed wildlife species incidental to otherwise lawful activities associated with the draft South of Tioga HCP. In addition, the HCP anticipates impacts to the federally threatened Monterey spineflower (*Chorizanthe pungens* var. *pungens*) and the federally endangered Monterey gilia (*Gilia tenuiflora* ssp. *arenaria*) and proposes avoidance and minimization measures for all three covered species and mitigation for unavoidable loss of suitable upland habitat. We invite public comment on the draft HCP and categorical exclusion screening form which includes the environmental action statement.

Background

The Service listed the Monterey spineflower as threatened on February 4, 1994 (59 FR 5499), Smith's blue butterfly as endangered on June 1, 1976 (41 FR 22041), and Monterey gilia as endangered on June 22, 1992 (57 FR 27848). Section 9 of the ESA (16 U.S.C. 1538) and its implementing regulations prohibit the ''take'' of fish or wildlife species listed as endangered or threatened. ''Take'' is defined under the ESA to include the following activities: ''[T]o harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct'' (16 U.S.C. 1532); however, under section 10(a)(1)(B) of the ESA (16 U.S.C. 1539(a)(1)(B)), we may issue permits to authorize incidental take of listed species. Incidental take is take that is incidental to, and not the purpose of, carrying out of an otherwise lawful activity. Regulations governing incidental take permits for endangered wildlife are in the Code of Federal Regulations (CFR) at 50 CFR 17.22. Issuance of an incidental take permit also must not jeopardize the existence of federally listed fish, wildlife, or plant species. The permittees would receive assurances under our ''No Surprises'' regulations (50 CFR 17.22(b)(5)) regarding conservation activities for the Monterey spineflower, Smith's blue butterfly, and Monterey gilia.

Proposed Project Activities

DBO Development #30, LLC, has applied for a permit for incidental take of the Smith's blue butterfly. The take would occur in association with the following activities: The removal of existing structures, utilities, and streets; the construction of 356 multi-family units, 216 hotel rooms, and a restaurant; and the restoration and preservation of 0.9 acre (ac) of occupied habitat. Within this 10.63-ac project site, the total area proposed for redevelopment measures 9.7 ac, and approximately 73 percent (7.8 ac) of the area proposed for redevelopment is located within existing developed or disturbed areas.

Monterey gilia, Monterey spineflower, and Smith's blue butterfly host plants are located within 1.2 ac of the project site. The project proposes to permanently remove 0.4 ac of occupied habitat. There is no designated critical habitat within the project site. The HCP includes avoidance and minimization measures for the covered species and mitigation for unavoidable loss of suitable upland habitat through establishment of a conservation easement.

Mitigation for unavoidable take of Smith's blue butterfly and its habitat consists of the permanent protection of approximately 0.9 ac of occupied habitat (including the restoration of 0.1 ac of disturbed habitat).

Preliminary Determinations

The Service has made a preliminary determination that issuance of an incidental take permit is neither a major Federal action that will significantly affect the quality of the human environment within the meaning of section 102(2)(C) of the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*), nor will it individually or cumulatively have more than a negligible effect on the Smith's blue butterfly in the HCP. The Service considers the impacts of the South of Tioga Project on the Monterey spineflower, Smith's blue butterfly, and Monterey gilia to be minor, as the affected area is small (approximately 0.4 ac) and the project includes the permanent protection of 0.9 ac of suitable habitat that is located adjacent to the project. Therefore, based on this preliminary determination, the permit qualifies for a categorical exclusion under NEPA.

Public Comments

If you wish to comment on the draft HCP and categorical exclusion screening form, you may submit comments by one of the methods in **ADDRESSES**.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may

be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public view, we cannot guarantee that we will be able to do so.

Authority

We provide this notice under section 10 of the ESA (16 U.S.C. 1531 *et seq.*) and NEPA regulations (40 CFR 1506.6).

Stephen Henry,

Field Supervisor, Ventura Fish and Wildlife Office, Ventura, California.

[FR Doc. 2019–24536 Filed 11–8–19; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–DTS#–29183; PPWOCRADI0, PCU00RP14.R50000]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The National Park Service is soliciting comments on the significance of properties nominated before October 19, 2019, for listing or related actions in the National Register of Historic Places.

DATES: Comments should be submitted by November 27, 2019.

ADDRESSES: Comments may be sent via U.S. Postal Service and all other carriers to the National Register of Historic Places, National Park Service, 1849 C St. NW, MS 7228, Washington, DC 20240.

SUPPLEMENTARY INFORMATION: The properties listed in this notice are being considered for listing or related actions in the National Register of Historic Places. Nominations for their consideration were received by the National Park Service before October 19, 2019. Pursuant to Section 60.13 of 36 CFR part 60, written comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Nominations submitted by State Historic Preservation Officers:

ALABAMA

Tuscaloosa County

Stillman College, 3601 Stillman Blvd., Tuscaloosa, SG100004680

IDAHO

Elmore County

Featherville School, 4348 N Pine-Featherville Rd., Featherville, SG100004709

MASSACHUSETTS

Worcester County

Olney Cook Artisan Shop, 54 Hartford Ave. E, Mendon, SG100004699

Dale and Ethan Allen Streets Historic District, 18, 31–33, 21–23 & 11–15 Dale St., 1 Allendale St., 22, 26, 25–27, 15 & 17 Ethan Allen St., Worcester, SG100004700

Dudley Hill Historic District, Center, Dudley Oxford, Dudley Southbridge, Ramshorn & Tanyard Rds., Dudley, SG100004707

MONTANA

Beaverhead County

Andrus Hotel, 45 E Glendale St., Dillon, SG100004711

Dillon City Hall Historic District, 125 N Idaho St., Dillon, SG100004712

Ravalli County

McCrossin, James, Cabin, 1237 MT 93 S, Hamilton vicinity, SG100004710

Stillwater County

Dean School, 1367 Nye Rd., Dean, SG100004713

OHIO

Erie County

Castalia Trout Club, 604 Washington St., Castalia, SG100004704

Hancock County

Findlay Country Club Golf Course, 1500 Country Club Dr., Findlay, SG100004705

Summit County

University Club, 105 Fir Hill, Akron, SG100004706

PENNSYLVANIA

Delaware County

Third Presbyterian Church, 420 E 9th St., Chester, SG100004702

Philadelphia County

Sykes Brothers Yarn Mill, (Textile Industry in the Kensington Neighborhood of Philadelphia, Pennsylvania MPS), 178–180 W Huntingdon St., Philadelphia, MP100004701

Wharton Street Memorial Methodist Episcopal Church and Sunday School, 5337 Catharine St., Philadelphia, SG100004703

TENNESSEE

Bradley County

Hardwick Farms, 4710 N Lee Hwy., Cleveland, SG100004696

Davidson County

Cayce, James A., Administration Service Building, (Public Housing in Nashville, 1938–1965 MPS), 701 S 6th St., Nashville, MP100004689

Hamilton County

McCoy Farm, 1715 Anderson Pike, Signal Mountain, SG100004697

Knox County

Lawhon, Charles L., Cottage, 1910 Prospect Place, Knoxville, SG100004685

Lauderdale County

Ripley Fire Lookout Tower, (Tennessee Division of Forestry Fire Lookout Towers MPS), Joe Crihfield Rd., Ripley, MP100004684

Lawrence County

Bank of Loretto, 200 Broad St., Loretto, SG100004682

Marion County

Ebenezer Cumberland Presbyterian Church, 3040 Griffith Hwy., Jasper, SG100004698

Marshall County

Presbyterian Church, U.S.A., 300 Water St., Lewisburg, SG100004693

Robertson County

Frierson Chapel, (Historic Rural African-American Churches in Tennessee MPS), Approx. 0.20 mi. off Old Coopertown Rd., Coopertown, MP100004694

Shelby County

Wooten Fallout Shelter, Lions Gate Dr., Memphis, SG100004683

Barksdale Mounted Police Station, 189 S Barksdale St., Memphis, SG100004695

Washington County

Jonesborough Historic District Boundary Increase, Roughly along E Main St. from Franklin Ave. & 624 E Main St.; Roughly along, S Cherokee St. from Depot St. to 504 S Cherokee St.; also Locust St., Jonesborough, BC100004686

WYOMING

Teton County

Game Creek, Address Restricted, Jackson vicinity, SG100004708

An owner objection was received for the following resource:

TENNESSEE

Washington County

Hillrise Park Historic District, Roughly bounded by Baxter St., Forest Ave., Ridgeway Rd., Woodland Ave., E Oakland Ave., E 9th Ave., Lester Harris Ave. & E Holston Ave., Johnson City, SG100004692

A request for removal has been made for the following resources:

TENNESSEE

Grundy County

Patton, John E., House, (Grundy County MRA), Roddy Creek Rd., Coalmont vicinity, OT87000540

Obion County

Dickey's Octagonal Barbershop, SW corner High & N Church Sts., Rives, OT75001772

Additional documentation has been received for the following resource:

TENNESSEE

Washington County

Jonesborough Historic District, Roughly bounded by Depot & College Sts., 3rd Ave. & jct. of Main St. and Franklin Ave., Jonesborough, AD69000183

Authority: Section 60.13 of 36 CFR part 60.

Dated: October 22, 2019.

Julie H. Ernstein,

Supervisory Archeologist, National Register of Historic Places/National Historic Landmarks Program.

[FR Doc. 2019–24541 Filed 11–8–19; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Cooperative Research Group on ROS-Industrial Consortium Americas

Notice is hereby given that, on October 17, 2019, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Southwest Research Institute—Cooperative Research Group on ROS-Industrial Consortium-Americas (''RIC-Americas'') 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, Glidewell Laboratories, Irvine, CA, and Amazon Web Services, Inc., Seattle, WA, have been added 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 RIC-Americas intends to file additional written notifications disclosing all changes in membership.

On April 30, 2014, RIC-Americas 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 9, 2014 (79 FR 32999).

The last notification was filed with the Department on September 10, 2019. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on October 17, 2019 (84 FR 55586).

Suzanne Morris,

Chief, Premerger and Division Statistics Unit Antitrust Division.

[FR Doc. 2019–24482 Filed 11–8–19; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Undersea Technology Innovation Consortium

Notice is hereby given that, on October 15, 2019, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Undersea Technology Innovation Consortium (''UTIC'') 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, Aeronix Inc., Melbourne, FL; Attollo, LLC, Lincoln, RI; Cambridge International Systems, Inc., Arlington, VA; Careen Inc. dba Windings Inc., New Ulm, MN; CogniTech Corporation, Salt Lake City, UT; Commonwealth Computer Research, Inc., Charlottesville, VA; Corvid Technologies, LLC, Mooresville, NC; DLT Solutions, Herndon, VA; ECI Defense Group, Lyles, TN; Entanglement Research Institute Inc., Newport, RI; Gromelski & Associates, Inc., Virginia Beach, VA; IERUS Technologies, Inc., Huntsville, AL; Immersion Consulting LLC, Annapolis, MD; Persistent Systems, LLC, New York, NY; RCT Systems, Inc., Baltimore, MD; Texas Research Institute Austin, Inc. (TRI Austin), Austin, TX; The Ascendancy Group, Virginia Beach, VA; and Trident Research LLC, Austin, TX, have been added as parties to this venture.

Also, Oewaves, Inc., Pasadena, CA, has withdrawn as a party from 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 UTIC intends to file additional written notifications disclosing all changes in membership.

On October 9, 2018, UTIC 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 November 2, 2018 (83 FR 55203).

The last notification was filed with the Department on July 11, 2019. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on August 9, 2019 (84 FR 39372).

Suzanne Morris,

Chief, Premerger and Division Statistics Unit Antitrust Division.

[FR Doc. 2019–24481 Filed 11–8–19; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Pet Care Products Task Force

Notice is hereby given that, on October 18, 2019, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Pet Care Products Task Force (''PCPTF'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the identities of the parties to the venture and (2) the nature and objectives of the venture. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust

plaintiffs to actual damages under specified circumstances.

Pursuant to Section 6(b) of the Act, the identities of the parties to the venture are: Bayer Health Care, LLC, Animal Health Division, Shawnee, KS; Central Garden & Pet Company, Schaumburg, IL; Elanco U.S. Inc., Greenfield, IN; The Hartz Mountain Corporation, Secaucus, NJ; and Pet IQ, Omaha, NE. The general area of PCPTF's planned activity is to develop proposed Standard Operating Procedures (''SOPs'') to amend or replace the current United States Environmental Protection Agency (''EPA'') SOP developed for pet care products in 2012 by (i) reviewing and analyzing existing pet care product exposure assessment methods from EPA, Health Canada Pest Management Regulatory Agency (''PMRA'') and European Medicines Agency (''EMA''); (ii) developing a scoping document that outlines options available for an exposure assessment method, including advantages and disadvantages for each option, and, where necessary, any related data refinement costs for each option; and (iii) meeting with the EPA Office of Pesticide Products to present options for the revised SOPS and to solicit feedback.

Suzanne Morris,

Chief, Premerger and Division Statistics Unit Antitrust Division.

[FR Doc. 2019–24485 Filed 11–8–19; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Medical Technology Enterprise Consortium

Notice is hereby given that, on October 17, 2019, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Attorney General and the Federal Trade Commission (''MTEC'') 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, Alentic Microscience Inc., Halifax, Nova Scocia, Canada; Allied Technologies and Consulting, LLC, Frederick, MD; Amicrobe, Inc., Carlsbad, CA; BioTether Sciences, Inc., San Rafael, CA; Boa Biomedical, Inc., Cambridge, MA; Booz Allen Hamilton, Inc., McLean, VA; bR3 UNIQ, Inc. dba QUADYSTER, Bettendorf, IA; Calimex USA Corporation, San Francisco, CA; Cognosante, Falls Church, VA; Concurrent Technologies Corporation, Johnstown, PA; CUBRC, Inc., Buffalo, NY; Dawson Technical Inc., Irvine, CA; Distributed Bio, South San Francisco, CA; Expression Networks LLC, Washington, DC; GoDx, Inc., Madison, WI; InnoSense LLC, Torrance, CA; J. David Gladstone Institutes, San Francisco, CA; Kane Biotech Inc., Winnipeg, Manitoba, MB; Kindred Biosciences, Inc., Burlingame, CA; Latham BioPharm Group Inc., Cambridge, MA; MO–SCI Corporation, Rolla, MO; MRI Global, Kansas City, MO; Nanohmics Inc., Austin, TX; NUES LLC, Silver Spring, MD; Odic Incorporated, Littleton, MA; Ontario Corp. dba Flosonics Medical, Sudbury, Ontario, Canada; PEER Technologies PLLC, Fairfax, VA; PolarityTE MD, Inc., Salt Lake City, UT; Praeses, LLC, Shreveport, LA; Presence Product Group, LLC, San Francisco, CA; Regents of the University of Colorado Denver, Aurora, CO; Rochal Industries LLC, San Antonio, TX; SmartPoints Technology, Inc., Stow, MA; Tasso, Inc., Seattle, WA; TBT Pharma, LLC, Baltimore, MD; The Children's Hospital of Philadelphia Research Institute, Philadelphia, PA; The Pennsylvania State University, University Park, PA; and Wello, Inc., Addison, TX, have been added as parties to this venture.

Also, Centaur Biopharmaceutical Services, Inc., Burlingame, CA, has 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 MTEC intends to file additional written notifications disclosing all changes in membership.

On May 9, 2014, MTEC 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 9, 2014 (79 FR 32999).

The last notification was filed with the Department on July 11, 2019. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on August 1, 2019 (84 FR 37680).

Suzanne Morris,

Chief, Premerger and Division Statistics Unit Antitrust Division.

[FR Doc. 2019–24477 Filed 11–8–19; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—American Society of Mechanical Engineers

Notice is hereby given that, on September 6, 2019, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), the American Society of American Society of Mechanical Engineers (''ASME'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing additions or changes to its standards development activities. 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, since April 22, 2019, ASME has published eight new standards, added one consensus committee charter, revised one consensus committee charter, initiated nine new standards activities, and withdrawn two proposed standards from consideration within the general nature and scope of ASME's standards development activities, as specified in its original notification. More detail regarding these changes can be found at *www.asme.org.*

On September 15, 2004, ASME 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 October 13, 2004 (69 FR 60895).

The last notification with the Attorney General was filed on April 22, 2019. A notice was filed in the **Federal Register** on May 13, 2019 (84 FR 20908).

Suzanne Morris,

Chief, Premerger and Division Statistics Unit Antitrust Division.

[FR Doc. 2019–24484 Filed 11–8–19; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Naval Surface Technology & Innovation Consortium

Notice is hereby given that, on October 8, 2019, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993,

15 U.S.C. 4301 *et seq.* (''the Act''), Naval Surface Technology & Innovation Consortium (''NSTIC'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the identities of the parties to the venture and (2) the nature and objectives of the venture. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

Pursuant to Section 6(b) of the Act, the identities of the parties to the venture are: 300 Below, Inc., Decatur, IL; Accenture Federal Services LLC, Arlington, VA; Accurate Energetic Systems, LLC, McEwen, TN; Ace Electronics Defense Systems, Aberdeen Proving Ground, MD; Acquisition Systems Associates, Inc., Tysons, VA; ADI Technologies Inc., Chantilly, VA; Advanced Ground Information Systems (AGIS) Inc., Jupiter, FL; Advanced Hydrogen Technologies Corporation (AHTC), Lenoir, NC; Aerojet Rocketdyne, Huntsville, AL; Aeronix Inc., Melbourne, FL; Agile Defense Inc., Reston, VA; Akita Innovations LLC, North Billerica, MA; Aleta Technologies, Inc., Huntsville, AL; Alion Science and Technology Corporation, New London, CT; Alliant Techsystems Operations LLC, Plymouth, MN; Alloy Surfaces Company, Inc., Chester Township, PA; Altamira Technologies Corporation, McLean, VA; American Defense International, Inc., Washington, DC; American Rheinmetall Munitions, Inc., Stafford, VA; American Rheinmetall Systems, Biddeford, ME; American Systems Corporation, Chantilly, VA; ANDRO Computational Solutions, LLC, Rome, NY; Anyar, Inc., Ft. Walton Beach, FL; Applied Composites, San Diego, CA; Applied Physical Sciences Corp., Groton, CT; Applied Research Associates, Inc., Albuquerque, NM; Applied Technology, Inc., King George, VA; Applied Visions, Inc. Secure Decisions Division, Northport, NY; APT Research Inc., Huntsville, AL; Aquabotix Technology Corporation, Jamestown, RI; Ardalyst Federal, LLC, Annapolis, MD; Area-I, Inc., Kennesaw, GA; ARES, Inc., Port Clinton, OH; Arrow Tech Associates, Inc., Burlington, VT; Artis LLC, Herndon, VA; Ashwin-Ushas Corporation, Holmdel, NJ; ASRC Federal Agile Decision Sciences, Huntsville, AL; ASSETT, Inc., Manassas, VA; Assured Information Security, Inc., Rome, NY; Asymmetric Technologies, LLC, Columbus, OH; ATA Engineering, Inc., San Diego, CA; A-Tech Corporation, Albuquerque, NM; ATK Launch Systems Inc., Corinne, UT; Auburn University, Auburn, AL; AURA Technologies, LLC, Raleigh, NC; Avineon, Inc., McLean, VA; BAE Systems Information & Electronic Systems Integration, Inc., Hudson, NH; Battelle Memorial Institute, Columbus, OH; Beast Code, Fort Walton Beach, FL; Bevilacqua Research Corporation, Huntsville, AL; Big Metal Additive, LLC, Wheat Ridge, CO; Bigelow Family Holdings, LLC, dba Mettle Ops, Sterling Heights, MI; BlazeTech Corporation, Woburn, MA; Boarhog LLC, San Diego, CA; Booz Allen Hamilton, Inc., McLean, VA; Bradshaw Engineering and Technical Services, LLC, Huntsville, AL; Bren-Tronics, Inc., Commack, NY; Broadband Antenna Tracking Systems Inc. (BATS), Indianapolis, IN; Bruker Detection Corporation, Billerica, MA; B–SKIES, INC., Ellicott City, MD; C Z and Associates, Inc., VA; CACI, INC.—FEDERAL, Chantilly, VA; Cera Nova Corporation, Marlborough, MA; Certus Solutions, LLC, Fredericksburg, VA; CFD Research Corporation, Huntsville, AL; CGS GROUP LLC, Artesia, NM; Chandler Automated Systems dba Vigilant Technologies, Tempe, AZ; Cirrus, LLC, Walla Walla, WA; Cisco Systems Inc., San Jose, CA; Clogic Defense, August, NJ; CogniTech Corporation, Salt Lake City, UT; ColdQuanta, Inc., Boulder, CO; Command Decisions Systems & Solutions, Inc., Stafford, VA; Command Post Technologies, Inc., Suffolk, VA; Composite Design & Development, Scarborough, ME; Concurrent Technologies Corporation, Johnstown, PA; Control Solutions LLC, Aurora, IL; Copious Imaging LLC, Lexington, MA; Corvid Technologies, Mooresville, NC; Creare LLC, Hanover, NH; Crossflow Technologies, Inc., Albertville, AL; Curtiss-Wright Electro-Mechancal Corporation, Cheswick, PA; Cybernet Systems Corporation, Ann Arbor, MI; Cypress International, Alexandria, VA; DataRobot, Boston, MA; Davidson Technologies, Inc., Huntsville, AL; Day & Zimmermann, Lone Star, LLC, Texarkana, TX; DE Technologies Inc., King of Prussia, PA; deciBel Research, Inc., Huntsville, AL; Defense Engineering Services LLC, Charleston, SC; Design Interactive, Inc., Orlando, FL; DHPC Technologies, Inc., Woodbridge, NJ; Digital Cloak, LLC, Stafford, VA; Disruptive Technology Associates, Ltd, Phoenix, AZ; DLT Solutions, LLC, Herndon, VA; DRS Laurel Technologies, Johnstown, PA; Dynetics Technical Solutions, Inc., Huntsville, AL; Dynetics, Inc., Huntsville, AL; EaglePicherTechnologies, LLC, Joplin, MO; Eduworks Corporation, Corvallis, OR; EFW Inc., an Elbit Systems of America, Fort Worth, TX; El Dorado Engineering, West Jordan, UT; ELTA North America, Annapolis Junction, MD; EngeniusMicro, Huntsville, AL; Ensign-Bickford Aerospace & Defense Company, Simsbury, CT; En'Urga Inc., West Lafayette, IN; Envistacom, LLC, Atlanta, GA; EOS Defense Systems USA, Inc., Huntsville, AL; eTRANSERVICES Corp., Fredericksburg, VA; EWA Government Systems, Inc., Herndon, VA; EWI, Columbus, OH; Fabrisonic LLC, Columbus, OH; Fibertek, Inc., Herndon, VA; FLIR Commercial Systems, Goleta, CA; Forge AI, Cambridge, MA; Franklin Engineering Group, Inc., Franklin, TN; FREEDOM PHOTONICS LLC, Goleta, CA; Frontier Technology Inc., Beavercreek, OH; General Dynamics Mission Systems, Fairfax, VA; General Dynamics Ordnance and Tactical Systems (Huntsville), Huntsville, AL; General Dynamics Ordnance and Tactical Systems Inc. (Saint Petersburg), Saint Petersburg, FL; General Dynamics OTS (Aerospace), Inc., Bothell, WA; General Dynamics OTS (Niceville), Inc., Niceville, FL; General Technical Services, LLC, Wall Township, NJ; GenXComm., Austin, TX; Geocent, L.L.C., Metairie, LA; Gibbs & Cox, Inc., Arlington, VA; Global Defense, Inc., Arlington, VA; GSD, LLC, Williamsburg, VA; Guidehouse LLP, McLean, VA; HART Technologies, Inc., Manassas, VA; HDT Expeditionary Systems, Inc., Fredericksburg, VA; HII Technical Solutions Corporation, Virginia Beach, VA; Honeywell, Phoenix, AZ; IAI North America, Inc., Arlington, VA; IERUSTECH, Huntsville, AL; II–VI Optical Systems, Murrieta, CA; In-Depth Engineering Corporation, Fairfax, VA; Indiana Microelectronics, LLC, West Lafayette, IN; Innovative Concepts Engineering Inc., Greenbelt, MD; Innovative Defense Technologies, Arlington, VA; Innovative Materials and Processes, LLC, Rapid City, SD; Innoveering LLC, Ronkonkoma, NY; Insight Public Sector, Tempe Arizona, AZ; Integration Innovation, Inc., Huntsville, AL; Intuitive Research and Technology Corporation, Huntsville, AL; IPG Photonics Corporation, Oxford, MA; Iris Technology Corporation, Irvine, CA; ISSAC Corp., Colorado Springs, CO; ITT Enidine, Inc., Orchard Park, NY; Jankel Tactical Systems, LLC, Duncan, SC; Jensen Hughes, Inc., Baltimore, MD; JOHN H NORTHROP & ASSOCIATES INC. (JHNA), Clifton, VA; Keysight Technologies, Colorado Springs, CO; Knight's Armament Company, Titusville, FL; Kopis Mobile

LLC, Flowood, MS; Kord Technologies Inc., Huntsville, AL; Kratos Technology & Training Solutions, Inc., San Diego, CA; Kudu Dynamics, LLC, Chantilly, VA; Kyma Technologies, Inc., Raleigh, NC; L3 Harris Technologies, Inc., Williamsport, PA; L–3 Mustang Technology, L.P., Plano, TX; L3 Technologies, Inc., Insight Technology Division, Londonderry, NH; L–3 Unidyne, Inc., Norfolk, VA; L3Harris Force X, Nashville, TN; L3Harris Technologies Harris Government Communication Systems, Palm Bay, FL; L3Harris, Inc.—Brashear Division, Pittsburgh, PA; L3Harris/C5S, Camden, NJ; La Jolla Logic, Inc., San Diego, CA; Lasertel, Inc., Tucson, AZ; Leidos Inc., Reston, VA; Lewis Machine & Tool Co., Eldridge, IA; lntevac Photonics, Inc., Santa Clara, CA; Lockheed Martin Aculight Corporation, Bothell, WA; Lockheed Martin Corporation, Riviera Beach, FL; Lockheed Martin Corporation, Missiles and Fire Control, Orlando, FL; Logistic Services International, Inc., Jacksonville, FL; Lone Star Analysis, Addison, TX; Luna Innovations Incorporated, Roanoke, VA; Management Services Group, Inc., Virginia Beach, VA; Manufacturing Techniques, Inc. (MTEQ), Lorton, VA; Marotta Controls, Inc., Montville, NJ; Marvin Test Solutions, Irvine, CA; Materials Sciences LLC, Horsham, PA; Matrix Research, Dayton, OH; MATSYS, Inc., Sterling, VA; MBDA Incorporated, Arlington, VA; McCormick Stevenson Corporation, Clearwater, FL; McNally Industries, LLC, Grantsburg, WI; McQ Inc., Fredericksburg, VA; Mercury Systems, Inc., Andover, MA; Metamagnetics Inc., Westborough, MA; MilDef, Inc., Brea, CA; Military Systems Group, Inc., Nashville, TN; Mills Marine & Ship Repair LLC, Suffolk, VA; Mission Solutions, LLC, Moorestown, NJ; MISTIC, Inc., Roswell, NM; Mistral Inc., Bethesda, MD; Modern Technology Solutions, Inc., Alexandria, VA; Moog Inc., Space & Defense Group, Elma, NY; NAG, LLC, dba NAG Marine, Norfolk, VA; Nammo Talley, Inc., Mesa, AZ; NanoElectromagnetics, LLC, Columbia, MO; NASCENTechnology Manufacturing Inc., Watertown, SD; National Technical Systems (NTS), Anaheim, CA; Navanti Group, LLC, Arlington, VA; Navatek LLC, Honolulu, HI; NetApp US Public Sector, Vienna, VA; New Mexico Institute of Mining and Technology, Socorro, NM; nLIGHT Inc., Vancouver, WA; Northrop Grumman Innovation Systems, Rocket Center, WV; Northrop Grumman Mission Systems, Linthicum, MD; NovaTech, Lynchburg, VA; Nufern, Inc., East Granby, CT; Nu-Trek Inc., San Diego, CA; Nutronics, Inc., Longmont, CO; Objective InterfaceSystems, Inc., Herndon, VA; Offset Strategic Services, Huntsville, AL; Opto-Knowledge Systems, Inc. (OKSI), Torrance, CA; ORBIS Sibro, Inc., Charleston, SC; Pacific Antenna Systems LLC, Camarillo, CA; Palantir USG, Inc., Palo Alto, CA; Parker Hannifin Corporation, Mayfield Heights, OH; PeopleTec, Inc., Huntsville, AL; Peraton, Herndon, VA; Persistent Systems, LLC, New York, NY; Perspecta Enterprise Solutions LLC, Herndon, VA; Perstecta Engineering Inc., Chantilly, VA; Planck Aerosystems, San Diego, CA; Plasan North America, Walker, MI; Plasma Processes, Huntsville, AL; Platform Systems, Incorporated dba Platform Aerospace, Hollywood, MD; Polaris Alpha Advanced Systems, Inc., Aberdeen Proving Ground, MD; Polaris Contract Manufacturing, Inc., Marion, MA; Polaris Sensor Technologies, Inc., Huntsville, AL; Practical Energetics Research/PER, Huntsville, AL; Praescient Analytics, Alexandria, VA; Pratt and Miller Engineering & Fabrication, Inc., New Hudson, MI; Princeton Infrared Technologies, Inc., Monmouth Jct., NJ; PURVIS Systems Incorporated, Middletown, RI; QED Systems Inc., Virginia Beach, VA; Qlik Tech, King of Prussia, PA; QUANTITATIVE SCIENTIFIC SOLUTIONS, LLC, Arlington, VA; Quantum Dimension, Inc., Huntington Beach, CA; QuesTek Innovations LLC, Evanston, IL; Raytheon BBN, Cambridge, MA; RAYTHEON COMPANY, Waltham, MA; RCT Systems, Baltimore, MD; Redfish Trading, LLC, San Antonio, TX; Rigil Corporation, Washington, DC; Riverside Research Institute, New York, NY; RKF Engineering Solutions, LLC, Bethesda, MD; Robotic Research, LLC, Gaithersburg, MD; RPI Group, Inc., Fredericksburg, VA; S2 Corporation, Bozeman, MT; Sabre Systems, Inc., Warrington, PA; Saft America Inc., Cockeysville, MD; SAVIT Corporation, Rockaway, NJ; Science Applications International Corporation (SAIC), Reston, VA; Sciperio Inc., Orlando, FL; SciTec, Inc., Princeton, NJ; Sechan Electronics, Inc., Lititz, PA; Selex Gaileo Inc., Arlington, VA; Sensing Strategies, Inc., Pennington, NJ; Sentar, Inc., Huntsville, AL; Senvol LLC, New York, NY; Serco Inc., New London, CT; Shared Spectrum Company, Vienna, VA; Shipcom Federal Solutions LLC, Houston, TX; Simulation Technologies, Inc., Huntsville, AL; Simulations, LLC, East Granby, CT; SitScape, Inc., Vienna, VA; Skayl, LLC, Westminster, MD; Soar Technology, Inc., Ann Arbor, MI; SOLUTE, Inc., San Diego, CA; Solution Now Enterprises, Winter Park, FL; Sonalysts, Inc., Waterford, CT; Southwest Research Institute (SwRI), San Antonio, TX; SPARC Research LLC, Warrington, VA; Spear Research, LLC, Nashua, NH; Specialized Technical Systems, LLC, Tewksbury, MA; SRC, Inc., Syracuse, NY; SRI International, Menlo Park, CA; Steelhead Composites LLC, Golden, CO; Steiner eOptics, Inc., Miamisburg, OH; Summit Technical Solutions, LLC, Colorado Springs, CO; SURVICE Engineering Company, LLC, Belcamp, MD; Systecon North America, Arlington, VA; Systems Engineering Group, Inc., Columbia, MD; Systems Planning and Analysis, Inc., Alexandria, VA; TDI Technologies, Inc., King of Prussia, PA; Technology Service Corporation, Arlington, VA; Teledyne Scientific and Imaging, LLC, Thousand Oaks, CA; Texas Research Institute Austin, Inc., Austin, TX; Thales Defense & Security, Inc., Clarksburg, MD; The Boeing Company, Saint Louis, MO; The Curators of the University of Missouri, Columbia, MO; The Informatics Applications Group, Inc. (TIAG), Reston, VA; The Pennsylvania State University Applied Research Laboratory Electro-Optics Center Division, Freeport, PA; The Regents of the University of Colorado (CU Boulder), Boulder, CO; TORC Robotics, Inc., Blacksburg, VA; Toyon Research Corporation, Goleta, CA; TPL, Inc., Albuquerque, NM; TriVector Services, Inc., Huntsville, AL; True Velocity, INC., Garland, TX; TRX Systems, Inc., Greenbelt, MD; Ultra Electronics Ocean Systems, Braintree, MA; Unconventional Concepts, Fort Walton Beach, FL; Unisys Corporation, Reston, VA; United Protective Technologies LLC, Locust, NC; Universal Technology Corporation, Dayton, OH; University of Mississippi, University, MS; University of Rhode Island, Kingston, RI; Veritay Technology, Inc., East Amherst, NY; Vertosoft LLC, Leesburg, VA; Virginia Polytechnic Institute and State University, Blacksburg, VA; W R SYSTEMS, LTD (WR), Norfolk, VA; Waltonen Engineering, Inc., Warren, MI; Whitespace Innovations, Inc., Huntsville, AL; Wireless Technology Assoc., Inc., Setauket, NY; Wyle Laboratories, Inc. (KBR), Huntsville, AL; XL Scientific LLC, dba Verus Research, Albuquerque, NM; Zekiah Technologies, Inc., LaPlata, MD, and the members of the National Armaments Consortium (NAC), whose last filing can be found at (84 FR 46565).

The general area of NSTIC's planned activity is to conduct research, development, and prototyping of

projects and programs in the following technology areas: Multi-function Materials, Cyber, Big Data Analytics/Artificial Intelligence/Machine Learning, Directed Energy Science & Engineering, Advanced Computing and Software Engineering, Autonomous and Unmanned Systems, Sensor Systems, Gun and Projectile Systems, Digital Engineering, Human Systems Integration, Quantum Technologies, Threat Engineering, Mission Engineering and Analysis, Integrated Warfare Systems, Virtualization, Asymmetric Warfare, Manufacturing, Lethality, Surface Offensive & Defensive Engagements, and Launcher Technology.

Suzanne Morris,

Chief, Premerger and Division Statistics Unit, Antitrust Division.

[FR Doc. 2019–24483 Filed 11–8–19; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–541]

Bulk Manufacturer of Controlled Substances Application: Rhodes Technologies

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before January 13, 2020.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on August 16, 2019, Rhodes Technologies, 498 Washington Street, Coventry, Rhode Island 02816 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled substance	Drug code	Schedule
Marihuana	7360	I
Tetrahydrocannabinols	7370	I
Dihydromorphine	9145	I
Methylphenidate	1724	II
Codeine	9050	II
Dihydrocodeine	9120	II
Oxycodone	9143	II
Hydromorphone	9150	II
Hydrocodone	9193	II
Levorphanol	9220	II
Morphine	9300	II
Oripavine	9330	II
Thebaine	9333	II
Oxymorphone	9652	II
Noroxymorphone	9668	II
Tapentadol	9780	II
Fentanyl	9801	II

The company plans to manufacture the listed controlled substances in bulk for conversion and sale to finished dosage form manufacturers. In reference to drug codes 7360 (marihuana), and 7370 (tetrahydrocannabinols), the company plans to bulk manufacture these drugs as synthetic cannabidiol (CBD) and tetrahydrocannabinol (THC). No other activities for drug codes 7360 and 7370 are authorized for this registration.

Dated: October 30, 2019.

William T. McDermott,

Assistant Administrator.

[FR Doc. 2019–24545 Filed 11–8–19; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–539]

Bulk Manufacturer of Controlled Substances Application: Cambrex Charles City

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before January 13, 2020.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA **Federal Register** Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on May 15, 2019, Cambrex Charles City, 1205 11th Street, Charles City, Iowa 50616–3466 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled substance	Drug code	Schedule
Gamma Hydroxybutyric Acid.	2010	I
Amphetamine	1100	II
Lisdexamfetamine	1205	II
Methylphenidate	1724	II
ANPP (4-Anilino-N-phenethyl-4-piperidine).	8333	II
Phenylacetone	8501	II
Cocaine	9041	II
Codeine	9050	II
Oxycodone	9143	II
Hydromorphone	9150	II
Hydrocodone	9193	II
Morphine	9300	II
Oripavine	9330	II
Thebaine	9333	II
Opium extracts	9610	II
Opium fluid extract	9620	II
Opium tincture	9630	II
Opium, powdered	9639	II
Oxymorphone	9652	II
Noroxymorphone	9668	II
Fentanyl	9801	II

The company plans to manufacture the listed controlled substances in bulk for conversion to other controlled substances and sale to its customers, for dosage form development, for clinical trials, and for use in stability qualification studies.

Dated: October 30, 2019.

William T. McDermott,

Assistant Administrator.

[FR Doc. 2019–24543 Filed 11–8–19; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–534]

Bulk Manufacturer of Controlled Substances Application: Cambridge Isotope Lab

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before January 13, 2020.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA **Federal Register** Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION:

In accordance with 21 CFR 1301.33(a), this is notice that on July 24, 2019 Cambridge Isotope Lab, 50 Frontage Road, Andover, Massachusetts 01810–5413 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled substance	Drug code	Schedule
Tetrahydrocannabinols	7370	I

The company plans to synthetically bulk manufacture the controlled substance to produce analytical standards for distribution to its customers. No other activity for this drug code is authorized for this registration.

Dated: October 29, 2019.

William T. McDermott,

Assistant Administrator.

[FR Doc. 2019–24544 Filed 11–8–19; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

[OMB Number: 1103–0117]

Agency Information Collection Activities; Proposed eCollection; eComments Requested; Extension of a Currently Approved Collection; Departmental Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

AGENCY: All components, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: As part of a Federal Government-wide effort to streamline the process to seek feedback from the public on service delivery, Department of Justice will be submitting a Generic Information Collection Request (Generic ICR): ''Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery'' to OMB for approval under the Paperwork Reduction Act (PRA).

DATES: The purpose of this notice is to allow 30 days for public comment until December 12, 2019.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Melody Braswell, Department Clearance Officer, *melody.braswell2@usdoj.gov;* or the DOJ Clearance Officer at 202–307–0890.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate the quality, utility, and clarity of the information to be collected; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Collection:

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

Abstract: The information collection activity will garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections 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.

Feedback collected under this generic clearance will provide useful information, but it will 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 uses require 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 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.

Below we provide the Department of Justice's projected average estimates for the next three years:

Current Action: Extension.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals and Households, Businesses and Organizations, State, Local or Tribal Government.

Average Expected Annual Number of Activities: 42.

Average Number of Respondents per Activity: 51,500.

Annual Responses: 309,000.

Frequency of Response: Once per request.

Average Minutes per Response: 30 min.

Burden Hours: 99,847.

Federal Government Cost: $176,925.

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.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405B, Washington, DC 20530.

Dated: November 5, 2019.

Melody D. Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of

information are encouraged. Your comments should address one or more of the following four points:

➢ Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the FBI, including whether the information will have practical utility;

➢ Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

➢ Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

➢ Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* New Collection.

2. *The Title of the Form/Collection:* FBI Special Agent Application Process Review Form.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* ''There is no agency form number for this collection''. The applicable component within the Department of Justice is the FBI.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* Individuals; Anyone who has filled out any part of the FBI Special Agent Application in the previous three years will be asked to complete a brief voluntary survey recalling their experience and preparation tactics for the application process. This information is being collected by the Federal Bureau of Investigation for the purpose of improving the ease of the application process, eliminating any systematic barriers to success for applicants, and better understanding how to recruit and retain qualified applicants.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* We estimate roughly 40,000 individuals have applied to the Special Agent position at the FBI in the previous 3 years, we will solicit this entire population to participate in the voluntary survey though it is unlikely all 40,000 WILL respond. The survey will take approximately 10 minutes to complete.

6. *An estimate of the total public burden (in hours) associated with the collection:* 6,667 total hours of public burden, 10 minutes per survey for 40,000 respondents.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: August 14, 2019

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2019–24470 Filed 11–8–19; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Amended Consent Decree Under the Comprehensive Environmental Response, Compensation, and Liability Act

On October 31, 2019, the Department of Justice lodged a proposed Amended Consent Decree with the United States District Court for the District of Minnesota in the lawsuit entitled *United States, et al.* v. *Reilly Tar & Chem. Corp., et al.,* Civil Action No. 4:80–cv–469.

On September 4, 1986, the Court had previously entered a Consent Decree in this action resolving claims brought by Plaintiffs the United States of America and the State of Minnesota against Reilly Tar & Chemical Corporation, Housing and Redevelopment of St. Louis Park, Oak Park Village Associates, Rustic Oaks Condominium Inc., and Phillip's Investment Co. (collectively, the ''Defendants''), and the consolidated actions brought by the City of St. Louis Park and the City of Hopkins against Reilly Tar & Chemical Corporation. Those actions were brought under Sections 106 and 107 of the Comprehensive Environmental Response, Compensation, and Liability Act (''CERCLA''), 42 U.S.C. 9606–07, seeking injunctive relief regarding the cleanup of the Reilly Tar & Chemical Corporation (St. Louis Park Plant) Superfund Site in St. Louis Park, Minnesota (the ''Site'') and recovery of certain response costs incurred in connection with releases and threatened releases of hazardous substances at and from the Site.

The proposed Amended Consent Decree addresses issues raised by the bankruptcy liquidation of Reilly Tar's successor in liability, updated state and federal Performance Standards for various contaminants of concern, as well as an evolved understanding of the conceptual site model. The proposed Amended Consent Decree reflects a cooperative approach among the remaining parties to address these issues. The City of St. Louis Park will formally undertake the obligation to finance and perform the remaining work addressing contaminated groundwater, obligations previously undertaken by the City of St. Louis Park pursuant to a side-agreement with Reilly Tar, and the Remedial Action Plan has been updated to incorporate current Maximum Contaminant Levels and state limits for the contaminants of concern.

The publication of this notice opens a period for public comment on the proposed Amended Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States, et al.* v. *Reilly Tar & Chem. Corp., et al.,* D.J. Ref. No. 90–7–1–21/2. 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 Amended 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 Amended 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 $29.50 (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 $10.75.

Randall M. Stone,

Acting Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2019–24469 Filed 11–8–19; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2012–0040]

The Standard on 4,4′-Methylenedianiline for General Industry; Extension of the Office of Management and Budget's (OMB) Approval of Information Collection (Paperwork) Requirements

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Request for public comments.

SUMMARY: OSHA solicits public comments concerning the proposal to extend the Office of Management and Budget's (OMB) approval of the information collection requirements specified in the Standard on 4,4′-Methylenedianiline (MDA) for General Industry.

DATES: Comments must be submitted (postmarked, sent, or received) by January 13, 2020.

ADDRESSES:

Electronically: You may submit comments and attachments electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Facsimile: If your comments, including attachments, are not longer than 10 pages you may fax them to the OSHA Docket Office at (202) 693–1648.

Mail, hand delivery, express mail, messenger, or courier service: When using this method, you must submit a copy of your comments and attachments to the OSHA Docket Office, Docket No. OSHA–2012–0040, Occupational Safety and Health Administration, U.S. Department of Labor, Room N–36535, 200 Constitution Avenue NW, Washington, DC 20210. Deliveries (hand, express mail, messenger, and courier service) are accepted during the OSHA Docket Office's normal business hours, 10:00 a.m. to 3:00 p.m., ET.

Instructions: All submissions must include the agency name and the OSHA docket number (OSHA–2012–0040) for the Information Collection Request (ICR). All comments, including any personal information you provide, are placed in the public docket without change, and may be made available online at *http://www.regulations.gov.* For further information on submitting comments, see the ''Public Participation'' heading in the section of this notice titled **SUPPLEMENTARY INFORMATION**.

Docket: To read or download comments or other material in the docket, go to *http://www.regulations.gov* or the OSHA Docket Office at the above address. All documents in the docket (including this **Federal Register** notice) are listed in the *http://www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not publicly available to read or download from the website. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. You may also contact Theda Kenney or Seleda Perryman at (202) 693–2222 to obtain a copy of the ICR.

FOR FURTHER INFORMATION CONTACT: Theda Kenney or Seleda Perryman, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor, telephone: (202) 693–2222.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Labor, as part of the continuing effort to reduce paperwork and respondent (*i.e.,* employer) burden, conducts a preclearance consultation program to provide the public with an opportunity to comment on proposed and continuing information collection requirements in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)). This program ensures that information is in the desired format, the reporting burden (time and costs) is minimal, the collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The Occupational Safety and Health Act of 1970 (OSH Act) (29 U.S.C. 651 *et seq.*) authorizes information collection by employers as necessary or appropriate for enforcement of the Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents (see 29 U.S.C. 657). The OSH Act also requires OSHA to obtain such information with a minimum burden upon employers, especially those operating small businesses, and to reduce to the maximum extent feasible unnecessary duplication of efforts in obtaining information (see 29 U.S.C. 657).

The information collection requirements specified in the 4,4′-Methylenedianiline Standard for General Industry (the ''MDA Standard'') (29 CFR 1910.1050) protect workers from the adverse health effects that may result from their exposure to MDA, including cancer, liver, and skin disease. The major paperwork requirements specify that employers must perform initial, periodic, and additional exposure monitoring; notify each worker in writing of their results as soon as possible but no longer than five (5) days after receiving exposure monitoring results; and routinely inspect the hands, face, and forearms of each worker potentially exposed to MDA for signs of dermal exposure to MDA. Employers must also: Establish a written compliance program; institute a respiratory protection program in accordance with OSHA's Respiratory Protection Standard (29 CFR 1910.134); and to develop a written emergency plan for any construction operation that could have an MDA emergency (*i.e.,* an unexpected and potentially hazardous release of MDA).

Employers must label any material or products containing MDA, including containers used to store MDA-contaminated protective clothing and equipment. They also must inform personnel who launder MDA-contaminated clothing of the requirement to prevent release of MDA, while personnel who launder or clean MDA-contaminated protective clothing or equipment must receive information about the potentially harmful effects of MDA. In addition, employers are to post warning signs at entrances or access ways to regulated areas, as well as train workers exposed to MDA at the time of their initial assignment, and at least annually thereafter.

Other paperwork provisions of the MDA standard require employers to provide workers with medical examinations, including initial, periodic, emergency and follow-up examinations. As part of the medical surveillance program, employers must ensure that the examining physician receives specific written information, and that they obtain from the physician a written opinion regarding the worker's medical results and exposure limitations.

The MDA standard also specifies that employers are to establish and maintain exposure monitoring and medical surveillance records for each worker who is subject to these respective requirements, make any required record available to OSHA compliance officers and the National Institute for Occupational Safety and Health (NIOSH) for examination and copying, and provide exposure monitoring and medical surveillance records to workers and their designated representatives. Finally, employers who cease to do business within the period specified for retaining exposure monitoring and medical surveillance records, and who have no successor employer, must

notify NIOSH at least 90 days before disposing of the records and transmit the records to NIOSH if so requested.

II. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- Whether the proposed information collection requirements are necessary for the proper performance of the agency's functions, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and costs) of the information collection requirements, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the burden on employers who must comply; for example, by using automated or other technological information collection and transmission techniques.

III. Proposed Actions

OSHA is requesting an adjustment decrease from 334 to 319 hours (a decrease of 15 hours). In the previous ICR, OSHA erroneously requested OMB approval of 334 hours rather than 317 hours. The additional 2 hours (to 319 hours) is due to the way OSHA is now doing its calculations. There is no change in cost under Item 13.

The agency will summarize the comments submitted in response to this notice and will include this summary in the request to OMB to extend the approval of the information collection requirements contained in the MDA Standard.

Type of Review: Extension of a currently approved collection.

Title: 4,4′-Methylenedianiline Standard for General Industry (29 CFR 1910.1050).

OMB Control Number: 1218–0184.

Affected Public: Business or other for-profits; Not-for-profit organizations; Federal Government; State, Local, or Tribal Government.

Number of Respondents: 10.

Total Responses: 574.

Frequency: On occasion.

Average Time per Response: Various.

Estimated Total Burden Hours: 319.

Estimated Cost (Operation and Maintenance): $0.

IV. Public Participation—Submission of Comments on This Notice and Internet Access to Comments and Submissions

You may submit comments in response to this document as follows: (1) Electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal; (2) by facsimile (fax); or (3) by hard copy. All comments, attachments, and other material must identify the agency name and the OSHA docket number (Docket No. OSHA–2012–0040) for the ICR. You may supplement electronic submissions by uploading document files electronically. If you wish to mail additional materials in reference to an electronic or facsimile submission, you must submit them to the OSHA Docket Office (see the section of this notice titled **ADDRESSES**). The additional materials must clearly identify electronic comments by your name, date, and the docket number so the agency can attach them to your comments.

Due to security procedures, the use of regular mail may cause a significant delay in the receipt of comments. For information about security procedures concerning the delivery of materials by hand, express delivery, messenger, or courier service, please contact the OSHA Docket Office at (202) 693–2350, (TTY (877) 889–5627).

Comments and submissions are posted without change at *http://www.regulations.gov.* Therefore, OSHA cautions commenters about submitting personal information such as social security numbers and dates of birth. Although all submissions are listed in the *http://www.regulations.gov* index, some information (*e.g.,* copyrighted material) is not publicly available to read or download from this website.

All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Information on using the *http://www.regulations.gov* website to submit comments and access the docket is available at the website's ''User Tips'' link. Contact the OSHA Docket Office for information about materials not available from the website, and for assistance in using the internet to locate docket submissions.

V. Authority and Signature

Loren Sweatt, Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*) and Secretary of Labor's Order No. 1–2012 (77 FR 3912).

Signed at Washington, DC, on November 5, 2019.

Loren Sweatt,

Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2019–24530 Filed 11–8–19; 8:45 am]

BILLING CODE 4510–26–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: (19–079)]

NASA Planetary Science Advisory Committee; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, as amended, the National Aeronautics and Space Administration (NASA) announces a meeting of the Planetary Science Advisory Committee. This Committee reports to the Director, Planetary Science Division, Science Mission Directorate, NASA Headquarters. The meeting will be held for the purpose of soliciting, from the scientific community and other persons, scientific and technical information relevant to program planning.

DATES: Friday, December 6, 2019, 1:00 p.m.–5:30 p.m., Eastern Time.

FOR FURTHER INFORMATION CONTACT: Ms. KarShelia Henderson, Science Mission Directorate, NASA Headquarters, Washington, DC 20546, (202) 358–2355, fax (202) 358–2779, or *khenderson@nasa.gov.*

SUPPLEMENTARY INFORMATION: The meeting will be available telephonically and by WebEx. You must use a touch-tone phone to participate in this meeting. Any interested person may dial the USA toll free conference call number 1–800–779–9966 or toll number 1–517–645–6359, passcode 5255996, to participate in this meeting by telephone. The WebEx link is *https://nasaenterprise.webex.com/,* the meeting number is 906 287 000 and the password is PAC@Dec6.

The agenda for the meeting includes the following topics:

—Planetary Science Division Update
—Reports from Specific Research & Analysis Programs

The agenda will be posted on the Planetary Advisory Committee web page: *https://science.nasa.gov/researchers/nac/science-advisory-committees/pac.*

It is imperative that the meeting be held on this date to accommodate the scheduling priorities of the key participants.

Patricia Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 2019–24528 Filed 11–8–19; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–2020–006]

Advisory Committee on the Records of Congress; Meeting

AGENCY: National Archives and Records Administration.

ACTION: Notice of meeting.

SUMMARY: We are announcing an upcoming meeting of the Advisory Committee on the Records of Congress. The committee advises NARA on the full range of programs, policies, and plans for the Center for Legislative Archives in NARA's Office of Legislative Archives, Presidential Libraries, and Museum Services (LPM).

DATES: The meeting will be on December 9, 2019, from 10:00 a.m. to 12:30 p.m.

ADDRESSES: National Archives and Records Administration; 700 Pennsylvania Ave. NW, Room 105; Washington, DC 20408.

FOR FURTHER INFORMATION CONTACT: The Center for Legislative Archives by phone at (202) 357–6802 or by email at *sharon.shaver@nara.gov*.

SUPPLEMENTARY INFORMATION: This meeting is open to the public in accordance with the Federal Advisory Committee Act (5 U.S.C. app 2) and implementing regulations.

Agenda

(1) Chair's Opening Remarks—Secretary of the U.S. Senate

(2) Recognition of Co-chair—Clerk of the U.S. House of Representatives

(3) Recognition of the Archivist of the United States

(4) Approval of the minutes of the last meeting

(5) Senate Archivist's report

(6) House Archivist's report

(7) Center for Legislative Archives update

(8) Other current issues and new business

Miranda J. Andreacchio,

Committee Management Officer.

[FR Doc. 2019–24487 Filed 11–8–19; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Office of Government Information Services (OGIS)

[NARA–2020–007]

Freedom of Information Act (FOIA) Advisory Committee; Meeting

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: We are announcing an upcoming Freedom of Information Act (FOIA) Advisory Committee meeting in accordance with the Federal Advisory Committee Act and the second United States Open Government National Action Plan.

DATES: The meeting will be on December 6, 2019, from 10:00 a.m. to 1:00 p.m. EDT. You must register for the meeting by midnight EST December 3, 2019.

ADDRESSES: National Archives and Records Administration (NARA); 700 Pennsylvania Avenue NW; William G. McGowan Theater; Washington, DC 20408.

FOR FURTHER INFORMATION CONTACT: Kirsten Mitchell, Designated Federal Officer for this committee, by mail at National Archives and Records Administration; Office of Government Information Services; 8601 Adelphi Road—OGIS; College Park, MD 20740–6001, by telephone at 202–741–5770, or by email at *foia-advisory-committee@nara.gov.*

SUPPLEMENTARY INFORMATION: *Agenda and meeting materials:* This is the sixth meeting of the third committee term. The Committee will hear about the work of the FOIA Advisory Committee's three subcommittees, focusing on records management, FOIA vision, and time/volume. We are posting meeting materials online at *https://www.archives.gov/ogis/foia-advisory-committee/2018-2020-term/meetings.*

Procedures: The meeting is open to the public. Due to building access restrictions, you must register through Eventbrite in advance if you wish to attend. You will also go through security screening when you enter the building. To register, use this link: *https://foia-advisory-committee-meeting.eventbrite.com.* We will also live-stream the meeting on the National Archives' YouTube channel at *https://www.youtube.com/user/usnationalarchives,* and include a captioning option. To request additional accommodations (*e.g.,* a transcript), email *foia-advisory-committee@nara.gov* or call 202–741–5770. Members of the media who wish to register, those who are unable to register online, and those who require special accommodations, should contact Kirsten Mitchell (contact information listed above).

Miranda J. Andreacchio,

Committee Management Officer.

[FR Doc. 2019–24489 Filed 11–8–19; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL FOUNDATION OF THE ARTS AND THE HUMANITIES

Institute of Museum and Library Services

40th Meeting of the National Museum and Library Services Board

AGENCY: Institute of Museum and Library Services (IMLS), National Foundation of the Arts and the Humanities (NFAH).

ACTION: Notice of meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act, notice is hereby given that the National Museum and Library Services Board will meet to advise the Director of the Institute of Museum and Library Services (IMLS) with respect to duties, powers, and authority of IMLS relating to museum, library, and information services, as well as coordination of activities for the improvement of these services.

DATES: The meeting will be held on December 5, 2019, from 9:00 a.m. until adjourned.

ADDRESSES: The meeting will be held at 955 L'Enfant Plaza North SW, First Floor Conference Room, Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Katherine Maas, Project Specialist and Alt. Designated Federal Officer, Institute of Museum and Library Services, Suite 4000, 955 L'Enfant Plaza North SW, Washington, DC 20024; (202) 653–4798; *kmaas@imls.gov* (*mailto:kmaas@imls.gov*).

SUPPLEMENTARY INFORMATION: The National Museum and Library Services Board is meeting pursuant to the National Museum and Library Service Act, 20 U.S.C. 9105a, and the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C. App.

The 40th Meeting of the National Museum and Library Services Board will be held on December 5, 2019. A plenary session (open to the public) will convene at 9:00 a.m., followed by an Executive Session (closed to the public)

discussion of specific agreements and programs before the Board.

The agenda for the plenary session of the National Museum and Library Services Board will be as follows:

I. Welcoming Remarks and Director's Report
II. Approval of Minutes
III. Office of Library Services Report
IV. Office of Museum Services Report
V. Financial and Operations Report
VI. Office of the Chief Information Officer Report
VII. Office of the General Counsel Report

As identified above, portions of the meeting of the National Museum and Library Services Board will be closed to the public pursuant to subsections (c)(4), (c)(6) and (c)(9) of section 552b of Title 5, United States Code, as amended. The closed session will consider information that may disclose: trade secrets and commercial or financial information obtained from a person and privileged or confidential; and information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action.

If you wish to attend the public session of the meeting, please inform IMLS as soon as possible by contacting Katherine Maas at (202) 653–4798 or *kmaas@imls.gov.* Please provide notice of any special needs or accommodations by November 20, 2019.

Dated: November 6, 2019.

Kim Miller,

Grants Management Specialist, Institute of Museum and Library Services.

[FR Doc. 2019–24517 Filed 11–8–19; 8:45 am]

BILLING CODE 7036–01–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts

Proposed Collection: Comment Request

ACTION: Notice.

SUMMARY: The National Endowment for the Arts, as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95). This program helps ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the National Endowment for the Arts, on behalf of the Federal Council on the Arts and the Humanities, is soliciting comments concerning renewal of the Application for International Indemnification. A copy of this collection request can be obtained by contacting the office listed below in the address section of this notice.

DATES: Written comments must be submitted to the office listed in the address section below on or before January 15, 2020. The National Endowment for the Arts is particularly interested in comments which:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used;

—Enhance the quality, utility and clarity of the information to be collected; and

—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 the electronic submissions of responses.

ADDRESSES: Patricia Loiko, National Endowment for the Arts, 400 7th Street SW, Washington, DC 20506–0001, telephone (202) 682–5541 (this is not a toll-free number), fax (202) 682–5721.

Gregory Gendron,

Director, Administrative Services.

[FR Doc. 2019–24553 Filed 11–8–19; 8:45 am]

BILLING CODE 4537–01–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts

Arts Advisory Panel Meetings

AGENCY: National Endowment for the Arts

ACTION: Notice of meetings.

SUMMARY: Pursuant to the Federal Advisory Committee Act, as amended, notice is hereby given that 28 meetings of the Arts Advisory Panel to the National Council on the Arts will be held by teleconference.

DATES: See the **SUPPLEMENTARY INFORMATION** section for individual meeting times and dates. All meetings are Eastern time and ending times are approximate:

ADDRESSES: National Endowment for the Arts, Constitution Center, 400 7th St. SW, Washington, DC 20506.

FOR FURTHER INFORMATION CONTACT: Further information with reference to these meetings can be obtained from Ms. Sherry Hale, Office of Guidelines & Panel Operations, National Endowment for the Arts, Washington, DC 20506; *hales@arts.gov,* or call 202/682–5696.

SUPPLEMENTARY INFORMATION: The closed portions of meetings are for the purpose of Panel review, discussion, evaluation, and recommendations on financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency. In accordance with the determination of the Chairman of September 10, 2019, these sessions will be closed to the public pursuant to subsection (c)(6) of section 552b of title 5, United States Code.

The upcoming meetings are:

Our Town (review of applications): This meeting will be closed.

Date and time: December 3, 2019; 11:00 a.m. to 1:30 p.m.

Our Town (review of applications): This meeting will be closed.

Date and time: December 3, 2019; 2:30 p.m. to 5:00 p.m.

Our Town (review of applications): This meeting will be closed.

Date and time: December 4, 2019; 11:00 a.m. to 1:30 p.m.

Our Town (review of applications): This meeting will be closed.

Date and time: December 4, 2019; 2:30 p.m. to 5:00 p.m.

Arts Education (review of applications): This meeting will be closed.

Date and time: December 5, 2019; 11:30 a.m. to 1:30 p.m.

Arts Education (review of applications): This meeting will be closed.

Date and time: December 5, 2019; 2:30 p.m. to 4:30 p.m.

Folk Arts Partnership (review of applications): This meeting will be closed.

Date and time: December 9, 2019; 1:00 p.m. to 3:00 p.m.

Media Arts (review of applications): This meeting will be closed.

Date and time: December 9, 2019; 11:30 a.m. to 1:30 p.m.

Media Arts (review of applications): This meeting will be closed.

Date and time: December 9, 2019; 2:30 p.m. to 4:30 p.m.

Folk & Traditional Arts (review of applications): This meeting will be closed.

Date and time: December 10, 2019; 1:00 p.m. to 3:00 p.m.

Musical Theater (review of applications): This meeting will be closed.

Date and time: December 10, 2019; 1:00 p.m. to 3:00 p.m.

Theater (review of applications): This meeting will be closed.

Date and time: December 10, 2019; 4:00 p.m. to 6:00 p.m.

Museums (review of applications): This meeting will be closed.

Date and time: December 11, 2019; 11:30 a.m. to 1:30 p.m.

Museums (review of applications): This meeting will be closed.

Date and time: December 11, 2019; 2:30 p.m. to 4:30 p.m.

Folk & Traditional Arts (review of applications): This meeting will be closed.

Date and time: December 12, 2019; 1:00 p.m. to 3:00 p.m.

Local Arts Agencies (review of applications): This meeting will be closed.

Date and time: December 12, 2019; 1:00 p.m. to 3:00 p.m.

Local Arts Agencies (review of applications): This meeting will be closed.

Date and time: December 12, 2019; 3:30 p.m. to 5:30 p.m.

Media Arts (review of applications): This meeting will be closed.

Date and time: December 12, 2019; 11:30 a.m. to 1:30 p.m.

Theater (review of applications): This meeting will be closed.

Date and time: December 12, 2019; 1:00 p.m. to 3:00 p.m.

Theater (review of applications): This meeting will be closed.

Date and time: December 12, 2019; 4:00 p.m. to 6:00 p.m.

Museums (review of applications): This meeting will be closed.

Date and time: December 13, 2019; 11:30 a.m. to 1:30 p.m.

Museums (review of applications): This meeting will be closed.

Date and time: December 13, 2019; 2:30 p.m. to 4:30 p.m.

Presenting & Multidisciplinary Works (review of applications):

This meeting will be closed.

Date and time: December 16, 2019; 1:00 p.m. to 3:00 p.m.

Presenting & Multidisciplinary Works (review of applications):

This meeting will be closed.

Date and time: December 17, 2019; 1:00 p.m. to 3:00 p.m.

Theater (review of applications): This meeting will be closed.

Date and time: December 17, 2019; 1:00 p.m. to 3:00 p.m.

Theater (review of applications): This meeting will be closed.

Date and time: December 17, 2019; 4:00 p.m. to 6:00 p.m.

Presenting & Multidisciplinary Works (review of applications):

This meeting will be closed.

Date and time: December 18, 2019; 1:00 p.m. to 3:00 p.m.

Presenting & Multidisciplinary Works (review of applications):

This meeting will be closed.

Date and time: December 19, 2019; 1:00 p.m. to 3:00 p.m.

Dated: November 6, 2019.

Sherry Hale,

Staff Assistant, National Endowment for the Arts.

[FR Doc. 2019–24518 Filed 11–8–19; 8:45 am]

BILLING CODE P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts

Proposed Collection: Comment Request

ACTION: Notice.

SUMMARY: The National Endowment for the Arts, as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95). This program helps ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the National Endowment for the Arts, on behalf of the Federal Council on the Arts and the Humanities, is soliciting comments concerning renewal of the Application for Domestic Indemnification. A copy of this collection request can be obtained by contacting the office listed below in the address section of this notice.

DATES: Written comments must be submitted to the office listed in the address section below on or before January 15, 2020. The National Endowment for the Arts is particularly interested in comments which:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used;

—Enhance the quality, utility and clarity of the information to be collected; and

—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 the electronic submissions of responses.

ADDRESSES: Patricia Loiko, National Endowment for the Arts, 400 7th Street SW, Washington, DC 20506–0001, telephone (202) 682–5541 (this is not a toll-free number), fax (202) 682–5721.

Gregory Gendron,

Director, Administrative Services.

[FR Doc. 2019–24552 Filed 11–8–19; 8:45 am]

BILLING CODE 7537–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Permit Applications Received Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of permit applications received.

SUMMARY: The National Science Foundation (NSF) is required to publish a notice of permit applications received to conduct activities regulated under the Antarctic Conservation Act of 1978. NSF has published regulations under the Antarctic Conservation Act in the Code of Federal Regulations. This is the required notice of permit applications received.

DATES: Interested parties are invited to submit written data, comments, or views with respect to this permit application by December 12, 2019. This application may be inspected by interested parties at the Permit Office, address below.

ADDRESSES: Comments should be addressed to Permit Office, Office of Polar Programs, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, Virginia 22314.

FOR FURTHER INFORMATION CONTACT: Nature McGinn, ACA Permit Officer, at the above address, 703–292–8030, or *ACApermits@nsf.gov.*

SUPPLEMENTARY INFORMATION: The National Science Foundation, as directed by the Antarctic Conservation Act of 1978 (Pub. L. 95–541, 45 CFR 670), as amended by the Antarctic Science, Tourism and Conservation Act of 1996, has developed regulations for the establishment of a permit system for various activities in Antarctica and designation of certain animals and certain geographic areas requiring special protection. The regulations establish such a permit system to designate Antarctic Specially Protected Areas.

Application Details

Permit Application: 2020–010

1. *Applicant:* Heather J. Lynch, Stony Brook University, 610 Life Sciences Building, Stony Brook, NY 11794.

Activity for Which Permit is Requested: Harmful Interference; Enter Antarctic Specially Protected Area (ASPA). The applicant would survey chinstrap penguin (*Pygoscelis antarctica*) colonies in the South Shetland Islands including multiple sites on Low Island. The outcomes of the surveys would be useful in determining population abundance and distribution of chinstrap penguins, important consumers of Antarctic krill. Surveys would be completed using direct manual counts (on foot) and by operating small, remotely piloted aircraft systems (RPAS) over colonies. RPAS would be operated by experienced pilots at altitudes of at least 30 meters above wildlife. Although no significant disturbance is expected, both manual counts and RPAS overflights have the potential to disturb chinstrap penguins as well as Adelie penguin (*Pygoscelis adeliae*), gentoo penguin (*P. papua*), southern giant petrel (*Macronectes giganteus*), southern fulmar (*Fulmarus glacialoides*), cape petrel (*Daption capense*), Antarctic blue-eyed shag (*Phalacrocorax atriceps*), Antarctic brown skua (*Catharacta antarctica*), south polar skua (*C. maccormicki*), kelp gull (*Larus dominicanus*), and Antarctic tern (*Sterna vittata*) based on the locations of the surveys. The applicant expects that several million chinstrap penguins would be surveyed by RPAS. The applicant would enter ASPA 152 to complete surveys at Low Island. The applicant would also collect samples of ticks, guano, and tissue samples salvaged from already dead gentoo penguins in support of the research.

Location: ASPA 152 Western Bransfield Strait; South Shetland Islands: Low Island, Smith Island, Snow Island, Elephant Island; Antarctic Peninsula region.

Dates of Permitted Activities: January 1–March 1, 2020.

Permit Application: 2020–017

2. *Applicant:* Joseph A. Covi, University of North Carolina at Wilmington, Department of Biology and Marine Biology, Wilmington, NC 28403.

Activity for Which Permit is Requested: Enter Antarctic Specially Protected Areas. The application proposes to enter four Antarctic Specially Protected Areas (ASPAs) on King George Island, South Shetland Islands, Antarctica for the purposes of collecting small sediment samples from freshwater lakes and ephemeral ponds. The applicant would enter ASPA 125, Fildes Peninsula; ASPA 132, Potter Peninsula; ASPA 150, Ardley Island, Maxwell Bay; and ASPA 171 Narebski Point, Barton Peninsula. The applicant plans to access the ASPAs by boat and on foot. Up to six sediment samples will be collected near the shoreline or from an inflatable boat from each of up to eight lakes and eight ephemeral ponds in total. Sediment core samples may be taken through holes drilled in the ice cover, as applicable. The applicant and agents will adhere to the management plans for each of the ASPAs that they propose to enter.

Location: King George Island, South Shetland Islands, Antarctica; ASPA 125, Fildes Peninsula; ASPA 132, Potter Peninsula; ASPA 150, Ardley Island, Maxwell Bay; and ASPA 171 Narebski Point, Barton Peninsula.

Dates of Permitted Activities: December 1, 2019–March 31, 2022.

Permit Application: 2020–018

3. *Applicant:* Zicheng Yu, Department of Earth and Environmental Science, Lehigh University, 1 West Packer Avenue, Bethlehem, PA 18015.

Activity for Which Permit is Requested: Enter Antarctic Specially Protected Area (ASPA). The applicant requests access to ASPA 113, 126, and 134 to collect small samples of moss and peat and carry out field measurements. Moss samples would primarily consist of two species, *Polytrichum strictum* and *Chorisodontium aciphyllum,* and would be collected by hand. Cores of peat moss up to 100 cm deep would be collected by box corer (3 inches by 4 inches) or permafrost corer (2-inch diameter). A limited number of samples would be collected from within the ASPAs and from other nearby locations within the Palmer Basin ASMA. No equipment or instrumentation would be installed in any ASPA. To minimize the potential for unintentional transfer of soils or organisms, the application and agents would clean sample collection tools, as well as clothing and shoes, between visits to different field sites. The samples would be processed at the home institution. Data gathered from this research will advance the understanding of peat moss banks to climate change during the last 3,000 years. The applicant would also operate a small, remotely piloted aircraft system equipped with a camera in order to map vegetation and peat moss beds.

Location: Antarctic Peninsula region; ASMA 7, Southwest Anvers Island and Palmer Basin; ASPA 113, Litchfield Island, Arthur Harbor, Anvers Island, Palmer Archipelago; ASPA 126, Byers Peninsula, Livingston Island, South Shetland Islands; ASPA 134 Cierva Point and offshore islands, Danco Coast, Antarctic Peninsula.

Dates of Permitted Activities: February 16, 2020–March 31, 2020.

Erika N. Davis,

Program Specialist, Office of Polar Programs.

[FR Doc. 2019–24542 Filed 11–8–19; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2019–0177]

Proposed Revisions To Draft Branch Technical Position 8–8 Onsite (Emergency Diesel Generators) and Offsite Power Sources Completion Time Extensions

AGENCY: Nuclear Regulatory Commission.

ACTION: Standard review plan-draft section revision; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is soliciting public comment on draft NUREG–0800, ''Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition,'' Branch Technical Position (BTP) 8–8, ''Onsite (Emergency Diesel Generators) and Offsite Power Sources Completion Time Extensions.'' The NRC seeks comments on the proposed draft section revision of the BTP concerning guidance for the completion time extension requests for onsite or offsite power sources.

DATES: Comments must be filed no later than January 13, 2020. 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:

• *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2019–0177. 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 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 accessing information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Mark Notich, Office of New Reactors, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–3053; email: *Mark.Notich@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2019–0177 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–2019–0177.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The draft revision and current revision to BTP 8–8, ''Onsite (Emergency Diesel Generators) and Offsite Power Sources Completion Time Extensions'' are available in ADAMS under Accession Nos. ML19219A184 and ML113640138, respectively.

• *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2019–0177 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. Further Information

The NRC seeks public comment on the proposed draft section revision of BTP 8–8. The changes to Standard Review Plan (SRP) Chapter 8 reflect the current staff reviews, methods, and practices based on lessons learned from the NRC's reviews of design certification and combined license applications completed since the last revision of this chapter. The draft SRP section would also provide guidance for reviewing an application for a combined license under part 52 of title 10 of the *Code of Federal Regulations* (10 CFR).

Following NRC staff evaluation of public comments, the NRC intends to finalize BTP 8–8 in ADAMS and post it on the NRC's public website at *https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0800/.* The SRP is guidance for the NRC staff. The SRP is not a substitute for the NRC regulations, and compliance with the SRP is not required.

III. Backfitting and Issue Finality

Chapter 8 of the SRP provides guidance to the staff for electrical engineering issues. BTP 8–8 of the SRP provides guidance for the review of information addressing onsite and offsite power sources completion time extensions.

Issuance of this SRP section revision does not constitute backfitting as defined in 10 CFR 50.109 (the Backfit Rule) nor is it inconsistent with the issue finality provisions in 10 CFR part 52. The NRC's position is based upon the following considerations.

1. *The SRP positions do not constitute backfitting, inasmuch as the SRP is guidance directed to the NRC staff with respect to its regulatory responsibilities.*

The SRP provides guidance to the NRC staff on how to review an application for NRC regulatory approval in the form of licensing. Changes in guidance intended for use by only the staff are not matters that constitute backfitting as that term is defined in 10 CFR 50.109(a)(1) or involve the issue finality provisions of 10 CFR part 52.

2. *Backfitting and issue finality—with certain exceptions discussed below—do not apply to current or future applicants.*

Applicants and potential applicants are not, with certain exceptions, the subject of either the Backfit Rule or any issue finality provisions under 10 CFR part 52. This is because neither the Backfit Rule nor the issue finality provisions of 10 CFR part 52 were intended to apply to every NRC action that substantially changes the expectations of current and future applicants.

The exceptions to the general principle are applicable whenever a 10 CFR part 50 operating license applicant references a construction permit or a 10 CFR part 52 combined license applicant references a license (*e.g.,* an early site permit) and/or an NRC regulatory approval (*e.g.,* a design certification rule) for which specified issue finality provisions apply.

The NRC staff does not currently intend to impose the positions represented in this final SRP section in a manner that constitutes backfitting or is inconsistent with any issue finality provision of 10 CFR part 52. If in the future the NRC staff seeks to impose positions stated in this SRP section in a manner that would constitute backfitting or be inconsistent with these issue finality provisions, the NRC staff must make the showing as set forth in the Backfit Rule or address the regulatory criteria set forth in the applicable issue finality provision, as applicable, that would allow the staff to impose the position.

3. *The NRC staff has no intention to impose the SRP positions on existing nuclear power plant licensees either now or in the future (absent a voluntary request for a change from the licensee, holder of a regulatory approval or a design certification applicant).*

The staff does not intend to impose or apply the positions described in this final SRP section to existing (already

issued) licenses (*e.g.,* operating licenses and combined licenses) and regulatory approvals. Hence, the issuance of this SRP guidance—even if considered guidance subject to the Backfit Rule or the issue finality provisions in 10 CFR part 52—would not need to be evaluated as if it were a backfit or as being inconsistent with issue finality provisions. If, in the future, the NRC staff seeks to impose a position in the SRP on holders of already issued licenses in a manner that would constitute backfitting or does not provide issue finality as described in the applicable issue finality provision, then the staff must make a showing as set forth in the Backfit Rule or address the criteria set forth in the applicable issue finality provision, as applicable, that would allow the staff to impose the position.

Dated at Rockville, Maryland, this 6th day of November, 2019.

For the Nuclear Regulatory Commission.

Dennis C. Morey,

Chief, Licensing Projects Branch, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2019–24551 Filed 11–8–19; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2020–20 and CP2020–19]

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 negotiated service agreements. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* November 14, 2019.

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 3007.301.[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 3010, and 39 CFR part 3020, 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 3015, and 39 CFR part 3020, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2020–20 and CP2020–19; *Filing Title:* USPS Request to Add Priority Mail Contract 558 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 5, 2019; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3020.30 *et seq.,* and 39 CFR 3015.5; *Public Representative:* Curtis E. Kidd; *Comments Due:* November 14, 2019.

[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).

This Notice will be published in the **Federal Register**.

Darcie S. Tokioka,

Acting Secretary.

[FR Doc. 2019–24520 Filed 11–8–19; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* November 12, 2019.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on November 5, 2019, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Contract 558 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2020–20, CP2020–19.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2019–24464 Filed 11–8–19; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87469; File No. SR–CboeEDGX–2019–068]

Self-Regulatory Organizations; Cboe EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Fee Schedule To Adopt a New Type of Tier Related to Automated Improvement Mechanism Customer Volume

November 5, 2019.

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 November 1, 2019, Cboe EDGX Exchange, Inc. (''Exchange'' or ''EDGX'') filed with the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

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 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''), effective November 1, 2019.

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 21% of the market share and currently the Exchange represents only 3% of the market share.[3] 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's Fees Schedule sets forth standard rebates and rates applied per contract. For example, the Exchange provides a standard rebate of $0.01 per contract for Customer orders that add liquidity in both Penny and Non-Penny Securities. Additionally, in response to the competitive environment, the Exchange also offers tiered pricing which provides Members opportunities to qualify for higher rebates or reduced fees where certain volume criteria and thresholds are met. Tiered pricing provides an incremental incentive for Members to strive for higher tier levels, which provides increasingly higher benefits or discounts for satisfying increasingly more stringent criteria.

For example, the Exchange currently offers four non-complex Customer Volume Tiers under Footnote 1 of the fee schedule which provide enhanced rebates between $0.10 and $0.21 per contract for qualifying Customer orders which meet certain total volume thresholds and yield fee codes ''PC''[4] and ''NM''.[5] Under the current non-complex Customer Volume Tiers, a Member receives a reduced fee between $0.10 and $0.21 per contract, where the Member has an ADV[6] in Customer orders greater or equal to a specified percentage of OCV[7] (Tiers 1–3). Members also have an opportunity to receive a reduced fee of $0.21 per contract under Tier 4 where the Member satisfies an additional criteria by also reaching another specified ADV threshold in Customer or Market Maker orders. The Exchange now proposes to adopt a new type of tier related to Customer volume under proposed footnote 9 (Automated Improvement Mechanism (''AIM'') Tier) applicable to orders yielding fee code ''BC'', which are appended to Customer AIM Agency orders. The Exchange notes that orders yielding fee code BC are currently provided a rebate of $0.14, and it now proposes to reduce this rebate to $0.11 and, instead, offer a rebate of $0.14 for such orders where a Member reaches the proposed AIM Tier.

Specifically, the proposed AIM Tier provides Members an additional opportunity and alternative means to receive a rebate for meeting the corresponding proposed criteria. Pursuant to the proposed changes, all orders yielding the fee code BC would receive a base rebate of $0.11 and a Member would receive an enhanced rebate of $0.14 on such orders where they have an ADV in Customer orders greater than or equal to .35% of the OCV. Members that achieve the proposed AIM Tier must therefore increase their overall Customer order flow, both adding and/or removing liquidity, as a percentage greater than or equal to 0.35% of the TCV. The Exchange believes the proposed enhanced rebates for both liquidity adding and removing Customer orders incentivizes increased overall order flow to the Book. The proposed tier provides both liquidity providing Members and liquidity executing Members on the Exchange an additional opportunity to receive a rebate. It is designed to provide Members that add liquidity by means of Customer orders on the Exchange a further incentive to contribute to a deeper, more liquid market, and Members executing Customer orders on the Exchange an incentive to increase transactions and take the execution opportunities provided by such increased liquidity. Increased overall Customer order flow benefits all market participants because it continues to attract liquidity to the Exchange by providing more trading opportunities, which attracts Market Makers. An increase in Market Maker activity, in turn, facilitates tighter spreads, signaling additional corresponding increase in order flow from other market participants, which

[3] *See* Cboe Global Markets U.S. Options Market Volume Summary (October 29, 2019), available at *https://markets.cboe.com/us/options/market_statistics/.*

[4] Appended to Customer Penny Pilot orders and provided a rebate of $0.01.

[5] Appended to Customer non-Penny Pilot orders and provided a rebate of $0.01.

[6] ''ADV'' means average daily volume calculated as the number of contracts added or removed, combined, per day. ADV is calculated on a monthly basis. *See* Cboe EDGX Options Exchange Fee Schedule.

[7] ''OCV'' means the total equity and ETF options volume that clears in the Customer range at the Options Clearing Corporation (''OCC'') for the month for which the fees apply, excluding volume on any day that the Exchange experiences an Exchange System Disruption and on any day with a scheduled early market close. *See* Cboe EDGX Options Exchange Fee Schedule.

contributes towards a robust, well-balanced market ecosystem. In addition to this, although the proposed based rebate for orders yielding fee code BC is lower than the current base rebate for such orders, Members still have an opportunity to receive a base rebate for such orders, which is in line with similar fees for Customer orders in place on other options exchanges.[8] Members will now be able to achieve the higher rebate for orders yield fee code BC pursuant to the proposed AIM Tier described above, which is tied to the levels of a Member's Customer order flow. Therefore, the reduced base rebate for orders yielding fee code BC is balanced by the rebate opportunity pursuant to the proposed AIM Tier and helps support the Exchange's objective in implementing the proposed tier to encourage an overall increase in Customer order flow and facilitate improved market quality on the Exchange.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6 of the Act,[9] in general, and furthers the requirements of Section 6(b)(4),[10] in particular, as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers. 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.

In particular, the Exchange believes the proposed tier is reasonable because it provides an additional opportunity for Members to receive a rebate by providing a different set of criteria they for which they can compete. The Exchange notes that volume-based incentives and discounts have been widely adopted by exchanges,[11] including the Exchange,[12] and are reasonable, equitable and non-discriminatory because they are open to all members on an equal basis and provide additional benefits or discounts that are reasonably related to (i) the value to an exchange's market quality and (ii) associated higher levels of market activity, such as higher levels of liquidity provision and/or growth patterns. Additionally, as noted above, the Exchange operates in highly competitive market. The Exchange is only one of several options venues to which market participants may direct their order flow, and it represents a small percentage of the overall market. Competing options exchanges offer similar tiered pricing structures to that of the Exchange, including schedules of rebates and fees that apply based upon members achieving certain volume and/or growth thresholds. These competing pricing schedules, moreover, are presently comparable to those that the Exchange provides, including pricing incentives tied to comparable tiers.[13]

Moreover, the Exchange believes the proposed AIM Tier is a reasonable means to encourage Members to increase Customer volume on the Exchange. Particularly, the Exchange believes the proposed tier is reasonable because it will encourage increased Customer volume, thus a deeper, more liquid market, and an increase in transaction opportunities for all market participants provided by the increased Customer liquidity. As stated, increased Customer order flow provides continued liquidity to the Exchange, in that it provides additional transaction opportunities which attract Market Makers. Increased Market Maker activity facilitates tighter spreads and signals an increase in additional order flow from other market participants. In turn, these increases benefit all Members by contributing towards a robust and well-balanced market ecosystem. Also, increased overall order flow benefits all investors by deepening the Exchange's liquidity pool, providing greater execution incentives and opportunities, offering additional flexibility for all investors to enjoy cost savings, supporting the quality of price discovery, promoting market transparency, and improving investor protection. Additionally, the Exchange believes the proposed reduction in the base rebate for orders yielding fee code BC is reasonable because Members still have an opportunity to receive a rebate for such orders, albeit at a lesser amount. Moreover, the reduced base rebate is still higher than offered at other exchanges for similar transactions.[14] As described above, the Exchange will continue to offer an opportunity to receive the $0.14 rebate, but will now tie it to a requirement to increase Members' Customer order flow. Accordingly, balancing the reduced base rebate for orders yielding fee code BC with the higher rebate opportunity for such orders helps support Exchange's objective in implementing an incentive to encourage an increase in Customer order flow and contribution to enhanced market quality on the Exchange.

The Exchange also believes that the proposed rebate amount and criteria under the AIM Tier does not represent a significant departure from the rebates currently offered, or required criteria, under the Exchange's existing Customer Volume Tiers. For example, under existing non-complex Customer Volume Tier 1 (applicable to orders yielding fee code PC or NC which are provided a standard rebate of $0.01), if a Member has a daily average volume (ADV) of 0.35% or greater than the OCV the Member receives a rebate of $0.10 per share. The Exchange believes the proposed tier criteria and rebate of $0.14 is comparable to this existing tier, especially given that orders yielding fees code PC or NC receive a standard rebate of $0.01 as compared to the $0.11 base rebate (as proposed) for orders yielding fee code BC.

The Exchange believes that the proposed tier represents an equitable allocation of fees and is not unfairly discriminatory because it applies uniformly to all Members. All Members are eligible for the proposed AIM tier, would have the opportunity to meet the tier's criteria (which the Exchange believes is less stringent that other existing Customer Volume tiers),[15] and would receive the proposed rebate if such criteria is met. While the Exchange has no way of knowing whether this

[8] *See* MIAX Options Section 1(a)(iii), Priority Customer Rebate Program, which provides a base rebate of $0.10 for Customer Price Improvement Mechanism (''PRIME'') Agency orders, which are comparable to orders yielding fee code BC on the Exchange (*i.e.,* Customer AIM Agency orders).

[9] 15 U.S.C. 78f.

[10] 15 U.S.C. 78f(b)(4).

[11] *See e.g.,* Cboe BZX U.S. Options Exchange Fee Schedule, Footnotes 1 and 12, Customer Penny Pilot and Non-Penny Pilot Add Volume Tiers which provide enhanced rebates for Customer orders where Members meet certain volume thresholds; *see also supra* note 8.

[12] *See e.g.,* Cboe EDGX U.S. Options Exchange Fee Schedule, Footnote 1, Customer Volume Tiers, which provide enhanced rebates between $0.10 and $0.21 per contract for non-complex Customer Penny and Non-Penny orders where Members meet certain volume thresholds.

[13] *See e.g.,* Cboe BZX U.S. Options Exchange Fee Schedule, Footnotes 1 and 12, Customer Penny Pilot and Non-Penny Pilot Add Volume Tiers, which provide enhanced rebates between $0.35–$1.05 per contract where Members, among other things including a cross-asset threshold, meet a specified level of ADAV in Customer orders as a percentage of OCV.

[14] *See supra* note 8.

[15] *See e.g.,* Cboe EDGX U.S. Options Exchange Fee Schedule, Footnote 1, Customer Volume Tiers 2–4, which require a Member to have an ADV of over 0.35% (as proposed in the AIM Tier) of the OCV.

proposed rule change would definitively result in any particular Member qualifying for the proposed tier or if it would otherwise impact Member activity, the Exchange anticipates at least three Members meeting, or being reasonably able to meet, the proposed criteria. Accordingly, the Exchange believes the proposed tier is reasonably designed to provide an incentive for Members interested in meeting the tier criteria to submit additional Customer volume to achieve the proposed rebate. The Exchange lastly notes that the proposed tier will not adversely impact any Member's pricing or their ability to qualify for other tiers. Rather, should a Member not meet the proposed criteria, the Member will merely not receive the proposed reduced fee. Furthermore, the proposed rebate would uniformly apply to all Members that meet the required criteria under proposed AIM Tier. Likewise, the Exchange believes that the proposed reduction in the base rebate for orders yielding fee code BC represents an equitable allocation of rebates and is not unfairly discriminatory because it is balanced by the higher rebate for such orders provided under the proposed AIM Tier and Members will continue to have the opportunity to receive a base rebate on such orders which will also continue to uniformly apply to all such orders.

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 intramarket or intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. Rather, as discussed above, the Exchange believes that the proposed change would encourage the submission of additional liquidity to a public exchange, thereby promoting market depth, price discovery and transparency and enhancing order execution opportunities for all Members. As a result, the Exchange believes that the proposed change furthers the Commission's goal in adopting Regulation NMS of fostering competition among orders, which promotes ''more efficient pricing of individual stocks for all types of orders, large and small.'' [16]

The Exchange believes the proposed rule change does impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. Particularly, the proposed change applies to all Members equally in that all Members are eligible for the proposed tier, have a reasonable opportunity to meet the tier's criteria and will all receive the proposed rebate if such criteria is met. Additionally, the proposed change is designed to attract additional order flow to the Exchange. The Exchange believes that the proposed tier would incentivize market participants to direct both liquidity providing and executable order flow to the Exchange. Greater overall order flow benefits all market participants on the Exchange by providing more trading opportunities and continuing to encourage Members to send orders, thereby contributing towards a robust and well-balanced market ecosystem, which benefits all market participants.

Next, the Exchange believes the proposed rule change does not impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. 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 21% of the market share.[17] 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.'' [18] 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'. . . .''.[19] 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 has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any written comments from members or other interested parties.

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 [20] and paragraph (f) of Rule 19b–4 [21] 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

[16] Securities Exchange Act Release No. 51808, 70 FR 37495, 37498–99 (June 29, 2005) (S7–10–04) (Final Rule).

[17] *See supra* note 3.

[18] See Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[19] 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)).

[20] 15 U.S.C. 78s(b)(3)(A).

[21] 17 CFR 240.19b–4(f).

• Send an email to *rule-comments@sec.gov.* Please include File Number SR–CboeEDGX–2019–068 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–2019–068. 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–CboeEDGX–2019–068 and should be submitted on or before December 3, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[22]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–24496 Filed 11–8–19; 8:45 am]

BILLING CODE 8011–01–P

[22] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87461; File No. SR–CboeBZX–2019–093]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating To Adopt Fees for a New Data Product on Its Equity Options Platform (''BZX Options'') To Be Known as Open-Close Data

November 5, 2019.

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 October 29, 2019, 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, 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 BZX Exchange, Inc. (the ''Exchange'' or ''BZX Options'') is filing with the Securities and Exchange Commission (''Commission'') a proposed rule change to adopt fees for a new data product on its equity options platform (''BZX Options'') to be known as Open-Close Data. 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.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to adopt fees for a new data product on BZX Options known as Open-Close Data, which is available for purchase to BZX Options Members and Non-Members.[3] Cboe LiveVol, LLC (''LiveVol''), a wholly owned subsidiary of the Exchange's parent company, Cboe Global Markets, Inc., will make the Open-Close Data available for purchase to Members and Non-Members on the LiveVol DataShop website (*datashop.cboe.com*). The Exchange proposes to amend its Fee Schedule to adopt fees for the product.[4]

The Exchange recently introduced the Open-Close Data product. Open-Close Data is a volume summary file for trading activity on BZX Options. The Exchange notes it is proprietary BZX Options trade data and does not include trade data from any other exchanges. It is also a historical data product and not a real time data feed. The Open-Close Data summarizes and buckets the volume by origin (customer, professional customer, broker-dealer, and market maker), buying/selling, and opening/closing criteria. The customer and professional customer volume is further broken down into trade size buckets (less than 100 contracts, 100–199 contracts, greater than 199 contracts). The data currently goes back to January 2018 and contains all series in an underlying security if it has volume.[5] The Exchange anticipates a wide variety of market participants to purchase Open-Close Data, including, but not limited to, individual customers, buy-side investors, investment banks and academic institutions. For example, the Exchange notes that academic institutions may utilize Open-Close Data and as a result promote research and studies of the options industry to the benefit of all market participants. The Exchange believes the Open-Close Data product may also provide helpful trading information regarding investor sentiment and may be used to create

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 86811 (August 29, 2019), 84 FR 46765 (September 5, 2019) (SR–CboeBZX–2019–079).

[4] The Exchange initially filed the proposed fees on business date August 30, 2019 (SR–CboeBZX–2019–080). On business date October 29, 2019, the Exchange withdrew that filing and submitted this filing.

[5] The Open-Close data file format specifications can be found at *https://datashop.cboe.com/Themes/Livevol/Content/static/OpenCloseSpecification.pdf.*

and test trading models and analytical strategies and provides comprehensive insight into trading on BZX Options. It is a completely voluntary product, in that the Exchange is not required by any rule or regulation to make this data available and that potential subscribers may purchase it only if they voluntarily choose to do so. The Exchange notes that its affiliate, Cboe Exchange, Inc. (''Cboe Options''), as well as other exchanges, offer a similar data product.[6]

The Exchange proposes to provide in its Fee Schedule that Members and non-Members may purchase Open-Close Data on a subscription basis (end of day file) or by ad hoc request for a specified month (historical file). The Exchange proposes to assess a monthly fee of $500 for subscribing to a daily update which will consist of Open/Close data covering all Exchange-listed securities. Members and non-Members purchasing Open/Close data on a subscription basis will receive access to a daily data file. The Exchange proposes to assess a fee of $400 per request per month for an ad-hoc request of historical Open/Close data covering all Exchange-listed securities. An ad-hoc request can be for any number of months beginning with January 2018 for which the data is available.[7] The proposed subscription and ad-hoc fees will apply both to Members or non-Members. The Exchange notes that other exchanges, including its affiliate Exchange Cboe Exchange, Inc. (''Cboe Options'') provide similar data products that may be purchased on both a subscription and ad-hoc basis and are similarly priced.[8]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[9] in general, and furthers the objectives of Section 6(b)(5) of the Act,[10] 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 to protect investors and the public interest, and that it is not designed to permit unfair discrimination among customers, brokers, or dealers. The Exchange also believes that its proposal to adopt fees for Open-Close Data is consistent with Section 6(b) of the Act in general, and furthers the objectives of Section 6(b)(4) of the Act[11] in particular, in that it is an equitable allocation of dues, fees and other charges among its members and other recipients of Exchange data.

In adopting Regulation NMS, the Commission granted self-regulatory organizations (''SROs'') 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. Particularly, Open-Close Data further broadens the availability of U.S. option market data to investors consistent with the principles of Regulation NMS. The data product also promotes increased transparency through the dissemination of Open-Close Data and benefits investors by providing access to the Open-Close Data, which may promote better informed trading, as well as research and studies of the options industry. Particularly, information regarding opening and closing activity across different option series may indicate investor sentiment, which can be helpful research and/or trading information. Subscribers to the data may be able to enhance their ability to analyze option trade and volume data, and create and test trading models and analytical strategies. The Exchange believes Open-Close Data provides a valuable tool that subscribers can use to gain comprehensive insight into the trading activity in a particular series, but also emphasizes such data is not necessary for trading. Moreover, the Exchange's affiliate Cboe Options, along with other exchanges, also offer a similar data product.

The Exchange operates in a highly competitive environment. Indeed, there are currently 16 registered options exchanges that trade options. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Particularly, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.''[12] Making similar data products available to market participants fosters competition in the marketplace, and constrains the ability of exchanges to charge supracompetitive fees. In the event that a market participant views one exchange's data product as more or less attractive than the competition they can and do switch between similar products. The proposed fees are a result of the competitive environment, as the Exchange seeks to adopt fees to attract purchasers of the recently introduced Open-Close Data product.

The Exchange believes the proposed fees are reasonable as the proposed fees are both modest and similar to, or even lower than, the fees assessed by other exchanges that provide similar data products.[13] Indeed, proposing fees that are excessively higher than established fees for similar data products would simply serve to reduce demand for the Exchange's data product, which as noted, is entirely optional. Like the Exchange's Open-Close Data product, other exchanges offer similar data products that each provide insight into trading on those markets and may likewise aid in assessing investor sentiment. Although each of these similar open-close data products provide only proprietary trade data and not trade data from other exchanges, it's possible investors are still able to gauge overall investor sentiment across different option series based on open and closing interest on any one exchange.[14] Similarly, market participants may be able to analyze option trade and volume data, and create and test trading models and analytical strategies using only open-close data relating to trading activity on one or more of the other markets that provide similar data products. As such, if a market participant views another exchange's open-close data as more attractive than its Open-Close Data product, then such market participant can merely choose not to purchase the Exchange's Open-Close Data and instead purchase another exchange's open-close data product, which offer similar data

[6] *See* Securities Exchange Act Release No. 55062 (January 8, 2007), 72 FR 2048 (January 17, 2007) (approving SR–CBOE–2006–88); *See also* Securities Exchange Act Release No. 56254 (August 15, 2007), 72 FR 47104 (August 22, 2007) (SR–ISE–2007–70).

[7] For example, a Member or non-Member that requests historical Open/Close Data for the months of October 2018 and November 2018, would be assessed a total of $800. The Exchange notes that it may make historical data prior to January 2018 available in the future and that such historical data would be available to all Member or non-Member.

[8] *See e.g.,* Cboe Options Fees Schedule, Livevol Fees, Open-Close Data. *See also* Nasdaq ISE Options 7 Pricing Schedule, Section 10.A.

[9] 15 U.S.C. 78f.

[10] 15 U.S.C. 78f(b)(5).

[11] 15 U.S.C. 78f(b)(4).

[12] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (''Regulation NMS Adopting Release'').

[13] *See e.g.,* Cboe Options Fees Schedule, Livevol Fees, Open-Close Data. *See also* Nasdaq ISE Options 7 Pricing Schedule, Section 10.A.

[14] The exchange notes that its open-close data product does not include data on any exclusive, singly-listed option series.

points, albeit based on that other market's trading activity.

The Exchange also believes the proposed fees are reasonable as they would support the Open-Close Data product, which is designed to aid investors by providing insight into trading on BZX Options. The Open-Close Data would provide options market participants with valuable information about opening and closing transactions executed on the Exchange, similar to other historical trade data products offered by competing options exchanges. In turn, this data would assist market participants in gauging investor sentiment and trading activity, resulting in potentially better informed trading decisions. As noted above, users may also use such data to create and test trading models and analytical strategies.

Selling historical market data, such as Open-Close Data, is also a means by which exchanges compete to attract business. To the extent that the Exchange is successful in attracting subscribers for the Open-Close Data, it may earn trading revenues and further enhance the value of its data products. If the market deems the proposed fees to be unfair or inequitable, firms can diminish or discontinue their use of the data and/or avail themselves of similar products offered by other exchanges.[15] The Exchange therefore believes that the proposed fees for Open-Close Data reflect the competitive environment and would be properly assessed on Member or non-Member users. The Exchange also believes the proposed fees are equitable and not unfairly discriminatory as the fees would apply equally to all users who choose to purchase such data. The Exchange's proposed fees would not differentiate between subscribers that purchase Open-Close Data, and are set at a modest level that would allow any interested Member or non-Member to purchase such data based on their business needs.

As noted above, the Exchange anticipates a wide variety of market participants to purchase Open-Close Data, including but not limited to individual customers, buy-side investors, investment banks and academic institutions. For example, on its affiliate exchange Cboe Options, which also offers an Open-Close Data product, approximately 38% of purchases of historical ad hoc Open-Close Data files are individuals, 33% are buy-side investors or investment banks and 25% are academic institutions. Accordingly, the Exchange anticipates that open-close data may be used not just for commercial or monetizing purposes, but also for educational use and research. The Exchange reiterates that the decision as to whether or not to purchase the Open-Close Data is entirely optional for all potential subscribers. Indeed, no market participant is required to purchase the Open-Close Data, and the Exchange is not required to make the Open-Close Data available to all investors. Rather, the Exchange is voluntarily making historical Open-Close Data available, as requested by customers, and market participants may choose to receive (and pay for) this data based on their own business needs. Potential purchasers may request the data at any time if they believe it to be valuable, or may decline to purchase such data.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange 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. Rather, the Exchange believes that the proposal will promote competition by permitting the Exchange to sell a data product similar to those offered by other competitor options exchanges.[16] The Exchange made Open-Close Data available for BZX Options in order to keep pace with changes in the industry and evolving customer needs, and believes the data product will contribute to robust competition among national securities exchanges. At least three other U.S. options exchanges offer a market data product that is substantially similar to the Open-Close Data. As a result, the Exchange believes this proposed rule change permits fair competition among national securities exchanges.

Furthermore, the Exchange operates in a highly competitive environment, and its ability to price Open-Close Data is constrained by competition among exchanges that offer similar data products to their customers. As discussed, there are currently a number of similar products available to market participants and investors. At least three other U.S. options exchanges offer a market data product that is substantially similar to the Open-Close Data, which the Exchange must consider in its pricing discipline in order to compete for the market data.[17] For example, proposing fees that are excessively higher than established fees for similar data products would simply serve to reduce demand for the Exchange's data product, which as discussed, market participants are under no obligation to utilize. In this competitive environment, potential purchasers are free to choose which, if any, similar product to purchase to satisfy their need for market information. As a result, the Exchange believes this proposed rule change permits fair competition among national securities exchanges.

The Exchange also does not believe the proposed fees would cause any unnecessary or inappropriate burden on intermarket competition as other exchanges are free to introduce their own comparable data product and lower their prices to better compete with the Exchange's offering. The Exchange does not believe the proposed rule change would cause any unnecessary or inappropriate burden on intramarket competition. Particularly, the proposed product and fees apply uniformly to any purchaser, in that it does not differentiate between subscribers that purchase Open-Close Data. The proposed fees are set at a modest level that would allow any interested Member or non-Member to purchase such data based on their business needs.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received written 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[18] and paragraph (f) of Rule 19b–4[19] 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

[15] *See e.g.,* Cboe Options Fees Schedule, Livevol Fees, Open-Close Data. *See also* Nasdaq ISE Options 7 Pricing Schedule, Section 10.A.

[16] *Id.*

[17] *See e.g.,* Cboe Options Fees Schedule, Livevol Fees, Open-Close Data. *See also* Nasdaq ISE Options 7 Pricing Schedule, Section 10.A and Nasdaq PHLX Options 7 Pricing Schedule, Section 10, PHLX Options Trade Outline (''PHOTO'').

[18] 15 U.S.C. 78s(b)(3)(A).

[19] 17 CFR 240.19b–4(f).

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–2019–093 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–2019–093. 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–CboeBZX–2019–093 and should be submitted on or before December 3, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

Jill M. Peterson,

Assistant Secretary.

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BILLING CODE 8011–01–P

[20] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87468; File No. SR–BX–2019–039]

Self-Regulatory Organizations; Nasdaq BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Relocate Rules From its Current Rulebook Into its New Rulebook Shell

November 5, 2019.

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 October 23, 2019, Nasdaq BX, Inc. (''BX'' or ''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 to relocate rules from its current Rulebook into its new Rulebook shell.

The text of the proposed rule change is available on the Exchange's website at *http://nasdaqbx.cchwallstreet.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 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 purpose of this rule change is to relocate BX rules into the new Rulebook shell with some amendments to the shell.[3] Nasdaq ISE, LLC (''ISE''), Nasdaq GEMX, LLC (''GEMX'') and Nasdaq MRX, LLC (''MRX'') recently relocated their rules.[4] BX proposes to relocate its rules so the Rulebook is similar to ISE, GEMX and MRX. The other Nasdaq affiliated markets will also relocate their Rulebooks in order to harmonize its rule structure, where applicable, across Nasdaq markets. The relocation and harmonization of the BX Rule structure is part of the Exchange's continued effort to promote efficiency and structural conformity of its rules with those of its Affiliated Exchanges. The Exchange believes that the placement of the BX Rules into their new location in the shell will facilitate the use of the Rulebook by Members and Members of Affiliated Exchanges.

The Exchange notes that the entire Rulebook is not being relocated at this time. Specifically, certain Equity Rules and the Disciplinary Rules are not being relocated. These rules will be relocated in other rule filings.

The Exchange proposes to update all cross-references within the Rule to the new relocated rule cites and also proposes to correct certain citations. The Exchange proposes to replace internal rule references to simply state ''this Rule'' where the rule is citing itself without a more specific cite included in the Rule. For example, if BX Chapter VI, Section 3 refers currently to ''Chapter VI, Section 3'' the Exchange will amend the phrase to simply ''this Rule.'' The Exchange proposes to conform numbering and lettering in certain rules to the remainder of the Rulebook. The Exchange proposes to reflect the use of the General Equity and Options Rules in place of Equity Rules, where applicable (*i.e.,* an Equity Rule that currently applies to both equities and options). Finally, the Exchange proposes to delete

[3] Previously, the Exchange added a shell structure to its Rulebook with the purpose of improving efficiency and readability and to align its rules closer to those of its five sister exchanges, The Nasdaq Stock Market LLC; Nasdaq PHLX LLC; ISE, GEMX and MRX (''Affiliated Exchanges''). *See* Securities Exchange Act Release No. 82174 (November 29, 2017), 82 FR 57492 (December 5, 2017) (SR–BX–2017–054).

[4] *See* Securities Exchange Act Release Nos. 86138 (June 18, 2019), 84 FR 29567 (June 24, 2019) (SR–ISE–2019–17); 86346 (July 10, 2019) 84 FR 33999 (July 16, 2019) (SR–GEMX–2019–08); and 86424 (July 22, 2019), 84 FR 36134 (July 26, 2019) (SR–MRX–2019–15).

any current Rules that are reserved in the Rulebook.

General 1

The Exchange proposes to relocate rule text from Rule 0111, ''Adoption of Rules'', Rule 0112, ''Effective Date'', Rule 0113, ''Interpretation,'' certain definitions from Rule 0120, ''Definitions'' and Rule 0121 ''Definitions in the By-Laws of the Exchange'' into General 1. The Exchange proposes to relocate certain definitions from Chapter VI, Section 1 into General 1.[5] The Exchange proposes to delete certain definitions which are repetitive.[6] The Exchange will also alphabetize the definitions within General 1 and conform the text where applicable. Definitions related to the equities rules [7] currently within Rule 1020 will be relocated into Equity 1 as explained below. The Exchange is conforming the format of all definitions. Finally, the Exchange notes that the description of ''MarketWatch'' was amended to remove the phrase ''a unit of BX Regulation'' because that phrase is repetitive.

General 2

General 2 would be comprised of the following rules:

Proposed new rule No.	Current rule No.
Section 1	Reserved.
Section 2	Chapter VI, Section 16 Fees, Dues and Other Charges.
Section 3	Reserved.
Section 4	2130. Nasdaq Ownership Restriction (re-title ''Limitation on Affiliation between the Exchange and Members'').
Section 5	0130. Regulation of the Exchange and Its Members.
Section 6	0115. Applicability.
Section 7	0150. Regulatory Independence.
Section 8	0160. Delegation, Authority and Access.
Section 9	1130. Reliance on Current Membership List.
Section 10	1150. Executive Representative.
Section 11	1160. Contact Information Requirements.
Section 12	1170. The Exchange's Business Continuity and Disaster Recovery Plan Testing (re-title ''Business Continuity and Disaster Recovery Plan Testing'').
Section 13	0140. Fingerprint-Based Background Checks of Employees and Independent Contractors.
Section 14	2140. Restrictions on Affiliation.
Section 15	3510. Business Continuity Plans.
Section 16	3520. Emergency Contact Information.

The Exchange is reserving Sections 1 and 3 at this time. The Exchange proposes to relocate Chapter VI, Section 16 Fees, Dues and Other Charges into the General section because this rule applies to both the equity and options products. This rule describes the power of BX's Board of Directors. The Exchange notes that the Board of Directors of BX has the power to set fees for the BX market, which includes fees for both options and equities.[8] The Exchange notes that Section 7, ''Regulatory Independence'' was amended to remove the placeholder for a date.

General 3

The Exchange proposes to relocate the rule text of Rule 1000, ''Membership, Registration and Qualification Requirements'' along with the title of Rule 1000 into General 3, Section 1.

General 4

The Exchange proposes to rename General 4 from ''Regulation'' to ''Registration Requirements.''

General 9

The Exchange proposes to adopt a new General 9, titled ''Regulation.'' The Exchange proposes to relocate the following rules into General 9:

Proposed new rule No.	Current rule No.
Section 1	2110, Standards of Commercial Honor and Principles of Trade; IM–2110–2, Trading Ahead of Customer Limit Order; IM–2110–3, Front Running Policy; IM–2110–4, Trading Ahead of Research Reports; IM–2110–5, Anti-Intimidation/Coordination; IM–2110–6, Confirmation of Callable Common Stock; IM–2110–7, Interfering With the Transfer of Customer Accounts in the Context of Employment Disputes; 2111, Trading Ahead of Customer Market Orders; and 2120, Use of Manipulative, Deceptive or Other Fraudulent Devices (re-title ''General Standards'').
Section 2	2150, Customers' Securities or Funds; IM–2150, Segregation of Customers' Securities.
Section 3	2210, Communications with the Public; IM–2210–1, Guidelines to Ensure That Communications With the Public Are Not Misleading; and IM–2210–4, Limitations on Use of the Exchange's Name.
Section 4	2211, Institutional Sales Material and Correspondence.
Section 5	2212, Telemarketing.
Section 6	2251, Forwarding of Proxy and Other Issuer-Related Materials.
Section 7	2261, Disclosure of Financial Condition; 2262, Disclosure of Control Relationship with Issuer; and 2269, Disclosure of Participation or Interest in Primary or Secondary Distribution (re-title ''Disclosure of Financial Condition, Control Relationship with Issuer and Participation or Interest in Primary or Secondary Distribution'').
Section 8	2266, SIPC Information.
Section 9	2290, Fairness Opinions.
Section 10	2310, Recommendations to Customers (Suitability); IM–2310–2, Fair Dealing with Customers; and IM–2310–3, Suitability Obligations to Institutional Customers.

[5] *See* note 13 below.

[6] The Exchange proposes to delete the term ''Exchange Act'' and ''SEC'' or ''Commission.''

[7] The terms ''Customer,'' ''Delegation Agreement,'' ''Equity Rules,'' ''Grandfathered Rules,'' ''Nasdaq BX Equities LLC'' or BX Equities LLC,'' ''Nasdaq BX Equities Market'' or ''System,'' and ''Security'' are being relocated into Equity 1 of the Rulebook as these terms are specific to the equity market.

[8] *See* By-Laws of BX, Article XII, Section 12.4 which provides the Board authority to set fees. In addition, the Exchange proposes to amend the word ''Participant'' in this rule to ''member'' to clearly indicate all members are subject to the Rule.

Proposed new rule No.	Current rule No.
Section 11	2320, Best Execution and Interpositioning; and IM–2320, Interpretive Guidance with Respect to Best Execution Requirements.
Section 12	2340, Customer Account Statements.
Section 13	2341, Margin Disclosure Statement.
Section 14	2360, Approval Procedures for Day-Trading Accounts; and 2361, Day-Trading Risk Disclosure Statement.
Section 15	2370, Borrowing From or Lending to Customers.
Section 16	2430, Charges for Services Performed.
Section 17	2441, Net Transactions with Customers.
Section 18	2460, Payments for Market Making.
Section 19	2510, Discretionary Accounts.
Section 20	3010, Supervision; IM–3010–1, Standards for Reasonable Review; and IM–3010–2, Guidance on Heightened Supervision Requirements.
Section 21	3012, Supervisory Control System.
Section 22	3013, Annual Certification of Compliance and Supervisory Processes; and IM–3013, Annual Compliance and Supervision Certification.
Section 23	3030, Outside Business Activities of an Associated Person.
Section 24	3040, Private Securities Transactions of an Associated Person.
Section 25	3050, Transactions for or by Associated Persons.
Section 26	3060, Influencing or Rewarding Employees of Others.
Section 27	3070, Reporting Requirements.
Section 28	3080, Disclosure to Associated Persons When Signing Form U4.
Section 29	3090, Transactions Involving Exchange Employees.
Section 30	3110, Books and Records and IM–3110. Customer Account Information.
Section 31	3120, Use of Information Obtained in Fiduciary Capacity.
Section 32	3140, Approval of Change in Exempt Status Under SEC Rule 15c3–3.
Section 33	3150, Reporting Requirements for Clearing Firms; and IM–3150, Exemptive Relief.
Section 34	3160, Extensions of Time Under Regulation T and SEC Rule 15c3–3.
Section 35	2040, Nonregistered Foreign Finder.
Section 36	Reserved.
Section 37	3011, Anti-Money Laundering Compliance Program.
Section 38	2520, Margin Requirements.
Section 39	3020, Fidelity Bonds.
Section 40	4110A, Capital Compliance.
Section 41	4120A, Regulatory Notification and Business Curtailment.
Section 42	4140A, Audit.
Section 43	Reserved.
Section 44	Reserved.
Section 45	Reserved.
Section 46	Reserved.
Section 47	Reserved.
Section 48	4521A, Notifications, Questionnaires and Reports.
Section 49	5230A, Payments Involving Publications that Influence the Market Price of a Security.
Section 50	1090, Foreign Members.
Section 51	1050, Research Analyst.

The word ''FINRA'' is being added in certain places for greater clarity. The Exchange is amending Rule 2212, Telemarketing, to update the Rule reference to NASD Rule 2212 to FINRA Rule 3230 in light of a FINRA rule change.[9] The Exchange is amending Rule 3010, Supervision, as well as IM–3010–1, Standards for Reasonable Review, to update the Rule reference to NASD Rule 3010 to FINRA Rule 3110 and 3170, respectively, in light of a FINRA rule change.[10] The Exchange also proposes to remove rule text from IM–3010–1 which states, ''FINRA is in the process of consolidating certain NASD rules into a new FINRA rulebook. If the provisions of NASD Interpretive Material 3010–1 are transferred into the FINRA rulebook, then Equity Interpretive Material 3010–1 shall be construed to require Exchange members and persons associated with a member to comply with the FINRA rule corresponding to NASD Interpretive Material 3010–1 (regardless of whether such rule is renumbered or amended) as if such rule were part of the Rules of the Exchange.'' The consolidation has already occurred with respect to this rule. The Exchange proposes to amend NASD Rule 3070 references within Rule 3070, Reporting Requirements, to FINRA Rule 4530 pursuant to a FINRA rule change.[11] The Exchange will also separately file another rule change to amend other NASD Rule references to the FINRA Rulebook. Finally, the Exchange is updating incorrect references to NASD Rules within General 9, Sections 3, 23 and 24.

Equity Rules

The Exchange proposes to amend the Equity Rules to re-title certain chapters in the new Rulebook. The Exchange proposes to relocate certain definitions currently within Rule 0120, Definitions, into Equity 1.[12] The Exchange proposes to re-title Equity 2 from ''Equity Trading Rules'' to ''Equity Market Participants.'' The Exchange proposes to re-title Equity 3 from ''Equity Market Participants'' to ''Equity Trading Rules.'' The Exchange proposes to title Equity 4, which is currently reserved, as ''Limit Up-Limit Down.'' The Exchange proposes to reserve Equity 6, which is currently titled ''Limit Up-Limit Down.'' The Exchange proposes to title Equity 10, which is currently reserved, as ''BX

[9] *See* Securities Exchange Act Release No. 66279 (January 30, 2012), 77 FR 5611 (February 3, 2012) (SR–FINRA–2011–059).

[10] *See* Securities Exchange Act Release No. 71179 (December 23, 2013), 79 FR 79542 (December 30, 2013) (SR–FINRA–2013–025).

[11] *See* Securities Exchange Act Release No. 63260 (November 5, 2010), 75 FR 69508 (November 12, 2010) (SR–FINRA–2010–034).

[12] *See* note 13 below. The term ''Exchange Manual'' is being eliminated.

Venture Market Listing Rules.'' Finally, the Exchange proposes to remove Equity 11, which is titled ''BX Venture Market Listing Rules.''

Options 1

The Exchange proposes to rename current Options 1 from ''Options Definitions'' to ''General Provisions.'' The Exchange proposes to relocate and alphabetize certain definitions from Chapter I, Section 1 into proposed General 1, Section 1. The Exchange also proposes to relocate definitions from Chapter VI, Section 1(a)–(c) and (h) into Options 1, Section 1. Certain definitions within Chapter 1, Section 1 and Chapter VI, Section 1 apply to both equities and options. These definitions [13] will be relocated to General 1, Section 1 from Chapter I, Section 1 and Chapter VI, Section 1. The Exchange proposes to conform the definitions by adding ''the term'' where necessary. The Exchange proposes to amend the term ''System'' from Chapter VI, Section 1 and apply that term to both ''System'' and ''Trading System'' and remove the separate definition for ''Trading System'' in Chapter I, Section 1(a)(62) which creates a circular reference to the term ''System.'' The Exchange also proposes to eliminate the defined term ''Participant'' from Chapter VI, Section 1. The Exchange defines an ''Options Participant'' or ''Participant'' within its rules today. The separate defined term'' Participant'' is confusing and unnecessary. The term ''Exchange'' is redundant of the same terms that was already being relocated to General 1 from the Equity Rules. The Exchange proposes to delete the terms ''Exchange'' and ''Order Entry Firms'' in this rule because they are duplicative.

In addition the Exchange proposes to relocate the following rules into Options 1:

Proposed new rule No.	Current rule No.
Section 1	Chapter I, Section 1, Definitions and Chapter VI, Section 1(a)–(c) and (h).
Section 2	Chapter I, Section 2, Applicability.
Section 3	Chapter I, Section 3, Regulation of BX and its Members.

The Exchange proposes to relocate Chapter V, Section 2, MarketWatch, to the end of the defined term ''MarketWatch'' which is currently within Chapter I, Section 1 and is being relocated to General 1 as that term applies to both options and equities. The sentence is merely descriptive and adds to the already defined term. The Exchange proposes to relocate Chapter VII, Section 1, Customer Orders and Order Entry Firms, into a definition for Order Entry Firms within Options 1, Section 1.

Options 2

The Exchange proposes to rename Options 2 from ''Options Trading Rules'' to ''Options Market Participants'' and relocate the following rules into this chapter:

Proposed new rule No.	Current rule No.
Section 1	Chapter VII, Section 2, Market Maker Registration; and Section 3 Continuing Market Maker Registration (re-title as ''Registration of Market Makers'').
Section 2	Reserved.
Section 3	Chapter VII, Section 13, Lead Market Makers Allocations (re-title as ''Lead Market Maker Allocations'').
Section 4	Chapter VII, Section 5, Obligations of Market Makers; and Section 14, LMM Obligations and Quotations (re-title as ''Obligations of Market Makers and Lead Market Makers'').
Section 5	Chapter VII, Section 6, Market Maker Quotations.
Section 6	Reserved.
Section 7	Chapter VII, Section 7, Securities Accounts and Orders of Market Makers.
Section 8	Chapter VII, Section 9, Financial Requirements for Market Makers.
Section 9	Chapter VII, Section 4, Good Standing for Market Makers.
Section 10	Chapter VII, Section 15, Directed Market Makers.

The Exchange proposes to reserve Sections 2 and 6. The Exchange proposes to relocate Chapter VII, Section 8, Letters of Guarantee, to Options 6, Section 4. The Exchange proposes to relocate Chapter VII, Sections 11, Mass Cancellation of Trading Interest, and Section 12, Order Exposure Requirements, to Options 3, Sections 19 and 22. Chapter VII, Section 1, Customer Orders and Order Entry Firms, was relocated to the definitions as described herein.

Options 2A

The Exchange proposes a new Options Section 2A titled ''Options Participation'' and proposes to relocate the following rules into this chapter:

Proposed new rule No.	Current rule No.
Section 1	Chapter II, Section 1, Options Participation.
Section 2	Chapter II, Section 2, Requirements for Options Participation.
Section 3	Chapter II, Section 3, Persons Associated with Options Participants.
Section 4	Chapter II, Section 4, Good Standing for Options Participants.

The Exchange proposes to reserve Sections 5–7.

Options 3

The Exchange proposes to rename Options 3 from ''Options Market Participants'' to ''Options Trading Rules'' and relocate the following rules into this chapter:

[13] The following definitions are being relocated from Chapter I, Section 1 and Chapter VI, Section 1 into General 1, Section 1: ''Board,'' ''BX,'' ''BX Regulation,'' ''BX Rules,'' ''he,'' ''him,'' or ''his,'' ''MarketWatch,'' ''primary market,'' ''SEC'' or Commission,'' and ''SRO.''

Proposed new rule No.	Current rule No.
Section 1	Chapter VI, Section 2, Days and Hours of Business.
Section 2	Chapter VI, Section 3. Units of Trading; and Section 4, Meaning of Premium Quotes and Orders (combined into one rule and retitle as ''Units of Trading and Meaning of Premium Quotes and Orders'').
Section 3	Chapter VI, Section 5, Minimum Increments.
Section 4	Chapter VI, Section 6, Entry and Display of Quotes.
Section 5	Chapter VI, Section 7, Entry and Display of Orders.
Section 6	Chapter V, Section 5, Unusual Market Conditions.
Section 7	Chapter VI, Section 1(d)–(g) Definitions; and Chapter VI, Section 21 Order and Quote Protocols (re-title as ''Types of Orders and Quote Protocols'').
Section 8	Chapter VI, Section 8, BX Opening and Halt Cross (re-title as ''Opening and Halt Cross'').
Section 9	Chapter V, Section 3, Trading Halts; and Section 4, Resumption of Trading After a Halt (re-title as to ''Trading Halts'').
Section 10	Chapter VI, Section 10, Book Processing (re-title as ''Order Book Allocation'').
Section 11	Reserved.
Section 12	Reserved.
Section 13	Chapter VI, Section 9, Price Improvement Auction (''PRISM'').
Section 14	Reserved.
Section 15	Chapter VI, Section 18, Risk Protections.
Section 16	Reserved.
Section 17	Chapter VI, Section 22, Kill Switch.
Section 18	Chapter VI, Section 23, Detection of Loss of Communication.
Section 19	Chapter VII, Section 11, Mass Cancellation of Trading Interest.
Section 20	Chapter V, Section 6, Nullification and Adjustment of Options Transactions including Obvious Errors.
Section 21	Chapter V, Section 1, Access to and Conduct on BX Options; and Chapter VI, Section 20 Exchange Sharing of Participant-Designated Risk Settings (re-title as ''Access to and Conduct on BX Options'').
Section 22	Chapter VI [sic], Section 12, Limitations on Order Entry.
Section 23	Chapter VI, Section 19, Data Feeds and Trade Information.
Section 24	Chapter VI, Section 13, Transaction Price Binding.
Section 25	Chapter VI, Section 12, Anonymity.
Section 26	Chapter VI, Section 17, Message Traffic Mitigation.
Section 27	Chapter V, Section 9, Limitation of Liability.
Section 28	Reserved.

The Exchange proposes to combine the BX Rules and retitle them as indicated herein. The Exchange proposes to reserve certain rules. Chapter VI, Section 16, Fees, Dues and Other Charges was relocated to General 2 and Chapter VI, Sections 14, Authorization to Give Up, and Section 15, Submission for Clearance, were relocated to Options 6. The Exchange amended Options 3, Section 21(b)(8) to refer to Section 22 with describes the limitation on orders on BX.

Options 4

The Exchange proposes to amend Options 4, Options Listing Rules, to remove Section 5, which is reserved, and renumber Section 6, Series of Options Contracts Open for Trading, as Section 5.[14] The Exchange also proposes to reserve Section 6 and reserve a new Section 10.

Options 4A

The Exchange proposes to relocate rules within new proposed Options 4A, which is proposed to be titled ''Options Index Rules'' as follows:

Proposed new rule No.	Current rule No.
Section 1	Chapter XIV, Section 1, Application of Index Rules.
Section 2	Chapter XIV, Section 2, Definitions.
Section 3	Chapter XIV, Section 3, Designation of a Broad-Based Index.
Section 4	Chapter XIV, Section 6, Designation of Narrow-Based and Micro-Narrow-Based Index Options.
Section 5	Chapter XIV, Section 4, Dissemination of Information.
Section 6	Chapter XIV, Section 5, Position Limits for Broad-Based Index Options.
Section 7	Chapter XIV, Section 7, Position Limits for Industry and Micro-Narrow Based Index Options.
Section 8	Reserved.
Section 9	Chapter XIV, Section 8, Exemptions from Position Limits.
Section 10	Chapter XIV, Section 9, Exercise Limits.
Section 11	Chapter XIV, Section 10, Trading Sessions.
Section 12	Chapter XIV, Section 11, Terms of Index Options Contracts.
Section 13	Chapter XIV, Section 12, Debit Put Spread Cash Account Transactions.
Section 14	Chapter XIV, Section 13, Disclaimers.
Section 15	Chapter XIV, Section 14, Exercise of American-Style Index Options.
Section 16	Reserved.

[14] The corresponding rule numbers are changing for removals of certain sections.

The Exchange proposes to add a clarifying note to Options 4A, Supplementary Material .01 to Section 2 to explain that no reporting authorities are listed because BX does not currently list index options.

Options 5

The Exchange proposes to rename Options 5 from ''Options Trade Administration'' to ''Order Protection and Locked and Crossed Markets.'' The current rules [15] within Options 5 are being relocated into Options 6B.

The Exchange proposes to relocate the following rules within Options 5 as follows:

Proposed new rule No.	Current rule No.
Section 1	Chapter XII, Section 1, Definitions.
Section 2	Chapter XII, Section 2, Order Protection.
Section 3	Chapter XII, Section 3, Locked and Crossed Markets.
Section 4	Chapter VI, Section 11(a), Order Routing.
Section 5	Chapter VI, Section 11(b) to be titled ''Cancellation of Orders and Error Account''.

The definitions of ''Exchange Act'' and ''SEC'' are being removed from Chapter XII, Section 1, Definitions, as these terms are repetitive of definitions within General 1.

Options 6

The Exchange proposes rename Options 6 from ''Order Protection and Locked and Cross Markets'' to ''Options Trade Administration'' and relocate rules within Options 6 as follows:

Proposed new rule No.	Current rule No.
Section 1	Chapter VI, Section 14, Authorization to Give Up.
Section 2	Chapter VI, Section 15, Submission for Clearance.
Section 3	Reserved.
Section 4	Chapter VII, Section 8, Letters of Guarantee.

Options 6A

The Exchange proposes to relocate rules within new proposed Options 6A titled ''Closing Transactions'' as follows:

Proposed new rule No.	Current rule No.
Section 1	Chapter X, Section 6, Contracts of Suspended Participants.
Section 2	Chapter V, Section 8, Failure to Pay Premium.

Options 6B

The Exchange proposes to relocate rules within new proposed Options 6B titled ''Exercises and Deliveries'' as follows:

Proposed new rule No.	Current rule No.
Section 1	Options 5, Section 101, Exercise of Options Contracts.
Section 2	Options 5, Section 102, Allocation of Exercise Notices.
Section 3	Options 5, Section 103, Delivery and Payment.

Options 6C

The Exchange proposes to relocate rules within new proposed Options 6C titled ''Margins'' as follows:

[15] Options 5 currently includes the following rules: Section 101 Exercise of Options Contracts, Section 102 Allocation of Exercise Notices, and Section 103, Delivery and Payment.

Proposed new rule No.	Current rule No.
Section 1	Chapter XIII, Section 1, General Rule.
Section 2	Chapter XIII, Section 2, Time Margin Must Be Obtained.
Section 3	Chapter XIII, Section 3, Margin Requirements.
Section 4	Reserved.
Section 5	Chapter XIII, Section 4, Margin Required Is Minimum.
Section 6	Reserved.

Chapter XIII, Section 5, Joint Back Office Participants, is being relocated to Options 6D.

Options 6D

The Exchange proposes to relocate rules within new proposed Options 6D titled ''Net Capital Requirements'' as follows:

Proposed new rule No.	Current rule No.
Section 1	Reserved.
Section 2	Reserved.
Section 3	Reserved.
Section 4	Chapter XIII, Section 5, Joint Back Office Participants.

With respect to the relocation of Joint Back Office Participants, Supplementary Material .01 was removed and the text was retained as part of the main rule in paragraph (c) of Section 4.

Options 6E

The Exchange proposes to relocate rules within new proposed Options 6E titled ''Records, Reports and Audits'' as follows:

Proposed new rule No.	Current rule No.
Section 1	Chapter IX, Section 1, Maintenance, Retention and Furnishing of Books, Records and Other Information.
Section 2	Chapter IX, Section 2, Reports of Uncovered Short Positions.
Section 3	Chapter IX, Section 3, Financial Reports and Audits.
Section 4	Reserved.
Section 5	Chapter IX, Section 4, Automated Submission of Trade Data.
Section 6	Chapter IX, Section 6, Risk Analysis of Market Maker Accounts.
Section 7	Chapter IX, Section 5, Regulatory Cooperation.
Section 8	Reserved.
Section 9	Chapter V, Section 7, Audit Trail.

The Exchange proposes to relocate Chapter IX, Section 7, Anti-Money Laundering Compliance Program, to Options 9, Section 21.

Options 7

The Exchange is updating cross-references within Options 7 to the introductory section of the Rule and Sections 2 and 4.

Options 9

The Exchange proposes to relocate rules within new proposed Options 9, which is currently reserved, and title the chapter as ''Business Conduct.'' The following rules will be relocated within Options 9 with certain rules reserved:

Proposed new rule No.	Current rule No.
Section 1	Reserved.
Section 2	Chapter III, Section 1, Adherence to Law and Chapter III; and Section 2 Conduct and Compliance with Rules (re-title as ''Adherence to Law and Compliance with BX Options Rules'').
Section 3	Reserved.
Section 4	Chapter III, Section 16, Disruptive Quoting and Trading Activity Prohibited.
Section 5	Reserved.
Section 6	Reserved.
Section 7	Reserved.
Section 8	Chapter III, Section 3, Rumors.
Section 9	Chapter III, Section 4, Prevention of the Misuse of Material Nonpublic Information.
Section 10	Chapter III, Section 5, Disciplinary Action by Other Organizations.
Section 11	Chapter III, Section 6, Other Restrictions on Participants.
Section 12	Chapter III, Section 15, Significant Business Transactions of Options Clearing Participants.
Section 13	Chapter III, Section 7, Position Limits.
Section 14	Chapter III, Section 8, Exemptions from Position Limits.
Section 15	Chapter III, Section 9, Exercise Limits.
Section 16	Chapter III, Section 10, Reports Related to Position Limits.
Section 17	Chapter III, Section 11, Liquidation Positions.
Section 18	Chapter III, Section 14, Limit on Outstanding Uncovered Short Positions.
Section 19	Chapter III, Section 12, Other Restrictions on Options Transactions and Exercises.

Proposed new rule No.	Current rule No.
Section 20	Chapter III, Section 13, Mandatory Systems Testing.
Section 21	Chapter IX, Section 7, Anti-Money Laundering Compliance Program.
Section 22	Reserved.
Section 23	Reserved.

Options 10

The Exchange proposes to relocate rules within new proposed Options 10 titled ''Doing Business with the Public'' as follows:

Proposed new rule No.	Current rule No.
Section 1	Chapter XI, Section 1, Eligibility.
Section 2	Chapter XI, Section 2, Registration of Options Principals.
Section 3	Chapter XI, Section 3, Registration of Representatives.
Section 4	Chapter XI, Section 5, Discipline, Suspension, Expulsion of Registered Persons.
Section 5	Chapter XI, Section 6, Branch Offices.
Section 6	Chapter XI, Section 7, Opening of Accounts.
Section 7	Chapter XI, Section 8, Supervision of Accounts.
Section 8	Chapter XI, Section 9, Suitability of Recommendations.
Section 9	Chapter XI, Section 10, Discretionary Accounts.
Section 10	Chapter XI, Section 11, Confirmation to Public Customers.
Section 11	Chapter XI, Section 12, Statement of Accounts to Customers.
Section 12	Chapter XI, Section 13, Statements of Financial Condition to Public Customers.
Section 13	Chapter XI, Section 15, Delivery of Current Options Disclosure Documents and Prospectus.
Section 14	Chapter XI, Section 16, Restrictions on Pledge and Lending of Customers' Securities.
Section 15	Chapter XI, Section 17, Transactions of Certain Public Customers.
Section 16	Chapter XI, Section 18, Guarantees.
Section 17	Chapter XI, Section 19, Profit Sharing.
Section 18	Chapter XI, Section 20, Assuming Losses.
Section 19	Chapter XI, Section 21, Transfer of Accounts.
Section 20	Chapter XI, Section 22, Communications with Public Customers; and Chapter XI, Section 14 Addressing of Communications to Public Customers (re-title as ''Communications with Public Customers'').
Section 21	Chapter XI, Section 23, Fidelity Bond.
Section 22	Chapter XI, Section 24, Public Customer Complaints.
Section 23	Chapter XI, Section 25, Telephone Solicitation.
Section 24	Chapter XI, Section 4, Other Affiliations of Registered Persons.
Section 25	Reserved.

The Exchange proposes to reserve Options 10, Section 25.

Options 11

Finally, the Exchange proposes to relocate Chapter X, Section 7 titled ''Penalty for Minor Rule Violations'' to Options 11 titled ''Minor Rule Plan Violations'' at Section 1. The Exchange proposes to relocate Chapter X, Section 1, ''Imposition of Suspension,'' Section 2, ''Investigation Following Suspension Violations,'' Section 3, ''Reinstatement Following Suspension,'' Section 4, ''Failure to Obtain Reinstatement,'' and Section 5, ''Termination of Rights by Suspension,'' into Options 11, Section 2, titled ''Suspension.''

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[16] in general, and furthers the objectives of Section 6(b)(5) of the Act,[17] in particular, in that it is designed to promote just and equitable principles of trade and to protect investors and the public interest by bringing greater transparency to its rules by relocating its Rules into the new Rulebook shell together with other rules which have already been relocated. The Exchange's proposal is consistent with the Act and will protect investors and the public interest by harmonizing its rule structure, where applicable, across Nasdaq markets so that Members can readily locate rules which cover similar topics. The relocation and harmonization of the BX Rule structure is part of the Exchange's continued effort to promote efficiency and conformity of its processes with those of its Affiliated Exchanges. The Exchange believes that the placement of the BX Rules into their new location in the shell will facilitate the use of the Rulebook by Members. Specifically, the Exchange believes that market participants that are members of more than one Nasdaq market will benefit from the ability to compare Rulebooks.

The Exchange is not substantively amending rule text unless noted otherwise within this rule change. The renumbering, re-lettering, deleting reserved rules, amending cross-references and other minor technical changes will bring greater transparency to BX's Rule structure. ISE, GEMX and MRX have already relocated their Rulebooks. The other Nasdaq affiliated markets will also relocate their Rulebooks in order to harmonize its rule structure, where applicable, across Nasdaq markets. The Exchange believes its proposal will benefit investors and the general public by increasing the transparency of its Rulebook and promoting easy comparisons among the various Nasdaq Rulebooks.

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 amendments do not impose an undue burden on competition because the

[16] 15 U.S.C. 78f(b).

[17] 15 U.S.C. 78f(b)(5).

amendments to relocate the Rules are non-substantive. This rule change is intended to bring greater clarity to the Exchange's Rules. Renumbering, re-lettering, deleting reserved rules and amending cross-references will bring greater transparency to BX's Rule structure.

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) of the Act [18] and Rule 19b–4(f)(6) thereunder.[19]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act [20] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii) [21] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that the Exchange could immediately relocate its rules. According to the Exchange, the proposal is intended to make it easier for members to locate the various Exchange rules, and is part of a larger effort to reorganize the Exchange's rules and those of its Affiliated Exchanges. 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. Accordingly, the Commission hereby waives the operative delay and designates the proposed rule change operative upon filing.[22]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BX–2019–039 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–BX–2019–039. 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–BX–2019–039, and should be submitted on or before December 3, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[23]

Jill M. Peterson,

Assistant Secretary.

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BILLING CODE 8011–01–P

[18] 15 U.S.C. 78s(b)(3)(A).

[19] 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.

[20] 17 CFR 240.19b–4(f)(6).

[21] 17 CFR 240.19b–4(f)(6)(iii).

[22] For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[23] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87464; File No. SR–CBOE–2019–107]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Extend the Operation of its SPXPM Pilot Program

November 5, 2019.

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 November 1, 2019, 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 and II 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 extend the operation of its SPXPM pilot program. The text of the proposed rule change is provided below.

[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).

[(additions are *italicized;* deletions are [bracketed])

* * * * *

Rules of Cboe Exchange, Inc.

* * * * *

Rule 4.13. Series of Index Options

* * * * *

Interpretations and Policies

.01–.12 No change.

.13 In addition to A.M.-settled S&P 500 Stock Index options approved for trading on the Exchange pursuant to Rule 4.13, the Exchange may also list options on the S&P 500 Index whose exercise settlement value is derived from closing prices on the last trading day prior to expiration (P.M.-settled third Friday-of-the-month SPX options series). The Exchange may also list options on the Mini-SPX Index (''XSP'') whose exercise settlement value is derived from closing prices on the last trading day prior to expiration (''P.M.-settled''). P.M.-settled third Friday-of-the-month SPX options series and P.M.-settled XSP options will be listed for trading for a pilot period ending [November 4, 2019]*May 4, 2020.*

* * * * *

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 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

On February 8, 2013, the Securities and Exchange Commission (the ''Commission'') approved a rule change that established a Pilot Program that allows the Exchange to list options on the S&P 500 Index whose exercise settlement value is derived from closing prices on the last trading day prior to expiration (''SPXPM'').[5] On July 31, 2013, the Commission approved a rule change that amended the Pilot Program that allows the Exchange to list options on the Mini-SPX Index (''XSP'') whose exercise settlement value is derived from closing prices on the last trading day prior to expiration (''P.M.-settled XSP'')[6] (together, SPXPM and P.M.-settled XSP to be referred to herein as the ''Pilot Products'').[7] The Exchange has extended the pilot period numerous times, which, pursuant to Rule 4.13.13,[8] is currently set to expire on the earlier of November 4, 2019 or the date on which the pilot program is approved on a permanent basis.[9] The Exchange hereby proposes to further extend the end date of the pilot period to May 4, 2020.

During the course of the Pilot Program and in support of the extensions of the Pilot Program, the Exchange submits reports to the Commission regarding the Pilot Program that detail the Exchange's experience with the Pilot Program, pursuant to the SPXPM Approval Order[10] and the P.M.-settled XSP Approval Order.[11] Specifically, the Exchange submits annual Pilot Program reports to the Commission that contain an analysis of volume, open interest, and trading patterns. The analysis examines trading in Pilot Products 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. The Exchange also submits periodic interim reports that contain some, but not all, of the information contained in the annual reports. In providing the annual and periodic interim reports (the ''pilot reports'') to the Commission, the Exchange has previously requested confidential treatment of the pilot reports under the Freedom of Information Act (''FOIA'').[12]

The pilot reports 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 also contain the information noted in Items (1) through (6) above for Expiration Friday, A.M.-settled, S&P 500 index options traded on Cboe Options, as well as the following analysis of trading patterns in the Pilot Products 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 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

[5] *See* Securities Exchange Act Release No. 68888 (February 8, 2013), 78 FR 10668 (February 14, 2013) (SR–CBOE–2012–120) (the ''SPXPM Approval Order''). Pursuant to Securities Exchange Act Release No. 80060 (February 17, 2017), 82 FR 11673 (February 24, 2017) (SR–CBOE–2016–091), the Exchange moved third-Friday P.M.-settled options into the S&P 500 Index options class, and as a result, the trading symbol for P.M.-settled S&P 500 Index options that have standard third Friday-of-the-month expirations changed from ''SPXPM'' to ''SPXW.'' This change went into effect on May 1, 2017, pursuant to Cboe Options Regulatory Circular RG17–054.

[6] *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'').

[7] For more information on the Pilot Products or the Pilot Program, *see* the SPXPM Approval Order and the P.M.-settled XSP Approval Order.

[8] The Exchange recently relocated prior Rule 24.9, containing the provision which governs the Pilot Program, to current Rule 4.13. *See* SR–CBOE–2019–092 (October 4, 2019), which did not make any substantive changes to prior Rule 24.9 and merely relocated it to Rule 4.13.

[9] *See* Securities Exchange Act Release Nos. 71424 (January 28, 2014), 79 FR 6249 (February 3, 2014) (SR–CBOE–2014–004); 73338 (October 10, 2014), 79 FR 62502 (October 17, 2014) (SR–CBOE–2014–076); 77573 (April 8, 2016), 81 FR 22148 (April 14, 2016) (SR–CBOE–2016–036); 80386 (April 6, 2017), 82 FR 17704 (April 12, 2017) (SR–CBOE–2017–025); 83166 (May 3, 2018), 83 FR 21324 (May 9, 2018) (SR–CBOE–2018–036); 84535 (November 5, 2018), 83 FR 56129 (November 9, 2018) (SR–CBOE–2018–069); and 85688 (April 18, 2019), 84 FR 17214 (April 24, 2019) (SR–CBOE–2019–023).

[10] *See supra* note 5.

[11] *See supra* note 6.

[12] 5 U.S.C. 552.

(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 periods are determined by the Exchange and the Commission. In proposing to extend the Pilot Program, the Exchange will continue to abide by the reporting requirements described herein, as well as in the SPXPM Approval Order and the P.M.-settled XSP Approval Order.[13] 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 Pilot Program is consistent with the Exchange Act. The Exchange is in the process of making public on its website data and analyses previously submitted to the Commission under the Pilot Program, and will make public any data and analyses it submits to the Commission under the Pilot Program in the future.

The Exchange proposes the extension of the Pilot Program in order to continue to give the Commission more time to consider the impact of the Pilot Program. To this point, Cboe Options believes that the Pilot Program has been well-received by its Trading Permit Holders and the investing public, and the Exchange would like to continue to provide investors with the ability to trade SPXPM and P.M.-settled XSP options. All terms regarding the trading of the Pilot Products shall continue to operate as described in the SPXPM Approval Order and the P.M.-settled XSP Approval Order. The Exchange merely proposes herein to extend the term of the Pilot Program to May 4, 2020.

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.[14] Specifically, the Exchange believes the proposed rule change is consistent with the 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. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[16] 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 proposed extension of the Pilot Program will continue to provide greater opportunities for investors. Further, the Exchange believes that it has not experienced any adverse effects or meaningful regulatory concerns from the operation of the Pilot Program. As such, the Exchange believes that the extension of the Pilot Program does not raise any unique or prohibitive regulatory concerns. Also, the Exchange believes that such trading has not, and will not, adversely impact fair and orderly markets on Expiration Fridays for the underlying stocks comprising the S&P 500 index. The extension of the Pilot Program will continue to provide investors with the opportunity to trade the desirable products of SPXPM and P.M.-settled XSP, while also providing the Commission further opportunity to observe such trading of the Pilot Products.

B. Self-Regulatory Organization's Statement on Burden on Competition

Cboe Options 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 continuation of the Pilot Program will impose any unnecessary or inappropriate burden on intramarket competition because it will continue to apply equally to all Cboe Options market participants, and the Pilot Products will be available to all Cboe Options market participants. The Exchange believes there is sufficient investor interest and demand in the Pilot Program to warrant its extension. The Exchange believes that, for the period that the Pilot Program has been in operation, it has provided investors with desirable products with which to trade. Furthermore, the Exchange believes that it has not experienced any adverse market effects or regulatory concerns with respect to the Pilot Program. The Exchange further does not believe that the proposed extension of the Pilot Program will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because it only applies to trading on Cboe Options. To the extent that the continued trading of the Pilot Products may make Cboe Options a more attractive marketplace to market participants at other exchanges, such market participants may elect to become Cboe Options market participants.

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 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[17] and subparagraph (f)(6) of Rule 19b–4 thereunder.[18]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act[19] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii)[20] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the

[13] Pursuant to Securities Exchange Act Release No. 75914 (September 14, 2015), 80 FR 56522 (September 18, 2015) (SR–CBOE–2015–079), the Exchange added SPXPM and P.M.-settled XSP options to the list of products approved for trading during Extended Trading Hours (''ETH''). The Exchange will also include the applicable information regarding SPXPM and P.M.-settled XSP options that trade during ETH in its annual and interim reports.

[14] 15 U.S.C. 78f(b).

[15] 15 U.S.C. 78f(b)(5).

[16] *Id.*

[17] 15 U.S.C. 78s(b)(3)(A).

[18] 17 CFR 240.19b–4(f)(6). In addition, Rule19b–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.

[19] 17 CFR 240.19b–4(f)(6).

[20] 17 CFR 240.19b–4(f)(6)(iii).

public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange states that waiver of the 30-day operative delay will allow it to extend the Pilot Program prior to its expiration on November 4, 2019, and maintain the status quo, thereby reducing market disruption. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest as it will allow the pilot program to continue uninterrupted, thereby avoiding investor confusion that could result from a temporary interruption in the pilot program. Accordingly, the Commission hereby waives the operative delay and designates the proposed rule change operative upon filing.[21]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CBOE–2019–107 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–2019–107. 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–2019–107 and should be submitted on or before December 3, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[22]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–24498 Filed 11–8–19; 8:45 am]

BILLING CODE 8011–01–P

[21] For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[22] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87470; File No. SR–FINRA–2019–022]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing of Partial Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Partial Amendment No. 1, To Amend FINRA Rule 5130 (Restrictions on the Purchase and Sale of Initial Equity Public Offerings) and FINRA Rule 5131 (New Issue Allocations and Distributions)

November 5, 2019.

I. Introduction

On July 26, 2019, Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''SEC'' or ''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 FINRA Rule 5130 (Restrictions on the Purchase and Sale of Initial Equity Public Offerings) and FINRA Rule 5131 (New Issue Allocations and Distributions) to exempt additional persons and offerings, modify current exemptions to enhance regulatory consistency, and address unintended operational impediments. The proposed rule change was published for comment in the **Federal Register** on August 8, 2019.[3] The Commission received six comment letters on the proposal.[4] On September 10, 2019, FINRA extended the time period in which the Commission must approve the proposed rule change, disapprove the proposed rule change or institute proceedings to determine

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 86558 (August 2, 2019), 84 FR 39029 (August 8, 2019) (Notice of Filing of File No. SR–FINRA–2019–022) (''Original Notice'').

[4] *See* Letter from Robert E. Buckholz, Chair, Federal Regulation of Securities Committee, American Bar Association Business Law Section, to Vanessa Countryman, Secretary, SEC, dated August 27, 2019 (''ABA''); letter from Elliott R. Curzon, Dechert LLP, to Jill M. Peterson, Assistant Secretary, SEC, dated August 29, 2019 (''Dechert 1''); letter from Dechert LLP, to Jill M. Peterson, Assistant Secretary, SEC, dated August 29, 2019 (''Dechert 2''); letter from Gail C. Bernstein, General Counsel, Investment Adviser Association, to Vanessa Countryman, Secretary, SEC, dated August 29, 2019 (''IAA''); letter from Aseel M. Rabie, Managing Director and Associate General Counsel, Securities Industry and Financial Markets Association, to Vanessa Countryman, Secretary, SEC, dated August 29, 2019 (''SIFMA''); and letter from Chris Peterson, to Vanessa Countryman, Secretary, SEC, dated September 13, 2019 (''Peterson'').

whether to approve or disapprove the proposed rule change to November 6, 2019.

On October 30, 2019, FINRA responded to the comments and filed Partial Amendment No. 1 to the proposal.[5] The Commission is publishing this notice to solicit comments on Partial Amendment No. 1 from interested persons, and is approving the proposed rule change, as modified by Partial Amendment No. 1, on an accelerated basis.

II. Description of the Proposed Rule Change

A. Description of Proposed Rule Change as Originally Filed

The following is a summary of the proposed rule change as originally filed by FINRA.[6]

As described in more detail in the Original Notice, FINRA proposes to amend FINRA Rule 5130 (Restrictions on the Purchase and Sale of Initial Equity Public Offerings) and FINRA Rule 5131 (New Issue Allocations and Distributions) in response to the comments it received based on *Regulatory Notice* 17–14,[7] as well as FINRA's experience with the Rules 5130 and 5131 (or ''the rules''). The proposed rule change would exempt additional persons from the scope of the rules, modify current exemptions to enhance regulatory consistency, address unintended operational impediments, and exempt certain types of offerings from the scope of the rules.

Family Offices

The proposed rule change would amend FINRA Rule 5130(i)(4) to define a ''family investment vehicle'' as a legal entity that is beneficially owned solely by one or more of the following persons: (1) ''Immediate family members'' as defined under FINRA Rule 5130(i)(5); (2) ''family members'' as defined under Advisers Act Rule 202(a)(11)(G)–1(d)(6); or (3) ''family clients'' as defined under Advisers Act Rule 202(a)(11)(G)–1(d)(4);[8] provided, however, that where the beneficial owners of such an entity include family clients, the person who has the sole authority to buy or sell securities for such an entity is an ''immediate family member'' as defined in FINRA Rule 5130(i)(5) or a ''family member'' as defined in Advisers Act Rule 202(a)(11)(G)–1(d)(6). Where the beneficial owners are not solely immediate family members or family members under FINRA Rule 5130(i)(5) or Advisers Act Rule 202(a)(11)(G)–1(d)(6), respectively, however, the proposed rule change would only provide relief from portfolio manager status if the person who has the authority to buy or sell securities for the account is an ''immediate family member,'' as defined in FINRA Rule 5130, or a ''family member,'' as defined in the Advisers Act.[9]

Sovereign Entities

The proposed rule change would exclude sovereign entities from the scope of owners of broker-dealers under Rule 5130(i)(10)(E). The proposed exclusion would not apply to affiliates of sovereign entities that are otherwise restricted. Accordingly, while a sovereign entity that owns a broker-dealer would not be considered a restricted person under the proposed rule change, the broker-dealer would continue to be a restricted person under FINRA Rule 5130.

The proposed rule change would also amend FINRA Rule 5130(i) (Definitions) to define the term ''sovereign entity'' for purposes of the rule as ''a sovereign nation or a pool of capital or an investment fund owned or controlled by a sovereign nation and created for the purpose of making investments on behalf of the sovereign nation.'' The proposed rule change would further define the term ''sovereign nation'' as ''a sovereign nation or its political subdivisions, agencies or instrumentalities.''

Foreign Employee Retirement Benefits Plans

The proposed rule change would also amend FINRA Rule 5130(c) (General Exemptions) to provide an exemption for an employee retirement benefits plan organized under and governed by the laws of a foreign jurisdiction, provided that such a plan or family of plans: (1) Has, in aggregate, at least 10,000 participants and beneficiaries and $10 billion in assets; (2) is operated in a non-discriminatory manner insofar as a wide range of employees, regardless of income or position, are eligible to participate without further amendment or action by the plan sponsor;[10] (3) is administered by trustees and managers that have a fiduciary obligation to administer the funds in the best interests of the participants and beneficiaries; and (4) is not sponsored by a broker-dealer. The proposed rule change would also amend Rule 5131(b)(2) to add a corresponding exemption (regarding employee retirement benefits plans) to Rule 5131.

Alternative Conditions for Foreign Investment Company Exemption

FINRA also proposes to amend paragraph (c)(6) of FINRA Rule 5130 to exempt sales to and purchases by an investment company organized under the laws of a foreign jurisdiction, provided that: (1) The investment company is listed on a foreign exchange for sale to the public or authorized for sale to the public by a foreign regulatory authority; (2) no person owning more than five percent of the shares of the investment company is a restricted person, the investment company has 100 or more direct investors, or the investment company has 1,000 or more indirect investors; and (3) the investment company was not formed for the specific purpose of investing in new issues.[11]

Exclusion for Foreign Offerings

In addition, the proposed rule change would expressly exclude from Rules 5130 and 5131 offerings that are conducted pursuant to Regulation S, which provides a safe harbor from the registration requirements of the Securities Act for offshore offers and sales of securities, as well as other offerings made outside of the United States or its territories (*i.e.,* not just

[5] *See* letter from Afshin Atabaki, Associate General Counsel, FINRA, to Vanessa Countryman, Secretary, Commission, dated October 30, 2019 (''FINRA Response''). FINRA Response to comments received and Partial Amendment No. 1 are available at *https://www.finra.org/industry/rule-filings/sr-finra-2019-022. See also* Section II.B., *infra.*

[6] *See* Original Notice, *supra* note 3, for a complete description of the proposal as originally filed.

[7] In April 2017, FINRA published *Regulatory Notice* 17–14 (Capital Formation) seeking comment on the effectiveness and efficiency of its rules, operations and administrative processes governing broker-dealer activities related to the capital-raising process and their impact on capital formation. FINRA received 11 comment letters in response to the *Regulatory Notice.* The *Regulatory Notice* and the comment letters are available at *http://www.finra.org/industry/notices/17-14.*

[8] The term ''family client'' includes not only family members but others, including key employees. *See* 17 CFR 275.202(a)(11)(G)–1(d)(4). Therefore, a family investment vehicle that is beneficially owned solely by family clients may include beneficial owners that are not family members.

[9] Further, the proposed relief is only with respect to a person's status as a portfolio manager under FINRA Rule 5130. The proposed relief does not extend to a person who has a beneficial interest in a family investment vehicle and is a restricted person based on his or her other activities, such as an associated person of a member.

[10] The definition of ''broad-based foreign retirement plan'' under Section 409A of the IRC includes a substantially similar condition. *See* 26 CFR 1.409A–1(a)(3)(v)(A). Section 409A imposes restrictions on the deferral of compensation by employees, directors and independent contractors. Section 409A provides an exemption for compensation deferred under certain broad-based foreign retirement plans.

[11] The proposed rule change would also impact an identical exemption cross referenced in paragraph (b)(2) of FINRA Rule 5131.

those that are expressly designated as Regulation S offerings).

Issuer-Directed Securities

To more closely align FINRA Rule 5130(d) with the issuer-directed provision in Rule 5131.01, the proposed rule change would also amend paragraphs (d)(1) and (d)(2) of Rule 5130 to expand the exemption for issuer-directed securities to allocations directed by affiliates and selling shareholders of the issuer. The proposed rule change would also clarify that the exemption applies to shares that are specifically directed in writing by the issuer.

Exclusion for Unaffiliated Charitable Organizations

The proposed rule change also would amend paragraph (e)(3) of Rule 5131 (Definitions) to exclude unaffiliated charitable organizations, as that term is elsewhere defined in the rule,[12] from the definition of ''covered non-public company'' so that an executive officer or director of a charitable organization that is not affiliated with the member allocating IPO shares would not become the subject of the rule's spinning provision solely on the basis of that service.

Addition of Anti-Dilution Provision to FINRA Rule 5131

The proposed rule change would also amend Rule 5131(b)'s spinning provision to add an anti-dilution provision to the rule (similar to the one in Rule 5130(e)), which would allow an executive officer or director of a public company or a covered non-public company (or a person materially supported by such a person) to retain the percentage equity ownership in the issuer at a level up to the ownership interest as of three months prior to the filing of the registration statement, provided that the other conditions are met.

B. Notice of Partial Amendment No. 1

1. Introduction

Set forth in Section II.B.2 below is the summary of Partial Amendment No. 1 to the proposed rule changes, as prepared and submitted by FINRA to the Commission.[13]

2. Self-Regulatory Organization's Description of the Proposal, as Modified by Partial Amendment No. 1

As discussed in the FINRA Response to comments,[14] Partial Amendment No. 1 makes the following changes to the proposed rule change:

➢ Amends proposed Rule 5130(i)(4) to remove the proposed limitation on portfolio managers of certain family investment vehicles;

➢ modifies proposed Rule 5130(c)(6) to provide that a foreign public investment company may not be formed for the specific purpose of permitting restricted persons to invest in new issues;

➢ revises proposed Rule 5130(c)(8) to also exclude employee retirement benefits plans organized in the United States that meet the proposed conditions;

➢ amends proposed Rule 5130(i)(9) to limit the proposed exclusion for foreign offerings to offerings that do not include shares that are concurrently registered for sale in the United States;

➢ adds proposed Rules 5130.01 and 5131.05 to clarify the application of the rules to independent allocations to non-U.S. persons by foreign non-member broker-dealers participating in an underwriting syndicate;

➢ revises current Rule 5131.01 and proposed Rules 5130(d)(1) and (d)(2) to clarify that the rules apply to securities directed by a single affiliate or a single selling shareholder;

➢ amends current Rule 5130(d)(1)(B) to expressly recognize employees or directors of affiliated franchisees;

➢ excepts certain transfers to immediate family members from current Rule 5131(d)(2)(B)'s public announcement requirement;

➢ amends current Rule 5131.03 to codify existing guidance regarding the disclosure of a release or waiver in a publicly filed registration statement;

➢ excludes from the definition of ''new issue'' in proposed Rule 5130(i)(9) offerings of a special purpose acquisition company (''SPAC'');

➢ modifies proposed Rule 5130(i)(11) to include other types of sovereign investment vehicles; and

➢ amends proposed Rule 5130(i)(10)(E) to remove the reference to persons listed in Schedule C of Form BD (Uniform Application for Broker-Dealer Registration).

FINRA is also proposing in this Partial Amendment No. 1 to make a technical correction to proposed FINRA Rule 5130(i)(9) to replace the references to offerings made pursuant to Section 4(1), 4(2) or 4(6) of the Securities Act of 1933 (''Securities Act'') with offerings made pursuant to Section 4(a)(1), 4(a)(2) or 4(a)(5) of the Securities Act.

Family Investment Vehicles

Proposed Rule 5130(i)(4) requires that where the beneficial owners of a family investment vehicle include family clients, which may include beneficial owners that are not family members, the person who has the sole authority to buy or sell securities for such an entity must be an ''immediate family member'' as defined in Rule 5130(i)(5) or a ''family member'' as defined in Rule 202(a)(11)(G)–1(d)(6) under the Investment Advisers Act of 1940 (''Advisers Act'') for the entity to be considered a family investment vehicle for purposes of Rule 5130.

Dechert 1, Dechert 2 and SIFMA state that the proposed limitation ignores practical realties of how family offices operate and is contrary to FINRA's stated goal of harmonizing Rule 5130 with the Advisers Act's treatment of family offices. Dechert 1 and Dechert 2 state that family offices often hire investment professionals that are not family members to provide investment advice based on delegated authority. Moreover, they note that the Commission, in adopting the Family Office Rule under the Advisers Act, recognized that non-family members that are integral to the functioning of the family office, including investment professionals that are hired by the family office, should be able to invest alongside family members in order to align their interests with the interests of the family.

FINRA does not believe that the proposed limitation serves any meaningful purpose given the Commission's express recognition that investment professionals that are non-family members may provide investment advice to family offices and invest together with family members in order to have aligned interests. In addition, FINRA's current definition of ''family investment vehicle'' allows investments by non-family members in such an entity,[15] without placing any

[12] An ''unaffiliated charitable organization'' is a tax-exempt entity organized under Section 501(c)(3) of the IRC that is not affiliated with the member and for which no executive officer or director of the member, or person materially supported by such executive officer or director, is an individual listed or required to be listed on Part VII of Internal Revenue Service Form 990 (*i.e.,* officers, directors, trustees, key employees, highest compensated employees and certain independent contractors). *See* FINRA Rule 5131(e)(9).

[13] The text of Partial Amendment No. 1, including Exhibit 4 (which reflects changes to the text of the proposed rule change pursuant to Partial Amendment No. 1) and Exhibit 5, (which reflects all proposed changes to the current rule text, as amended by Partial Amendment No. 1), is available on FINRA's website at: *https://www.finra.org/industry/rule-filings/sr-finra-2019-022.*

[14] *See supra* note 5.

[15] The definition of ''immediate family member'' under FINRA Rule 5130 includes any individual who is materially supported by the family, which could encompass non-family members. *See* FINRA Rule 5130(i)(5).

limitations on the person with the authority to make investment decisions for the entity. Therefore, in this Partial Amendment No. 1, FINRA is revising proposed Rule 5130(i)(4) to remove the proposed limitation.

Foreign Public Investment Companies

Proposed Rule 5130(c)(6) provides that a foreign public investment company that is formed for the specific purpose of investing in new issues would not be eligible for an exemption. The ABA suggests that FINRA modify the proposed condition to provide that the investment company may not be formed for the specific purpose of permitting restricted persons to invest in new issues, which is more narrowly tailored to address the concerns Rule 5130 is designed to address while preserving a foreign public investment company's flexibility to make portfolio decisions. FINRA agrees with the comment by the ABA regarding the scope of the proposed condition regarding new issue investments by foreign public investment companies. In this Partial Amendment No. 1, FINRA is revising proposed Rule 5130(c)(6) to narrow the scope of the condition to provide that a foreign public investment company may not be formed for the specific purpose of permitting restricted persons to invest in new issues. This change also impacts an identical exemption in Rule 5131(b)(2).

Foreign Employee Retirement Benefits Plans

Proposed Rule 5130(c)(8) provides an exemption for foreign employee retirement benefits plans, subject to specified conditions. SIFMA requests that the proposed exemption be extended to employee retirement benefits plans organized in the United States that do not otherwise qualify for an exemption under the current provisions of Rule 5130 relating to Employee Retirement Income Security Act benefits plans and state or municipal government benefits plans. FINRA agrees with SIFMA's comment, which is also consistent with FINRA staff's prior exemptive relief to such plans. In this Partial Amendment No. 1, FINRA is revising proposed Rule 5130(c)(8) to extend the exemption to employee retirement benefits plans organized in the United States that meet the proposed conditions. In addition, this change impacts a corresponding exemption to Rule 5131(b)(2).

Foreign Offerings

Proposed Rule 5130(i)(9) excludes from the definition of ''new issue'' offerings made under Regulation S of the Securities Act or otherwise made outside of the United States or its territories. SIFMA and the ABA request that FINRA clarify the scope of the exclusion, including in situations where shares offered and sold in a foreign offering are concurrently registered for sale in the United States or where foreign non-member broker-dealers participating in an underwriting syndicate independently allocate shares to non-U.S. persons.

The proposed blanket exclusion from the definition of ''new issue'' is limited to a foreign offering, pursuant to Regulation S or otherwise, where shares in the offering are not concurrently registered for sale in the United States. While shares in a foreign offering that are concurrently registered for sale in the United States would not be categorically excluded from the definition of ''new issue'' under Rules 5130 and 5131, FINRA does not believe that the concerns the rules are designed to address are implicated where foreign non-member broker-dealers that are participating in an underwriting syndicate with members are independently allocating new issues to non-U.S. persons.

In this Partial Amendment No. 1, FINRA is revising proposed Rule 5130(i)(9) to clarify that the exclusion for foreign offerings does not extend to shares of such offerings that are concurrently registered for sale in the United States. This change will also impact the definition of ''new issue'' under Rule 5131.[16] This Partial Amendment No. 1 also adds Supplementary Material .01 to Rule 5130 and Supplementary Material .05 to Rule 5131 to clarify that the rules are not intended to restrict new issue allocations to non-U.S. persons by foreign non-member broker-dealers participating in the underwriting syndicate, provided that such allocation decisions are not made at the direction or request of a member or an associated person of a member.

Issuer-Directed Securities

Proposed Rules 5130(d)(1) and (d)(2) expand the exclusion for issuer-directed securities to allocations directed by affiliates and selling shareholders of the issuer, which is consistent with the issuer-directed provision in current Rule 5131.01.

SIFMA requests that FINRA revise current Rule 5131.01 and proposed Rules 5130(d)(1) and (d)(2) to clarify that a single affiliate or a single selling shareholder may direct securities. The ABA requests that FINRA also amend current Rule 5130(d)(1)(B), which relates to issuer-directed allocations to broker-dealer personnel, or members of their immediate family, who are employees or directors of the issuer, the issuer's parent, or a subsidiary of the issuer or the issuer's parent, to expressly recognize employees or directors of franchisees of such entities.

In response to the comments, in this Partial Amendment No. 1, FINRA is revising current Rule 5131.01 and proposed Rules 5130(d)(1) and (d)(2) to make a technical change to clarify that the issuer-directed provisions apply to securities directed by a single affiliate or a single selling shareholder. Further, in this Partial Amendment No. 1, FINRA is amending current Rule 5130(d)(1)(B) to expressly recognize employees or directors of a franchisee in a franchisor/franchisee relationship.

Lock-Up Agreements

Current Rule 5131(d)(2) requires that any lock-up agreement applicable to the officers and directors of an issuer entered into in connection with a new issue stipulate that, at least two business days before the release or waiver of any lock-up or other restriction on the transfer of the issuer's shares, the book-running lead manager must notify the issuer of the impending release or waiver and the impending release or waiver must be announced through a major news service. The rule provides an exception where the release or waiver is for a transfer that is not for consideration and where the transferee has agreed in writing to be bound by the same lock-up agreement terms in place for the transferor.

The ABA suggests that FINRA eliminate the ''consideration'' element for purposes of the exception to the rule. By way of example, the ABA notes that it may be difficult to ascertain whether a transfer is for ''consideration'' in certain situations involving transfers to immediate family members. The ABA also requests that FINRA codify guidance published in *Regulatory Notice* 10–60 (November 2010) regarding disclosure of a release or waiver in a publicly filed registration statement.

FINRA continues to believe that the lack of consideration (that is, where there is no exchange of something of value) is relevant for purposes of satisfying the exception to the public announcement requirement under Rule 5131(d)(2). However, FINRA agrees with the ABA that it may be difficult to determine whether a transfer is for consideration in situations involving transfers to immediate family members.

[16] Rule 5131(e)(7) defines the term ''new issue'' by reference to Rule 5130(i)(9).

Moreover, FINRA does not believe that a transfer of securities to an immediate family member who is subject to the same lock-up restrictions as the transferor necessitates a public announcement. Therefore, in this Partial Amendment No. 1, FINRA is amending current Rule 5131(d)(2)(B) to extend the exception to transfers to immediate family members as defined in Rule 5130(i)(5), provided that the transferee has agreed in writing to be bound by the same lock-up agreement terms in place for the transferor. In addition, in this Partial Amendment No. 1, FINRA is amending current Rule 5131.03 to provide that the disclosure of a release or waiver in a publicly filed registration statement in connection with a secondary offering satisfies the requirement for an announcement through a major news service, which codifies the prior guidance published in *Regulatory Notice* 10–60.

SPACs

Rule 5130(i)(9) currently excludes from the definition of ''new issue'' offerings of business development companies, direct participation programs and real estate investment trusts. FINRA excluded offerings of these entities based on the fact that their securities typically commence trading at the public offering price with little potential for trading at a premium because their assets at the time the initial public offering trades consist of the capital they have raised through the offering process. Moreover, FINRA states that if there is a premium, it is generally small.

FINRA states in its filing that a SPAC is a blind pool that offers units in an SEC-registered initial public offering (''IPO'') to investors for the purpose of completing an acquisition of an existing private company in the future. FINRA also states that the IPO consists of common stock of the SPAC and typically includes a warrant to purchase common stock of the SPAC in the event that the SPAC completes an acquisition. The SPAC has generally 18 months to 24 months after the IPO to find a suitable target and sign a purchase agreement to acquire the target company. FINRA also states that SPACs are generally focused on a particular industry segment, and they hire management in those areas to explore and evaluate acquisition opportunities.

FINRA further states that the money raised by a SPAC from the issuance of units in an IPO is deposited in a trust account that is funded with an amount of money equaling the total of the proceeds from the IPO (less certain offering expenses). Because a SPAC's assets at the time of the IPO consist of the capital raised through the offering process (less certain offering expenses), FINRA states that there is little potential for SPACs to trade at a premium at the time of the IPO prior to signing an acquisition or merger agreement with a suitable target company. Moreover, FINRA states that SPACs rarely trade at a premium, and if there is a premium, it is generally small.

The ABA requests that FINRA consider excluding offerings of SPACs from the definition of ''new issue'' because such offerings have similar trading characteristics to offerings of other entities that FINRA has already excluded from the definition of ''new issue,'' including offerings of registered closed-end investment companies, business development companies, direct participation programs and real estate investment trusts.

FINRA agrees that offerings of SPACs have similar characteristics to other offerings that are currently excluded from the definition of ''new issue'' and, thus, offerings of SPACs should also be excluded. In this Partial Amendment No. 1, FINRA is revising proposed Rule 5130(i)(9) to exclude offerings of SPACs. As noted above, FINRA states that this change will also impact the definition of ''new issue'' under Rule 5131 because the term has the same meaning under both rules.

Owners of Broker-Dealers

Proposed Rule 5130(i)(10)(E) excludes sovereign entities from the scope of owners of broker-dealers. Proposed Rule 5130(i)(11) defines a ''sovereign entity'' as a sovereign nation or a pool of capital or an investment fund owned or controlled by a sovereign nation and created for the purpose of making investments on behalf of the sovereign nation. The ABA requests that FINRA make a technical change to the proposed definition to also include other vehicles owned or controlled by a sovereign nation that are created for the purpose of making investments for the benefit of the sovereign nation. FINRA is revising proposed Rule 5130(i)(11) in this Partial Amendment No. 1 to make this technical change.

Rule 5130(i)(10)(E) currently includes as restricted persons any person listed, or required to be listed, in Schedule C of Form BD that has an ownership interest above specified thresholds. FINRA (then NASD) originally included the reference to Schedule C because it shows any additions, deletions and other changes to Schedules A and B of Form BD. SIFMA requests that the reference to Schedule C be removed from Rule 5130(i)(10)(E) because it is superfluous. In this Partial Amendment No. 1, FINRA is deleting from proposed Rule 5130(i)(10)(E) the reference to persons listed in Schedule C of Form BD because currently the changes made on Schedule C are reflected in the Central Registration Depository system through the composite Schedules A and B.

III. Discussion and Commission Findings

After careful review of the proposal and the comment letters, the Commission finds that the proposed rule change, as modified by Partial Amendment No. 1, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities association.[17] In particular, the Commission finds that the proposed rule change, as amended, is consistent with Section 15A(b)(6) of the Act,[18] which requires, among other things, that FINRA's rules 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, issues, brokers, or dealers. The Commission also finds that the proposed rule change, as amended, is consistent with Section 15A(b)(9) of the Act, which requires that FINRA rules not impose any burdens on competition not necessary or appropriate in furtherance of the purposes of the Act.[19]

FINRA states that the proposed rule change, as modified by Partial Amendment No. 1, will further these purposes by promoting capital formation and aiding member compliance efforts while maintaining the integrity of the public offering process and investor confidence in the capital market. FINRA also states that the proposed rule change to Rules 5130 and 5131 will remove unnecessary impediments to capital formation and lessen burdens in the public offering process. Specifically, FINRA states that the proposed rule change will reduce both the costs and uncertainty in determining whether an investor is subject to the restrictions of Rules 5130 and 5131. FINRA states that the proposed rule change also may increase the pool of investors eligible to purchase

[17] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[18] 15 U.S.C. 78*o*–3(b)(6).

[19] 15 U.S.C. 78*o*–3(b)(9).

new issues and, thus, encourage capital formation. Moreover, the proposed rule change creates two alternative conditions that a qualifying foreign investment company have $100 or more direct investors at 1,000 or more indirect investor. These proposed alternative conditions would provide additional flexibility to foreign investment companies to demonstrate their eligibility for the exemption, and thereby enhance their ability to purchase new issues. The proposed rule change would also further the above purposes by clarifying the scope of Rule 5130 and 5131 by excluding Regulation S offerings and other offering made outside the United States or its territories from the scope of the rules. The proposed rule change would also harmonize Rule 5130 and 5131 with other FINRA rules relating to securities offerings, FINRA Rules 5110 and 5121, which currently exclude foreign offerings. FINRA believes that the proposed rule change will remove the burdens associated with complying with both U.S. and foreign regulatory regimes relating to public offerings and will lead to an increase in the pool of eligible investors for offshore offerings of new issues without undermining the fairness of U.S. public capital markets. FINRA believes that an increase in the pool of eligible investors could lead to a lower cost of capital for issuers engaged in foreign offerings.

To further the purposes of Rules 5130 and 5131, the proposed change would also align the issuer-directed provisions of Rules 5130 and 5131, provide regulatory consistency across the rules, and remove the compliance costs of applying different standards.

FINRA also proposes to exclude ''unaffiliated charitable organizations'' from the definition of ''covered non-public company,'' stating that the concerns addressed by the rules are not implicated with respect to executive officers and directors of charitable organizations that are not affiliated with a member. According to FINRA, this should ease the burden on the firms as they will no longer be required to consider whether an investment banking relationship exists vis-à-vis the member and an unaffiliated charitable organization when an individual with a beneficial interest in an account is an executive officer or director (or materially supported by such a person) of such an organization.

FINRA also proposes to add an anti-dilution provision to Rule 5131 to ameliorate the current inconsistency between the Rules 5130 and 5131 in terms of equity ownership interest. The proposed rule change would add an anti-dilution provision to Rule 5131 (similar to that of Rule 5130) to address the unintentional result of officers or directors of public companies and covered non-public companies may experience diminished ownership interest upon a public offering and a transfer of wealth from them to those investors that are able to purchase shares in the new offering.

FINRA does not believe that the proposed rule change, as modified by Partial Amendment No. 1, will result in any burden on competition that is not necessary or appropriate in furtherance of the purpose of the Act. FINRA also believes that the proposed rule change, as modified by Partial Amendment No. 1 will remove unnecessary impediments to capital formation and lessen burdens in the public offering process. Thus, the proposed rule change, as modified by Partial Amendment No. 1, strikes the appropriate balance by promoting capital formation and aiding member compliance efforts while maintaining the protections that Rules 5130 and 5131 are designed to provide. Consequently, the Commission finds that the proposed rule change is designed to promote capital formation and aid member compliance efforts, while maintaining the integrity of the public offering process and investor confidence in the capital markets.

For these reasons, the Commission finds that the proposed rule change, as modified by Partial Amendment No. 1, is consistent with Sections 15A(b)(6) and 15A(b)(9) of the Act and the rules and regulations thereunder applicable to a national securities association.

IV. Accelerated Approval of Proposed Rule Change, as Modified by Partial Amendment No. 1

The Commission finds good cause to approve the proposed rule change, as modified by Partial Amendment No. 1, prior to the 30th day after the date of publication of notice of the filing of Partial Amendment No. 1 in the **Federal Register**. As discussed above, the proposed rule change, as modified by Partial Amendment No. 1, would exempt additional persons from the scope of these rules, modify current exemptions to enhance regulatory consistency, address unintended operational impediments, and exempt certain types of offerings from the scope of these rules. As such, the proposed rule change, as modified by Partial Amendment No. 1, would promote capital formation and aid member compliance efforts while maintaining the protections that Rules 5130 and 5131 are designed to provide (*i.e.,* maintaining the integrity of the public offering process and investor confidence in the capital markets).

Accordingly, the Commission finds good cause, pursuant to Section 19(b)(2) of the Act,[20] to approve the proposed rule change, SR–FINRA–2019–022, as modified by Partial Amendment No. 1, on an accelerated basis.

V. Solicitation of Comments on Partial Amendment No. 1

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether Partial Amendment No. 1 to 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–FINRA–2019–022 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–FINRA–2019–022. 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 FINRA. 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

[20] 15 U.S.C. 78s(b)(2).

submissions. You should submit only information that you wish to make available publicly. All submissions should refer to the File Number SR–FINRA–2019–022 and should be submitted on or before December 3, 2019.

VI. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act [21] that the proposed rule change, as modified by Partial Amendment No. 1 (SR–FINRA–2019–022) be, and it hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[22]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–24494 Filed 11–8–19; 8:45 am]

BILLING CODE 8011–01–P

[21] *Id.*

[22] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87462; File No. SR–CBOE–2019–104]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Extend the Nonstandard Expirations Pilot Program

November 5, 2019.

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 October 31, 2019, 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 and II 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.

[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).

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 renew an existing pilot program until May 4, 2020. The text of the proposed rule change is provided below.

(additions are *italicized;* deletions are [bracketed])

* * * * *

Rules of Cboe Exchange, Inc.

* * * * *

Rule 4.13. Series of Index Options

(a)–(d) No change.

(e) Nonstandard Expirations Pilot Program.

(1)–(2) No change.

(3) Duration of Nonstandard Expirations Pilot Program. The Nonstandard Expirations Pilot Program shall be through [November 4, 2019] *May 4, 2020.*

* * * * *

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 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

On September 14, 2010, the Securities and Exchange Commission (the ''Commission'') approved a Cboe Options proposal to establish a pilot program under which the Exchange is permitted to list P.M.-settled options on broad-based indexes to expire on (a) any Friday of the month, other than the third Friday-of-the-month, and (b) the last trading day of the month.[5] On January 14, 2016, the Commission approved a Cboe Options proposal to expand the pilot program to allow P.M.-settled options on broad-based indexes to expire on any Wednesday of month, other than those that coincide with an EOM.[6] On August 10, 2016, the Commission approved a Cboe Options proposal to expand the pilot program to allow P.M.-settled options on broad-based indexes to expire on any Monday of month, other than those that coincide with an EOM.[7] Under the terms of the Nonstandard Expirations Pilot Program (''Program''), Weekly Expirations and EOMs are permitted on any broad-based index that is eligible for regular options trading. Weekly Expirations and EOMs are cash-settled and have European-style exercise. The proposal became effective on a pilot basis for a period of fourteen months that commenced on the next full month after approval was received to establish the Program [8] and was subsequently extended.[9] Pursuant to Rule 4.13(e)(3),[10] the Program is scheduled to expire on November 4, 2019. The Exchange believes that the Program has been successful and well received by its Trading Permit Holders and the investing public during that the time that it has been in operation. The

[5] *See* Securities Exchange Act Release 62911 (September 14, 2010), 75 FR 57539 (September 21, 2010) (order approving SR–CBOE–2009–075).

[6] *See* Securities Exchange Act Release 76909 (January 14, 2016), 81 FR 3512 (January 21, 2016) (order approving SR–CBOE–2015–106).

[7] *See* Securities Exchange Act Release 78531 (August 10, 2016), 81 FR 54643 (August 16, 2016) (order approving SR–CBOE–2016–046).

[8] *Id.*

[9] *See* Securities Exchange Act Release 65741 (November 14, 2011), 76 FR 72016 (November 21, 2011) (immediately effective rule change extending the Program through February 14, 2013). *See also* Securities Exchange Act Release 68933 (February 14, 2013), 78 FR 12374 (February 22, 2013) (immediately effective rule change extending the Program through April 14, 2014); 71836 (April 1, 2014), 79 FR 19139 (April 7, 2014) (immediately effective rule change extending the Program through November 3, 2014); 73422 (October 24, 2014), 79 FR 64640 (October 30, 2014) (immediately effective rule change extending the Program through May 3, 2016); 76909 (January 14, 2016), 81 FR 3512 (January 21, 2016) (extending the Program through May 3, 2017); 80387 (April 6, 2017), 82 FR 17706 (April 12, 2017) (extending the Program through May 3, 2018); 83165 (May 3, 2018), 83 FR 21316 (May 9, 2018) (SR–CBOE–2018–038) (extending the Program through November 5, 2018); 84534 (November 5, 2019 [sic]), 83 FR 56119 (November 9, 2018) (SR–CBOE–2018–070) (extending the Program through May 6, 2019); and 85650 (April 15, 2019), 84 FR 16552 (April 19, 2019) (SR–CBOE–2019–022) (extending the Program through November 4, 2019).

[10] The Exchange recently relocated prior Rule 24.9, containing the provision which governs the Program, to current Rule 4.13. *See* SR–CBOE–2019–092 (October 4, 2019), which did not make any substantive changes to prior Rule 24.9 and merely relocated it to Rule 4.13.

Exchange hereby proposes to extend the Program until May 4, 2020. This proposal does not request any other changes to the Program.

Pursuant to the order approving the establishment of the Program, two months prior to the conclusion of the pilot period, Cboe Options is required to submit an annual report to the Commission, which addresses the following areas: Analysis of Volume & Open Interest, Monthly Analysis of Weekly Expirations & EOM Trading Patterns and Provisional Analysis of Index Price Volatility. The Exchange has submitted, under separate cover, the annual report in connection with the present proposed rule change. 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 Program is consistent with the Exchange Act. The Exchange is in the process of making public all data and analyses previously submitted to the Commission under the Program, and will make public any data and analyses it makes to the Commission under the Program in the future.

If, in the future, the Exchange proposes an additional extension of the Program, or should the Exchange propose to make the Program permanent (which the Exchange currently intends to do), the Exchange will submit an annual report (addressing the same areas referenced above and consistent with the order approving the establishment of the Program) to the Commission at least two months prior to the expiration date of the Program. The Exchange will also make this report public. Any positions established under the Program will not be impacted by the expiration of the Program.

The Exchange believes there is sufficient investor interest and demand in the Program to warrant its extension. The Exchange believes that the Program has provided investors with additional means of managing their risk exposures and carrying out their investment objectives. Furthermore, the Exchange has not experienced any adverse market effects with respect to the Program.

The Exchange believes that the proposed extension of the Program will not have an adverse impact on capacity.

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.[11] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[12] 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 facilitation 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)[13] 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 Program has been successful to date and states that it has not encountered any problems with the Program. The proposed rule change allows for an extension of the Program for the benefit of market participants. Additionally, the Exchange believes that there is demand for the expirations offered under the Program and believes that that Weekly Expirations and EOMs will continue to provide the investing public and other market participants increased opportunities to better manage their risk exposure.

B. Self-Regulatory Organization's Statement on Burden on Competition

Cboe Options 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. Specifically, the Exchange believes that, by extending the expiration of the Program, the proposed rule change will allow for further analysis of the Program and a determination of how the Program shall be structured in the future. In doing so, the proposed rule change will also serve to promote regulatory clarity and consistency, thereby reducing burdens on the marketplace and facilitating investor protection.

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.

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

[13] *Id.*

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the 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[14] and subparagraph (f)(6) of Rule 19b–4 thereunder.[15]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act[16] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii)[17] permits the Commission to 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 proposal may become operative immediately upon filing. The Exchange states that waiver of the 30-day operative delay will allow it to extend the Pilot Program prior to its expiration on November 4, 2019, and maintain the status quo, thereby reducing market disruption. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest as it will allow the pilot program to continue uninterrupted, thereby avoiding investor confusion that could result from a temporary interruption in the pilot program. Accordingly, the Commission hereby waives the operative delay and designates the proposed rule change operative upon filing.[18]

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

[14] 15 U.S.C. 78s(b)(3)(A).

[15] 17 CFR 240.19b–4(f)(6). In addition, Rule19b–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.

[16] 17 CFR 240.19b–4(f)(6).

[17] 17 CFR 240.19b–4(f)(6)(iii).

[18] For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CBOE–2019–104 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–CBOE–2019–104. 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 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–2019–104 and should be submitted on or before December 3, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–24505 Filed 11–8–19; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87460; File No. SR–CboeEDGX–2019–066]

Self-Regulatory Organizations; Cboe EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Adopt Fees for a New Data Product on its Equity Options Platform (''EDGX Options'') To Be Known as Open-Close Data

November 5, 2019.

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 October 29, 2019, 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 Options'') is filing with the Securities and Exchange Commission (''Commission'') a proposed rule change to adopt fees for a new data product on its equity options platform (''EDGX Options'') to be known as Open-Close Data. 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 adopt fees for a new data product on EDGX Options known as Open-Close Data, which is available for purchase to EDGX Options Members and Non-Members.[3] Cboe LiveVol, LLC (''LiveVol''), a wholly owned subsidiary of the Exchange's parent company, Cboe Global Markets, Inc., will make the Open-Close Data available for purchase to Members and Non-Members on the LiveVol DataShop website (*datashop.cboe.com*). The Exchange proposes to amend its Fee Schedule to adopt fees for the product.[4]

The Exchange recently introduced the Open-Close Data product. Open-Close Data is a volume summary file for trading activity on EDGX Options. The Exchange notes it is proprietary EDGX Options trade data and does not include trade data from any other exchanges. It is also a historical data product and not a real time data feed. The Open-Close Data summarizes and buckets the volume by origin (customer, professional customer, broker-dealer, and market maker), buying/selling, and opening/closing criteria. The customer and professional customer volume is further broken down into trade size buckets (less than 100 contracts, 100–199 contracts, greater than 199 contracts). The data currently goes back to January 2018 and contains all series in an underlying security if it has

[19] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 86806 (August 29, 2019), 84 FR 46767 (September 5, 2019) (SR–CboeEDGX–2019–054).

[4] The Exchange initially filed the proposed fees on business date August 30, 2019 (SR–CboeEDGX–2019–055). On business date October 29, 2019, the Exchange withdrew that filing and submitted this filing.

volume.[5] The Exchange anticipates a wide variety of market participants to purchase Open-Close Data, including, but not limited to, individual customers, buy-side investors, investment banks and academic institutions. For example, the Exchange notes that academic institutions may utilize Open-Close Data and as a result promote research and studies of the options industry to the benefit of all market participants. The Exchange believes the Open-Close Data product may also provide helpful trading information regarding investor sentiment and may be used to create and test trading models and analytical strategies and provides comprehensive insight into trading on EDGX Options. It is a completely voluntary product, in that the Exchange is not required by any rule or regulation to make this data available and that potential subscribers may purchase it only if they voluntarily choose to do so. The Exchange notes that its affiliate, Cboe Exchange, Inc. (''Cboe Options''), as well as other exchanges, offer a similar data product.[6]

The Exchange proposes to provide in its Fee Schedule that Members and non-Members may purchase Open-Close Data on a subscription basis (end of day file) or by ad hoc request for a specified month (historical file). The Exchange proposes to assess a monthly fee of $500 for subscribing to a daily update which will consist of Open/Close data covering all Exchange-listed securities. Members and non-Members purchasing Open/Close data on a subscription basis will receive access to a daily data file. The Exchange proposes to assess a fee of $400 per request per month for an ad-hoc request of historical Open/Close data covering all Exchange-listed securities. An ad-hoc request can be for any number of months beginning with January 2018 for which the data is available.[7] The proposed subscription and ad-hoc fees will apply both to Members or non-Members. The Exchange notes that other exchanges, including its affiliate Exchange Cboe Exchange, Inc. (''Cboe Options'') provide similar data products that may be purchased on both a subscription and ad-hoc basis and are similarly priced.[8]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[9] in general, and furthers the objectives of Section 6(b)(5) of the Act,[10] 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 to protect investors and the public interest, and that it is not designed to permit unfair discrimination among customers, brokers, or dealers. The Exchange also believes that its proposal to adopt fees for Open-Close Data is consistent with Section 6(b) of the Act in general, and furthers the objectives of Section 6(b)(4) of the Act [11] in particular, in that it is an equitable allocation of dues, fees and other charges among its members and other recipients of Exchange data.

In adopting Regulation NMS, the Commission granted self-regulatory organizations (''SROs'') 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. Particularly, Open-Close Data further broadens the availability of U.S. option market data to investors consistent with the principles of Regulation NMS. The data product also promotes increased transparency through the dissemination of Open-Close Data and benefits investors by providing access to the Open-Close Data, which may promote better informed trading, as well as research and studies of the options industry. Particularly, information regarding opening and closing activity across different option series may indicate investor sentiment, which can be helpful research and/or trading information. Subscribers to the data may be able to enhance their ability to analyze option trade and volume data, and create and test trading models and analytical strategies. The Exchange believes Open-Close Data provides a valuable tool that subscribers can use to gain comprehensive insight into the trading activity in a particular series, but also emphasizes such data is not necessary for trading. Moreover, the Exchange's affiliate Cboe Options, along with other exchanges, also offer a similar data product.

The Exchange operates in a highly competitive environment. Indeed, there are currently 16 registered options exchanges that trade options. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Particularly, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [12] Making similar data products available to market participants fosters competition in the marketplace, and constrains the ability of exchanges to charge supracompetitive fees. In the event that a market participant views one exchange's data product as more or less attractive than the competition they can and do switch between similar products. The proposed fees are a result of the competitive environment, as the Exchange seeks to adopt fees to attract purchasers of the recently introduced Open-Close Data product.

The Exchange believes the proposed fees are reasonable as the proposed fees are both modest and similar to, or even lower than, the fees assessed by other exchanges that provide similar data products.[13] Indeed, proposing fees that are excessively higher than established fees for similar data products would simply serve to reduce demand for the Exchange's data product, which as noted, is entirely optional. Like the Exchange's Open-Close Data product, other exchanges offer similar data products that each provide insight into trading on those markets and may likewise aid in assessing investor sentiment. Although each of these similar open-close data products provide only proprietary trade data and not trade data from other exchanges, it's possible investors are still able to gauge overall investor sentiment across different option series based on open and closing interest on any one

[5] The Open-Close data file format specifications can be found at *https://datashop.cboe.com/Themes/Livevol/Content/static/OpenCloseSpecification.pdf.*

[6] *See* Securities Exchange Act Release No. 55062 (January 8, 2007), 72 FR 2048 (January 17, 2007) (approving SR–CBOE–2006–88); *See also* Securities Exchange Act Release No. 56254 (August 15, 2007), 72 FR 47104 (August 22, 2007) (SR–ISE–2007–70).

[7] For example, a Member or non-Member that requests historical Open/Close Data for the months of October 2018 and November 2018, would be assessed a total of $800. The Exchange notes that it may make historical data prior to January 2018 available in the future and that such historical data would be available to all Member or non-Member.

[8] *See e.g.,* Cboe Options Fees Schedule, Livevol Fees, Open-Close Data. *See also* Nasdaq ISE Options 7 Pricing Schedule, Section 10.A.

[9] 15 U.S.C. 78f.

[10] 15 U.S.C. 78f(b)(5).

[11] 15 U.S.C. 78f(b)(4).

[12] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (''Regulation NMS Adopting Release'').

[13] *See e.g.,* Cboe Options Fees Schedule, Livevol Fees, Open-Close Data. *See also* Nasdaq ISE Options 7 Pricing Schedule, Section 10.A.

exchange.[14] Similarly, market participants may be able to analyze option trade and volume data, and create and test trading models and analytical strategies using only open-close data relating to trading activity on one or more of the other markets that provide similar data products. As such, if a market participant views another exchange's open-close data as more attractive than its Open-Close Data product, then such market participant can merely choose not to purchase the Exchange's Open-Close Data and instead purchase another exchange's open-close data product, which offer similar data points, albeit based on that other market's trading activity.

The Exchange also believes the proposed fees are reasonable as they would support the Open-Close Data product, which is designed to aid investors by providing insight into trading on EDGX Options. The Open-Close Data would provide options market participants with valuable information about opening and closing transactions executed on the Exchange, similar to other historical trade data products offered by competing options exchanges. In turn, this data would assist market participants in gauging investor sentiment and trading activity, resulting in potentially better informed trading decisions. As noted above, users may also use such data to create and test trading models and analytical strategies.

Selling historical market data, such as Open-Close Data, is also a means by which exchanges compete to attract business. To the extent that the Exchange is successful in attracting subscribers for the Open-Close Data, it may earn trading revenues and further enhance the value of its data products. If the market deems the proposed fees to be unfair or inequitable, firms can diminish or discontinue their use of the data and/or avail themselves of similar products offered by other exchanges.[15] The Exchange therefore believes that the proposed fees for Open-Close Data reflect the competitive environment and would be properly assessed on Member or non-Member users. The Exchange also believes the proposed fees are equitable and not unfairly discriminatory as the fees would apply equally to all users who choose to purchase such data. The Exchange's proposed fees would not differentiate between subscribers that purchase Open-Close Data, and are set at a modest level that would allow any interested Member or non-Member to purchase such data based on their business needs.

As noted above, the Exchange anticipates a wide variety of market participants to purchase Open-Close Data, including but not limited to individual customers, buy-side investors, investment banks and academic institutions. For example, on its affiliate exchange Cboe Options, which also offers an Open-Close Data product, approximately 38% of purchases of historical ad hoc Open-Close Data files are individuals, 33% are buy-side investors or investment banks and 25% are academic institutions. Accordingly, the Exchange anticipates that open-close data may be used not just for commercial or monetizing purposes, but also for educational use and research. The Exchange reiterates that the decision as to whether or not to purchase the Open-Close Data is entirely optional for all potential subscribers. Indeed, no market participant is required to purchase the Open-Close Data, and the Exchange is not required to make the Open-Close Data available to all investors. Rather, the Exchange is voluntarily making historical Open-Close Data available, as requested by customers, and market participants may choose to receive (and pay for) this data based on their own business needs. Potential purchasers may request the data at any time if they believe it to be valuable, or may decline to purchase such data.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange 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. Rather, the Exchange believes that the proposal will promote competition by permitting the Exchange to sell a data product similar to those offered by other competitor options exchanges.[16] The Exchange made Open-Close Data available for EDGX Options in order to keep pace with changes in the industry and evolving customer needs, and believes the data product will contribute to robust competition among national securities exchanges. At least three other U.S. options exchanges offer a market data product that is substantially similar to the Open-Close Data. As a result, the Exchange believes this proposed rule change permits fair competition among national securities exchanges.

Furthermore, the Exchange operates in a highly competitive environment, and its ability to price Open-Close Data is constrained by competition among exchanges that offer similar data products to their customers. As discussed, there are currently a number of similar products available to market participants and investors. At least three other U.S. options exchanges offer a market data product that is substantially similar to the Open-Close Data, which the Exchange must consider in its pricing discipline in order to compete for the market data.[17] For example, proposing fees that are excessively higher than established fees for similar data products would simply serve to reduce demand for the Exchange's data product, which as discussed, market participants are under no obligation to utilize. In this competitive environment, potential purchasers are free to choose which, if any, similar product to purchase to satisfy their need for market information. As a result, the Exchange believes this proposed rule change permits fair competition among national securities exchanges.

The Exchange also does not believe the proposed fees would cause any unnecessary or in appropriate burden on intermarket competition as other exchanges are free to introduce their own comparable data product and lower their prices to better compete with the Exchange's offering. The Exchange does not believe the proposed rule change would cause any unnecessary or inappropriate burden on intramarket competition. Particularly, the proposed product and fees apply uniformly to any purchaser, in that it does not differentiate between subscribers that purchase Open-Close Data. The proposed fees are set at a modest level that would allow any interested Member or non-Member to purchase such data based on their business needs.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received written 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)

[14] The exchange notes that its open-close data product does not include data on any exclusive, singly-listed option series.

[15] *See e.g.,* Cboe Options Fees Schedule, Livevol Fees, Open-Close Data. *See also* Nasdaq ISE Options 7 Pricing Schedule, Section 10.A.

[16] *Id.*

[17] *See e.g.,* Cboe Options Fees Schedule, Livevol Fees, Open-Close Data. *See also* Nasdaq ISE Options 7 Pricing Schedule, Section 10.A and Nasdaq PHLX Options 7 Pricing Schedule, Section 10, PHLX Options Trade Outline (''PHOTO'').

of the Act [18] and paragraph (f) of Rule 19b–4 [19] 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–CboeEDGX–2019–066 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–2019–066. 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–CboeEDGX–2019–066 and should be submitted on or before December 3, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–24493 Filed 11–8–19; 8:45 am]

BILLING CODE 8011–01–P

[18] 15 U.S.C. 78s(b)(3)(A).

[19] 17 CFR 240.19b–4(f).

[20] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

Investment Company Act Release No. 33681; File No. 812–15036

Gabelli ETFs Trust, et al.

November 5, 2019.

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), and 22(d) of the Act and rule 22c-1 under the Act, 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, and 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.

Applicants: Gabelli ETFs Trust (the ''Trust''), Gabelli Funds, LLC (the ''Adviser'') and G.distributors, LLC (the ''Distributor'').

Summary of Application: Applicants request an order (''Order'') that permits: (a) ActiveShares ETFs (as described in the Reference Order (as 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 affiliated persons of an ActiveShares ETF to deposit securities into, and receive securities from, the ActiveShares ETF in connection with the purchase and redemption of creation units; and (d) certain registered management investment companies and unit investment trusts outside of the same group of investment companies as the ActiveShares ETFs to acquire Shares of the ActiveShares ETFs. The Order would incorporate by reference terms and conditions 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 May 22, 2019 and amended on September 16, 2019 and October 31, 2019.

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 writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on December 2, 2019, 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 writing to the Commission's Secretary.

ADDRESSES: Secretary, U.S. Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090. Applicants: Gabelli ETFs Trust, Gabelli Funds, LLC, G.distributors, LLC, One Corporate Center, Rye, NY 10580–1422.

FOR FURTHER INFORMATION CONTACT: Deepak T. Pai, Senior Counsel, at (202) 551–6876 or Andrea Ottomanelli Magovern, 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 the State of Delaware and will consist of one or more series operating as ActiveShares ETFs. The Trust will be registered as an

[1] Precidian ETFs Trust, *et al.,* Investment Company Act Rel. Nos. 33440 (April 8, 2019) (notice) and 33477 (May 20, 2019) (order).

open-end management investment company under the Act. Applicants seek relief with respect to ten Funds (as defined below, and those Funds, the ''Initial Funds''). The Funds will operate as ActiveShares ETFs as described in the Reference Order.[2]

2. The Adviser, a New York limited liability company, will be the investment adviser to the Initial Funds. An Adviser (as defined below) will serve as investment adviser to each Fund. The 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 will be registered under the Advisers Act.

3. The Distributor is a Delaware limited liability company 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), and 22(d) of the Act and rule 22c–1 under the Act, 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, and 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 requested Order would permit applicants to offer ActiveShares ETFs. Because the relief requested is the same as the relief granted by the Commission under the Reference Order and because the Adviser has entered into a licensing agreement with Precidian Funds LLC in order to offer ActiveShares ETFs,[3] the Order would incorporate by reference the terms and conditions of the Reference Order.

5. Applicants request that the Order apply to the Initial Funds and to any other existing or future open-end management investment company or series thereof that: (a) Is advised by the Adviser or any entity controlling, controlled by, or under common control with the Adviser (any such entity included in the term ''Adviser''); (b) operates as an ActiveShares ETF as described in the Reference Order; and (c) complies with the terms and conditions of the Order and of the Reference Order, which is incorporated by reference into the Order (each such company or series and any Initial Fund, a ''Fund'').[4]

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. Section 12(d)(1)(J) of the Act provides that the Commission may exempt any person, security, or transaction, or any class of persons, securities or transactions, from any provision of section 12(d)(1) if the exemption is consistent with the public interest and the protection of investors. Applicants submit that for the reasons stated in the Reference Order the requested relief meets the exemptive standards under sections 6(c), 17(b) and 12(d)(1)(J) of the Act.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–24468 Filed 11–8–19; 8:45 am]

BILLING CODE 8011–01–P

[2] To facilitate arbitrage, an ActiveShares ETF disseminates a ''verified intraday indicative value'' or ''VIIV,'' reflecting the value of its portfolio holdings, calculated every second during the trading day. To protect the identity and weightings of its portfolio holdings, an ActiveShares ETF sells and redeems its Shares in creation units to authorized participants only through an unaffiliated broker-dealer acting on an agency basis.

[3] Aspects of the Funds are covered by intellectual property rights, including but not limited to those which are described in one or more patent applications.

[4] 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 of the Reference Order, which is incorporated by reference into the Order.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87476; File No. SR–OCC–2019–807]

Self-Regulatory Organizations; The Options Clearing Corporation; Notice of Filing of Advance Notice Related to Proposed Changes to The Options Clearing Corporation's Rules, Margin Policy, Margin Methodology, Clearing Fund Methodology Policy, and Clearing Fund and Stress Testing Methodology To Address Specific Wrong-Way Risk

November 6, 2019.

Pursuant to Section 806(e)(1) of Title VIII of the Dodd-Frank Wall Street Reform and Consumer Protection Act, entitled Payment, Clearing and Settlement Supervision Act of 2010 (''Clearing Supervision Act'')[1] and Rule 19b–4(n)(1)(i)[2] under the Securities Exchange Act of 1934 (''Act'' or ''Exchange Act''),[3] notice is hereby given that on October 10, 2019, the Options Clearing Corporation (''OCC'') filed with the Securities and Exchange Commission (''Commission'') an advance notice 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 advance notice from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Advance Notice

This advance notice is submitted in connection with proposed enhancements to OCC's Rules, margin policy and methodology, Clearing Fund policy, and Clearing Fund and stress testing methodology to adopt new margin charges and other risk measures to address the specific wrong-way risk presented by certain cleared positions.

The proposed amendments to OCC's Rules are included in Exhibit 5A of the filing. The proposed amendments to OCC's Margin Policy and Margins Methodology are included in Exhibits 5B and 5C, respectively. The proposed amendments to OCC's Clearing Fund Methodology Policy (''CFM Policy'') and Stress Testing and Clearing Fund Methodology Description (''Methodology Description'') are included in Exhibits 5D and 5E, respectively. Material proposed to be added to the Rules, Margin Policy and Margins Methodology as currently in effect is marked by underlining, and

[1] 12 U.S.C. 5465(e)(1).

[2] 17 CFR 240.19b–4(n)(1)(i).

[3] 15 U.S.C. 78a *et seq.*

material proposed to be deleted is marked in strikethrough text; however, the proposed Specific Wrong-Way Risk Add-On chapter of the Margins Methodology is presented without marking to improve readability as the entire chapter is newly proposed rule text.[4] Material proposed to be added to the CFM Policy and Methodology Description is marked by double underlining, and material proposed to be deleted is marked in double strikethrough text.[5]

The advance notice is available on OCC's website at *https://www.theocc.com/about/publications/bylaws.jsp.* All terms with initial capitalization that are not otherwise defined herein have the same meaning as set forth in the OCC By-Laws and Rules.[6]

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Advance Notice

In its filing with the Commission, OCC 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. OCC has prepared summaries, set forth in sections A and B below, of the most significant aspects of these statements.

(A) Clearing Agency's Statement on Comments on the Advance Notice

Written comments were not and are not intended to be solicited with respect to the advance notice and none have been received. OCC will notify the Commission of any written comments received by OCC.

(B) Advance Notices Filed Pursuant to Section 806(e) of the Payment, Clearing, and Settlement Supervision Act

Description of the Proposed Change

Background

As a central counterparty (''CCP''), OCC is exposed to wrong-way risk, which is the risk that arises when exposure to a counterparty is adversely correlated with the credit quality and probability of default of that counterparty. Specific wrong-way risk (''SWWR'') arises when an exposure to a participant is highly likely to increase when the creditworthiness of that participant is deteriorating.[7] For example, SWWR arises where a Clearing Member's cleared positions contain equity securities issued by the Clearing Member or its affiliates (*i.e.,* the Clearing Member Group) (such positions referred to herein as ''SWWR Equity positions'') as the equity issued by the Clearing Member Group may be assumed to have a price at or near zero in a default or bankruptcy scenario, and those positions (*e.g.,* equity used as a hedge, stock loans, options on equity, single-stock futures) may experience substantial losses. In addition, SWWR may arise where uncollateralized exchange-traded notes (''ETNs'') issued by a Clearing Member or its affiliates (''SWWR ETN positions'') are part of the Clearing Member's cleared positions (these positions, collectively with ''SWWR Equity positions,'' are hereinafter referred to as ''SWWR positions''). SWWR may also arise when a Clearing Member posts equity securities or ETNs issued by it or of its affiliates as margin collateral.

OCC currently accounts for SWWR as it relates to margin collateral by generally prohibiting a Clearing Member from pledging equities issued by it or one of its affiliates as margin collateral unless this pledge provides a hedge against a cleared position in the same account.[8] OCC does not, however, currently account for SWWR as it relates to cleared positions. As a result, OCC is proposing a new ''add-on'' charge[9] for its margin methodology, the System for Theoretical Analysis and Numerical Simulations (''STANS''),[10] and new stress test scenarios that may result in intra-day margin calls and, in more extreme cases, intra-month increases in the size of OCC's Clearing Fund[11] to address the wrong-way risk of OCC's cleared positions involving Clearing Member-issued securities. In addition, OCC proposes to introduce certain restrictions on stock lending activity related to SWWR positions.

Proposed Changes

OCC proposes to enhance its management of SWWR by: (1) Imposing certain restrictions on stock lending activity at OCC; (2) adopting a new SWWR margin add-on for STANS (''SWWR Add-on''); (3) introducing new stress test scenarios to capture the SWWR of cleared positions involving Clearing Member-issued ETNs beyond certain pre-defined thresholds; and (4) making other clarifying and conforming changes to the CFM Policy and Methodology Description. The proposed changes are intended to address the credit risks arising from SWWR positions at OCC. The proposed changes are described in detail below.

1. Prohibition on Lending Clearing Member/Affiliate-Issued Securities

OCC operates two programs for stock loan transactions: (1) The Stock Loan/Hedge Program and (2) the Market Loan Program (collectively, the ''Stock Loan Programs''). In the Stock Loan/Hedge Program, prospective Lending and Borrowing Clearing Members identify each other (independent of OCC), agree to bilaterally negotiated terms of the stock loan (in this case, a ''Hedge Loan''), and then send the details of the stock loan to the Depository Trust Company (''DTC'') designating the stock loan as a Hedge Loan for guaranty and clearance at OCC. The Lending Clearing Member then instructs DTC to transfer

[4] OCC also has filed a proposed rule change with the Commission in connection with the proposed changes. *See* SR–OCC–2019–010.

[5] OCC also filed with the Commission proposed rule change and advance notice filings concerning enhancements to its CFM Policy and Methodology Description, which are currently pending Commission review. *See* OCC filings SR–OCC–2019–009 and SR–OCC–2019–806. OCC has marked proposed changes to the CFM Policy and Methodology Description described herein in double marking to clearly differentiate those changes from other changes currently pending Commission review.

[6] OCC's By-Laws and Rules can be found on OCC's public website: *http://optionsclearing.com/about/publications/bylaws.jsp.*

[7] *See* Securities Exchange Act Release No. 78961 (September 28, 2016), 81 FR 70786, 70816, n. 317 (October 13, 2016) (S7–03–14) (''Standards for Covered Clearing Agencies''). *See also* Committee on Payment and Settlement Systems and Technical Committee of the International Organization of Securities Commissions, *Principles for financial market infrastructures* (Apr. 16, 2012), available at *http://www.bis.org/publ/cpss101a.pdf.*

[8] *See* OCC Rule 604, Interpretation and Policy .16.

[9] Under OCC's Margin Policy, OCC may collateralize certain exposures through the use of add-on charges.

[10] *See* Securities Exchange Act Release No. 53322 (February 15, 2006), 71 FR 9403 (February 23, 2006) (SR–OCC–2004–20). A detailed description of the STANS methodology is available at *http://optionsclearing.com/risk-management/margins/.*

[11] Under OCC's existing stress testing and Clearing Fund methodology, OCC runs on a daily basis a set of stress test scenarios designed to measure the exposure of the Clearing Fund to the portfolios of individual Clearing Member Groups and determine whether any such exposure is sufficiently large as to necessitate OCC calling for additional resources so that OCC continues to maintain sufficient financial resources to guard against potential losses under a wide range of stress scenarios, including extreme but plausible market conditions (''Sufficiency Scenarios,'' and such scenarios collectively constituting ''Sufficiency Stress Tests''). *See* Securities Exchange Act Release No. 83714 (July 26, 2018), 83 FR 37570 (August 1, 2018) (SR–OCC–2018–803) and Securities Exchange Act Release No. 83735 (July 27, 2018), 83 FR 37855 (August 2, 2018) (SR–OCC–2018–008). Under OCC Rule 609, the CFM Policy, and the Methodology Description, if a Sufficiency Stress Test identifies exposures that exceed 75% of the current Clearing Fund requirement less deficits (the ''75% threshold'' or ''Sufficiency Stress Test Threshold 1''), OCC may require additional margin deposits from the Clearing Member Group(s) driving the breach. If a Sufficiency Stress Test identifies exposures that exceed 90% of the current Clearing Fund, OCC would perform an intra-month resizing of the Clearing Fund. *Id.*

a specified number of shares of Eligible Stock [12] to the account of the Borrowing Clearing Member, and the Borrowing Clearing Member instructs DTC to transfer the appropriate amount of cash collateral to the account of the Lending Clearing Member. In the Market Loan Program, stock loans are initiated through the matching of bids and offers that are either agreed upon by the Market Loan Clearing Members or matched anonymously through a Loan Market (such stock loans being ''Market Loans''). In order to initiate a Market Loan, the Loan Market sends a matched transaction to OCC, which in turn sends two separate but linked settlement instructions to DTC to effect the movement of Eligible Stock and cash collateral between the accounts of the Market Loan Clearing Members through OCC's account at DTC.

Regardless of whether a transaction is initiated under the Stock Loan/Hedge Program or Market Loan Program, OCC novates the transaction and becomes the lender to the Borrowing Clearing Member and the borrower to the Lending Clearing Member. As the principal counterparty to the Borrowing and Lending Clearing Members, OCC guarantees the return of the full value of cash collateral to a Borrowing Clearing Member and guarantees the return of the Loaned Stock (or value of that Loaned Stock) to the Lending Clearing Member.[13] As noted above, OCC may be exposed to SWWR in its Stock Loan Programs where Clearing Members lend equity securities or ETNs issued by the Clearing Member or its affiliates. Specifically, the lending of Clearing Member or Member Affiliate-issued equity or ETNs creates a long exposure and liability in the case when a Clearing Member defaults and its own or affiliated equity or ETN declines.

OCC proposes to mitigate SWWR in its Stock Loan Programs by prohibiting Clearing Members from lending any Eligible Stock issued by such Clearing Member or any affiliate of such Clearing Member. The proposed restriction would apply to both SWWR Equity positions and SWWR ETN positions. OCC does not believe that the proposed restriction on lending SWWR Equity positions would have a material impact on Clearing Members in the Stock Loan Programs as Clearing Members do not typically engage in lending of their own equity securities and borrowers typically do not accept equity securities issued by their lending counterparty.[14] The proposed restrictions on lending SWWR ETN positions would, however, impact a very small segment of Clearing Members that lend SWWR ETNs.[15] OCC believes that the impact of the proposed changes would be limited by the fact that, unlike listed options, Clearing Members are able to lend SWWR positions on an uncleared basis outside of OCC. The proposed restrictions on lending activity in the Stock Loan Programs would not prevent Clearing Members from lending equities or ETNs issued by the Clearing Member or any affiliate of such Clearing Member on a bilateral basis if members wish to do so.

The proposed prohibition on lending Clearing Member or Member Affiliate-issued Eligible Stock would be included in new OCC Rules 2202(f) and 2202A(f) for the Stock Loan/Hedge Program and Market Loan Program, respectively. OCC would also make conforming changes to its Margin Policy and Margins Methodology to reflect the newly proposed restrictions in stock lending activity.

The proposed change would only apply to stock lending activity as of the time of implementation of the proposed change. The proposed change would not be applied retroactively to existing open positions, and Clearing Members with open stock loans involving Clearing Member or Member Affiliate-issued Eligible Stock would not be forced to terminate those existing positions. Any SWWR stock lending positions in existence as of the implementation of the proposed change would be subject to the SWWR charges described below until such positions are closed out through the normal course stock loan termination process.

2. SWWR Add-on

OCC proposes to adopt a new margin add-on (*i.e.,* the SWWR Add-on) to address SWWR from cleared positions involving Clearing Member and affiliate issued equities and ETNs. The SWWR Add-on would be calculated for each margin tier account of a Clearing Member Group having positions related to either publicly traded equities or ETNs issued by the Clearing Member Group and would cover all types of positions (equity used as collateral, equity and ETN options, single-stock futures). The proposed SWWR Add-on is comprised of three main components: (1) ''SWWR Equity Charge,'' (2) ''SWWR ETN Charge,'' and (3) ''SWWR Residual.'' Each of these components is discussed below.

a. SWWR Equity Charge

Under the proposal, when a Clearing Member defaults, it is assumed that the price of any equity security issued by the Clearing Member Group would fall to zero. As a result, OCC would calculate the SWWR Equity Charge by assuming that a Clearing Member's and its affiliates' equity securities would be priced at zero and value all cleared positions accordingly (*i.e.,* all stocks, single stock futures, call options, and put options would be valued at zero) to provide full protection for the risk of potential market exposure to products on a Clearing Member Group's own equity in a default or bankruptcy scenario. In each margin account, the profit and loss (''P&L'') of SWWR Equity positions would be calculated as the difference of the theoretical value of such securities (*i.e.,* zero) and the closing price of the position multiplied by the net quantity.[16] Moreover, any potential gain from the SWWR positions would be excluded by flooring the SWWR Equity Charge at zero.[17] As a result, OCC believes that the proposed SWWR Equity Charge would adequately cover the SWWR arising from a Clearing Member's SWWR Equity positions.

[12] OCC's By-Laws define ''Eligible Stock'' to mean, in part, any security that is eligible for lending in the Stock Loan/Hedge Program and the Market Loan Program. *See* Article I, Section 1.E(3) of the OCC By-Laws. Eligible Stock may include ETNs issued by OCC's Clearing Members.

[13] Under the Market Loan Program, OCC also provides a limited guaranty of dividend and rebate payments.

[14] As of the start of September 2019, OCC had 107 Clearing Members, of which 64 have member or affiliate-issued securities eligible for lending in the Stock Loan Programs. OCC analyzed SWWR Equity lending activity for its Clearing Members from January 2018 through the beginning of September 2019. During this period, less than 10 Clearing Members had stock lending activity in SWWR Equity positions, and loans of SWWR Equity positions constituted less than three percent of each of those Clearing Members' average notional stock lending activity for the period.

[15] OCC analyzed SWWR ETN lending activity for its Clearing Members from January 2018 through the beginning of September 2019. Only 11 of OCC's 107 Clearing Members have member or affiliate issued ETNs. During this period, less than 10 Clearing Members had stock lending activity for SWWR ETN positions. For the majority of these Clearing Members, lending in SWWR ETN positions constituted approximately 13 percent or less of each of those Clearing Members' average notional stock lending activity for the period. For Clearing Members that averaged higher notational lending activity, OCC has observed significant reductions in this activity over recent months.

[16] Because SWWR of equity-related positions would be fully covered as part of margins, these positions would be removed from Clearing Fund shortfall calculations under OCC's stress testing and Clearing Fund methodology. Accordingly, OCC proposes to revise its Methodology Description to reflect the exclusion of SWWR Equity positions from the synthetic accounts used in OCC's stress testing.

[17] For example, suppose the P&L from the SWWR equity price going to 0 for all SWWR equity-related positions were a loss of $1 million. The SWWR Equity Charge in this case would be $1 million. If the P&L were a gain of $1 million, the SWWR Equity Charge would be $0.

b. SWWR ETN Charge

In addition to SWWR that arises from equity securities issued by a Clearing Member or its affiliates, OCC is also exposed to SWWR from open positions related to the uncollateralized ETNs issued by a Clearing Member/Group, which are adversely correlated with the credit quality of that Clearing Member Group. These ETNs are generally equivalent to unsecured senior debt issued by the Clearing Member/Group. While a Clearing Member default can be triggered by its failure to meet other obligations, the firm may or may not default on its ETNs. Hence, the recovery rate for ETNs is uncertain and could be between 0% and 100%.

To address SWWR presented by ETNs issued by a Clearing Member/Group, OCC proposes to calculate an SWWR ETN Charge as part of the SWWR Add-on. OCC notes that, unlike SWWR Equity positions, for which it is assumed that the price of any equity security issued by the Clearing Member Group would fall to zero, the recovery rate for ETNs would not necessarily fall to zero. As a result, the proposed SWWR ETN Charge would utilize an industry standard recovery rate assumption designed to reflect the credit risk associated with such ETN positions.[18] OCC would also adopt additional stress test scenarios to monitor and measure SWWR ETN position exposures and allow for OCC to call for additional financial resources from its Clearing Members when certain thresholds are breached. These SWWR stress test scenarios are discussed in further detail below.

c. SWWR Residual

To ensure that OCC appropriately calculates margins to capture SWWR Equity and SWWR ETN position exposures, OCC proposes to include an SWWR Residual component in SWWR Add-on. Under the proposal, OCC would continue to calculate base STANS margin requirements for Clearing Members with SWWR positions including SWWR Equity and SWWR ETN positions under its current methodology (*i.e.,* without assuming that all SWWR Equity positions fall to a value of zero and without assuming all SWWR ETN positions are valued at the recovery rate times their current price).[19] OCC would then also calculate a residual STANS margin with the SWWR Equity and SWWR ETN positions removed since for SWWR their P&L would be captured through the SWWR Equity and SWWR ETN Charges. The SWWR Residual would then be the difference between the residual margin and the base margin. If the sum of the SWWR Equity Charge, SWWR ETN Charge and SWWR Residual would result in a net credit to the Clearing Member,[20] then the SWWR Residual would be adjusted to ensure that OCC always uses a more conservative measure that captures the greater of either the base STANS margin or the residual STANS margin plus the SWWR Equity and SWWR ETN Charges.[21]

3. Enhancements to Sufficiency Stress Test Scenarios for ETNs

OCC proposes to revise its CFM Policy and Methodology Description to introduce new stress test scenarios designed to capture SWWR exposures for Clearing Member-issued ETNs that are not accounted for in the SWWR ETN Charge and that exceed certain thresholds of OCC's Clearing Fund (''SWWR Sufficiency Scenarios'').[22] Under the proposal, certain Sufficiency Scenarios [23] would be evaluated with Clearing Member-issued ETNs declining to zero within the respective Clearing Member's accounts. Such scenarios would include, but would not be limited to, the 1987 ''Black Monday'' market event on a Cover 1 basis and the two most extreme moves from the 2008 historical market event on a Cover 2 basis.

SWWR Sufficiency Scenarios would value Clearing Member-issued ETNs at a price of zero within their own accounts capturing impacts to any cleared positions tied to those ETNs. Calls, equities, and single-stock futures would all be valued at zero and puts would be valued at their strike price. For these scenarios, margin assets for shortfall calculations would not be adjusted by the SWWR ETN Charge. In addition, other scenarios may be created that embed the SWWR Equity risk by not excluding positions related to the Clearing Member Group's own equity but using an equity price of zero to value all related products.

In the event an SWWR Sufficiency Scenario identifies exposures that exceed 75% of the current Clearing Fund requirement less deficits, OCC may require additional margin deposits from the Clearing Member Group(s) driving the breach. If an SWWR Sufficiency Stress Scenario identifies exposures that exceed 90% of the current Clearing Fund, OCC would perform an intra-month resizing of the Clearing Fund. The proposed change would enable OCC to more accurately measure its credit risks as they relate to SWWR and better test the sufficiency of its overall financial resources and would allow OCC to call for additional financial resources when SWWR ETN position exposures exceed certain thresholds of OCC's Clearing Fund. As a result of these proposed enhancements, OCC believes it would have sufficient financial resources to cover the SWWR associated with SWWR ETN positions if such positions were to be liquidated for less than the assumed recovery rate.

OCC notes that, under its current CFM Policy, in the event results of a daily Sufficiency Stress Test over the final

[18] ETNs issued by a Clearing Member Group would still be stressed in OCC's Clearing Fund as only a part of the credit risk is covered by the SWWR ETN Charge. Additionally, any credit from margin assets would be adjusted by the direct charges related to the risk of the equity and ETNs issued by each Clearing Member Group.

[19] STANS margin requirements are comprised of the sum of several components, each reflecting a different aspect of risk. The base component of the STANS margin requirement for each account is obtained using a risk measure known as 99% Expected Shortfall. The Expected Shortfall component is established as the estimated average of potential losses higher than the 99% value at risk threshold. The term ''value at risk'' or ''VaR'' refers to a statistical technique that, generally speaking, is used in risk management to measure the potential risk of loss for a given set of assets over a particular time horizon. This base component is then adjusted by the addition of a stress test component, which is obtained from consideration of the increases in 99% Expected Shortfall that would arise from market movements that are especially large and/or in which various kinds of risk factors exhibit perfect or zero correlations in place of their correlations estimated from historical data (''Dependence Add-on''), or from extreme adverse idiosyncratic movements in individual risk factors to which the account is particularly exposed (''Concentration Add-on'').

[20] For example, where a customer of a Clearing Member has net short positions referencing that Clearing Member's issued equities, such positions may actually present so-called ''right-way risk'' whereby the position would result in a gain or margin credit for that account as the credit quality of the Clearing Member deteriorates.

[21] For example, suppose that there are no SWWR ETN positions and the Expected Shortfall of a portfolio including all positions was a $10 million loss and the Expected Shortfall with the SWWR Equity-related positions removed was a greater loss of $11 million. In this case, the SWWR Residual would be −$1 million. If the Expected Shortfall with the SWWR Equity-related positions removed was reduced to a loss of $9 million then the SWWR Residual would depend on the SWWR Equity Charge: If the SWWR Equity Charge was more negative than −$1 million, then the SWWR Residual would be +$1 million; if the SWWR Equity Charge was $0, then SWWR Residual would be $0; and if SWWR Equity Charge was between $0 and −$1 million (*e.g.,* −$0.4 million), then SWWR Residual would be positive and the opposite value of SWWR Equity Charge (*e.g.,* +$0.4 million). Thus, the sum of the SWWR Equity Charge, SWWR ETN Charge, and SWWR Residual cannot be positive.

[22] OCC notes that it may also develop additional Informational Scenarios to monitor SWWR; however, these Informational Scenarios would not be used to call for additional financial resources from Clearing Members.

[23] *See supra* note 1111.

five business days preceding the monthly Clearing Fund sizing exceed 90% of the projected Clearing Fund size for the upcoming month, the Clearing Fund size is set such that the peak Sufficiency Stress Test draw is no greater than 90% of the Clearing Fund size. OCC proposes to revise the CFM Policy to provide that OCC generally does not intend to mutualize exposures resulting from the proposed SWWR Sufficiency Scenarios and therefore SWWR Sufficiency Scenarios would not be included for purposes of this anti-procyclicality measure. The proposed change is generally aligned with OCC's intention to appropriately charge individual Clearing Members based on the SWWR they bring to OCC.

4. Other Clarifying and Conforming Changes to CFM Policy and Methodology Description

In addition to the proposed changes described above, OCC would revise the CFM Policy and Methodology Description to provide that, with respect to stress test portfolio construction, SWWR single-name equity positions would be removed from stress test portfolios as they are fully collateralized in margins. Additionally, the Methodology Description would be revised to provide that when adding STANS margin asset amounts to scenario gains and losses, the SWWR Equity Charge, SWWR ETN Charge, and certain other Add-ons from STANS margin asset amounts are excluded.

Finally, OCC would revise its Methodology Description to clarify that for Idiosyncratic Scenarios,[24] the four riskiest names used to calculate idiosyncratic stress test exposures would exclude any equity issued by the Clearing Member's own firms and make other clarifying, non-substantive changes to the Methodology Description concerning stress testing price shocks for products with multiple risk factors and Idiosyncratic Scenarios that are unrelated to the proposal described herein.

Clearing Member Outreach

To inform Clearing Members of the proposed changes, OCC has provided an overview of the proposed changes to the Financial Risk Advisory Council (''FRAC''), a working group comprised of exchanges, Clearing Members and indirect participants of OCC. OCC has also performed direct outreach to Clearing Members that would be most impacted by the proposed changes. To-date, OCC has not received any material objections or concerns in response to this outreach.

Implementation Timing

OCC expects to implement the proposed changes within sixty (60) days after the date that OCC receives all necessary regulatory approvals for the proposed changes. OCC will announce the implementation date of the proposed change by an Information Memorandum posted to its public website at least two (2) weeks prior to implementation.

Expected Effect on and Management of Risk

The proposed changes are designed to enhance OCC's overall framework for managing credit risk and reduce the overall level of risk presented to and presented by OCC. OCC believes that prohibiting Clearing Members from lending their own or Member Affiliate-issued securities in the Stock Loan Programs and introducing the proposed SWWR Add-on charge would improve OCC's ability to manage the credit risks presented by its Clearing Members' SWWR positions and would reduce the risk that OCC's financial resources would be insufficient in the event of a Clearing Member default. As a result, the proposed change is designed, in general, to enhance OCC's framework for measuring and managing its credit risks so that it can continue to provide prompt and accurate clearance and settlement of securities and derivatives transactions in the event of a Clearing Member default.

In addition, OCC believes that introducing new SWWR Sufficiency Scenarios designed to capture SWWR exposures for Clearing Member-issued ETNs that are not accounted for in the SWWR ETN Charge would provide OCC with a more comprehensive approach to managing OCC's credit risks as they relate to SWWR ETN positions. The proposed change would enable OCC to more accurately measure its credit risks and better test the sufficiency of its overall financial resources and would allow OCC to call for additional financial resources when those exposures exceed certain thresholds of OCC's Clearing Fund.

OCC also proposes a number of other clarifying and conforming changes to its CFM Policy and Methodology Description required to implement the proposed SWWR Add-on and SWWR Sufficiency Scenarios described herein and to more clearly describe OCC's stress testing practices. OCC believes that these changes would enhance OCC's overall framework for measuring and managing its credit risks so that it can continue to provide prompt and accurate clearance and settlement of securities in the event of a Clearing Member default.

Consistency With the Payment, Clearing and Settlement Supervision Act

The stated purpose of the Clearing Supervision Act is to mitigate systemic risk in the financial system and promote financial stability by, among other things, promoting uniform risk management standards for systemically important financial market utilities and strengthening the liquidity of systemically important financial market utilities.[25] Section 805(a)(2) of the Clearing Supervision Act[26] also authorizes the Commission to prescribe risk management standards for the payment, clearing and settlement activities of designated clearing entities, like OCC, for which the Commission is the supervisory agency. Section 805(b) of the Clearing Supervision Act[27] states that the objectives and principles for risk management standards prescribed under Section 805(a) shall be to:

- promote robust risk management;
- promote safety and soundness;
- reduce systemic risks; and
- support the stability of the broader financial system.

OCC believes that the proposed changes described herein are consistent with the objectives and principles of Section 805(b) of the Clearing Supervision Act[28] and the risk management standards adopted by the Commission in Rule 17Ad–22 under the Act for the reasons set forth below.[29]

OCC believes the proposed changes are consistent with the objectives and principles of Section 805(b) of the Clearing Supervision Act.[30] The proposed changes are designed to improve OCC's overall framework for managing SWWR brought by its Clearing Members. OCC believes that prohibiting Clearing Members from

[24] OCC has proposed in separate proposed rule change and advance notice filings to adopt a new set of stress scenarios to be used in the monthly sizing of OCC's Clearing Fund that are designed to capture the risks of extreme moves in individual or small subsets of securities (''Idiosyncratic Scenarios''). These Idiosyncratic Scenarios would consider the four single-name securities with the worst P&L in a Clearing Member's portfolio. *See supra* note 5.

[25] 12 U.S.C. 5461(b).

[26] 12 U.S.C. 5464(a)(2).

[27] 12 U.S.C. 5464(b).

[28] *Id.*

[29] 17 CFR 240.17Ad–22. *See* Securities Exchange Act Release Nos. 68080 (October 22, 2012), 77 FR 66220 (November 2, 2012) (S7–08–11) (''Clearing Agency Standards''); 78961 (September 28, 2016), 81 FR 70786 (October 13, 2016) (S7–03–14) (''Standards for Covered Clearing Agencies''). OCC is a ''covered clearing agency'' as defined in Rule 17Ad–22(a)(5) and therefore must comply with the requirements of Rule 17Ad–22(e).

[30] 12 U.S.C. 5464(b).

lending their own or Member Affiliate-issued securities in the Stock Loan Programs and introducing the proposed SWWR Add-on charge would enhance OCC's ability to manage the credit risks presented by its Clearing Members' SWWR positions and would reduce the risk that OCC's financial resources would be insufficient in the event of a Clearing Member default. In addition, OCC believes that introducing new SWWR Sufficiency Scenarios designed to capture SWWR exposures for Clearing Member-issued ETNs that are not accounted for in the SWWR ETN Charge would provide OCC with a comprehensive approach to managing OCC's credit risks as they relate to SWWR ETN positions. The proposed change would enable OCC to more accurately measure its credit risks and better test the sufficiency of its overall financial resources and would allow OCC to call for additional financial resources when those exposures exceed certain thresholds of OCC's Clearing Fund. OCC also proposes a number of other clarifying and conforming changes to its CFM Policy and Methodology Description required to implement the proposed SWWR Add-on and SWWR Sufficiency Scenarios described herein and to more clearly describe OCC's stress testing practices. Accordingly, OCC believes the proposed changes are designed to promote robust risk management, promote safety and soundness, reduce systemic risks, and support the stability of the broader financial system.

OCC also believes the proposed changes are consistent with the risk management standards adopted by the Commission in Rule 17Ad–22 under the Act. Rule 17Ad–22(b)(2) [31] requires a registered clearing agency that performs CCP services to establish, implement, maintain and enforce written policies and procedures reasonably designed to, in part, use margin requirements to limit its credit exposures to participants under normal market conditions and use risk-based models and parameters to set such margin requirements. In addition, Rules 17Ad–22(e)(6)(i) and (v) [32] require a covered clearing agency that provides CCP services to 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, at a minimum: (1) Considers and produces margin levels commensurate with the risks and particular attributes of each relevant product, portfolio, and market, and (2) uses an appropriate method for measuring credit exposure that accounts for relevant product risk factors and portfolio effects across products.

The proposed changes to OCC's margin and Clearing Fund policies and methodologies to adopt the SWWR Add-on would utilize a risk-based model designed to limit OCC's credit exposures to Clearing Members that present SWWR exposure to OCC through the clearing of Clearing Member-issued equity and ETN positions. OCC believes the proposed SWWR Add-on is reasonably designed to produce margin levels commensurate with the risks and particular attributes SWWR Equity and ETN positions and would use an appropriate method for measuring credit exposure that accounts for relevant product risk factors such as SWWR.

The proposed SWWR Add-on would include both an SWWR Equity Charge and SWWR ETN Charge to address the SWWR attributes and exposures presented to OCC by each type of product. For example, the SWWR Equity Charge assumes that when a Clearing Member defaults the price of any equity security issued by the Clearing Member Group would fall to zero. As a result, OCC would calculate the SWWR Equity Charge by assuming that a Clearing Member's and its affiliates' equity securities would be priced at zero and value all cleared positions accordingly to provide full protection for the risk of potential market exposure to products on a Clearing Member Group's own equity in a default or bankruptcy scenario. Moreover, the SWWR Add-on charge would include an SWWR Residual component to ensure that OCC takes the more conservative of the base STANS margin requirement or margin requirements including the SWWR Equity Charge (particularly in circumstances where using the SWWR Equity Charge would result in a net credit to the Clearing Member).

In addition, OCC would adopt an SWWR ETN Charge to address the SWWR presented by Clearing Member-issued ETNs. ETNs have different characteristics than equity securities and more closely reflect those characteristics of other unsecured debt obligations. For example, if a Clearing Member defaults that does not necessarily imply that it will automatically default on its ETNs. Therefore, ETNs are not necessarily valued at 0 and in fact may retain 100% of their value and be exposed to normal market risk. OCC proposes to measure the risk of these positions using an industry standard recovery rate assumption designed to calculate a margin charge that reflects the expected credit risk associated with such ETN positions. The potential market risk of the ETNs would still be covered by including ETNs in regular margin calculations, whereas the SWWR Equity positions are assumed to be heading towards bankruptcy and necessarily valued near 0 in a default situation.

For these reasons, OCC believes the proposed SWWR Add-on would enhance OCC's margin system by providing for a risk-based model that: (1) Sets margin requirements designed to limit OCC's SWWR exposures to its participant; (2) considers and produces margin levels commensurate with the risks and particular attributes SWWR positions cleared by OCC; and (3) uses an appropriate method for measuring such SWWR exposures consistent with the requirements of Rules 17Ad–22(b)(2), (e)(6)(i) and (e)(6)(v).[33]

Rules 17Ad–22(e)(4)(iii) and (vi) [34] require that a covered clearing agency establish, implement, maintain and enforce written policies and procedures reasonably designed to effectively identify, measure, monitor, and manage its credit exposures to participants and those arising from its payment, clearing, and settlement processes, including by: (1) Maintaining additional financial resources at the minimum to enable it to cover a wide range of foreseeable stress scenarios that include, but are not limited to, the default of the participant family that would potentially cause the largest aggregate credit exposure for the covered clearing agency in extreme but plausible market conditions and (2) testing the sufficiency of its total financial resources available to meet these minimum financial resource requirements. OCC believes that introducing new SWWR Sufficiency Scenarios designed to capture SWWR exposures for Clearing Member-issued ETNs that are not accounted for in the SWWR ETN Charge would enable OCC to more accurately measure its credit risks and better test the sufficiency of its overall financial resources, particularly in stressed marked conditions. The proposed change would also allow OCC to call for additional financial resources when those exposures exceed certain thresholds of OCC's Clearing Fund. The proposed change is therefore designed to enhance OCC's overall framework for measuring and managing its credit risks and would reduce the risk that OCC's financial resources would be

[31] 17 CFR 240.17Ad–22(b)(2).

[32] 17 CFR 240.17Ad–22(e)(6)(i) and (v).

[33] 17 CFR 240.17Ad–22(b)(2), (e)(6)(i), and (e)(6)(v).

[34] 17 CFR 240.17Ad–22(e)(4)(iii) and (vi).

insufficient in the event of a Clearing Member default consistent with Rules 17Ad–22(e)(4)(iii) and (vi).[35]

Rule 17Ad–22(e)(4)[36] generally requires that a covered clearing agency establish, implement, maintain and enforce written policies and procedures reasonably designed to effectively identify, measure, monitor, and manage its credit exposures to participants and those arising from its payment, clearing, and settlement processes. By prohibiting Clearing Members from lending Eligible Stock issued by the Clearing Member or any affiliate of such Clearing Member, OCC would mitigate the SWWR that currently exists in its Stock Loan Programs and thereby reduce the risk that OCC's financial resources would be insufficient in the event such a Clearing Member would default. OCC believes the proposed change is therefore reasonably designed to help OCC manage the credit risks associated with SWWR Equity and SWWR ETN positions in the Stock Loan Programs and is therefore consistent with Rule 17Ad–22(e)(4).[37]

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 the proposed change was filed with the Commission or (ii) the date any additional information requested by the Commission is received. OCC 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.

OCC 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–OCC–2019–807 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–OCC–2019–807. 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 office of the self-regulatory organization.

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–2019–807 and should be submitted on or before November 27, 2019.

By the Commission.

Jill M. Peterson,

Assistant Secretary.

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[35] *Id.*

[36] 17 CFR 240.17Ad–22(e)(4).

[37] *Id.*

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87475; File No. SR–OCC–2019–806]

Self-Regulatory Organizations; The Options Clearing Corporation; Notice of Filing of Advance Notice Related to Proposed Changes to The Options Clearing Corporation's Rules, Clearing Fund Methodology Policy, and Clearing Fund and Stress Testing Methodology

November 6, 2019.

Pursuant to Section 806(e)(1) of Title VIII of the Dodd-Frank Wall Street Reform and Consumer Protection Act, entitled Payment, Clearing and Settlement Supervision Act of 2010 (''Clearing Supervision Act'')[1] and Rule 19b–4(n)(1)(i)[2] under the Securities Exchange Act of 1934 (''Exchange Act'' or ''Act''),[3] notice is hereby given that on October 10, 2019, the Options Clearing Corporation (''OCC'') filed with the Securities and Exchange Commission (''Commission'') an advance notice 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 advance notice from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Advance Notice

This advance notice is submitted in connection with proposed enhancements to OCC's Clearing Fund and stress testing rules and methodology designed to: (1) Incorporate a new set of stress test scenarios to be used in the monthly sizing of OCC's Clearing Fund that are designed to capture the risks of extreme moves in individual or small subsets of securities; (2) enhance OCC's stress testing methodology for modeling certain volatility index futures; (3) modify OCC's methodology for allocating Clearing Fund contribution requirements to standardize the margin risk component of the allocation formula for all Clearing Members; (4) adopt an additional threshold for notifying senior management of intra-

[1] 12 U.S.C. 5465(e)(1).

[2] 17 CFR 240.19b–4(n)(1)(i).

[3] 15 U.S.C. 78a *et seq.*

day margin calls based on certain stress test results; (5) correct certain rules concerning OCC's cooling-off period and replenishment/assessment powers; and (6) make other clarifying and conforming changes to OCC's Rules, Clearing Fund Methodology Policy (''Policy''), and Stress Testing and Clearing Fund Methodology Description (''Methodology Description'').

The proposed amendments to OCC's Rules can be found in Exhibit 5A. Proposed changes to the Policy can be found in Exhibit 5B. Proposed changes to the Methodology Description can be found in Exhibit 5C. Material proposed to be added to the Rules, Policy, and Methodology Description as currently in effect is marked by underlining, and material proposed to be deleted is marked in strikethrough text.[4]

The advance notice is available on OCC's website at *https://www.theocc.com/about/publications/bylaws.jsp.* All terms with initial capitalization that are not otherwise defined herein have the same meaning as set forth in the OCC By-Laws and Rules.[5]

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Advance Notice

In its filing with the Commission, OCC 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. OCC has prepared summaries, set forth in sections A and B below, of the most significant aspects of these statements.

(A) Clearing Agency's Statement on Comments on the Advance Notice

Written comments were not and are not intended to be solicited with respect to the advance notice and none have been received. OCC will notify the Commission of any written comments received by OCC.

(B) Advance Notices Filed Pursuant to Section 806(e) of the Payment, Clearing, and Settlement Supervision Act

Description of the Proposed Change

Background

In September 2018, OCC implemented new rules for sizing and monitoring its Clearing Fund and overall Pre-Funded Financial Resources,[6] which included the adoption of a new Policy and Methodology Description.[7] Under the requirements of the Policy, OCC bases its determination of the Clearing Fund size on the results of stress tests conducted daily using standard predetermined parameters and assumptions. These daily stress tests consider a range of relevant stress scenarios and possible price changes in liquidation periods, including but not limited to: (1) Relevant peak historic price volatilities; (2) shifts in other market factors including, as appropriate, price determinants and yield curves; and (3) the default of one or multiple Clearing Members. OCC also conducts reverse stress tests for informational purposes aimed at identifying extreme default scenarios and extreme market conditions for which the OCC's financial resources may be insufficient.

As described in the Methodology Description, the newly adopted methodology includes two types of scenarios: ''Historical Scenarios'' and ''Hypothetical Scenarios.'' Historical Scenarios intend to replicate historical events in current market conditions, which includes the set of currently existing securities, their prices, and volatility levels. These scenarios provide OCC with information regarding pre-defined reference points determined to be relevant benchmarks for assessing OCC's exposure to Clearing Members and the adequacy of its financial resources. Hypothetical Scenarios represent events in which market conditions change in ways that have not yet been observed. The Hypothetical Scenarios are derived using statistical methods (*e.g.,* draws from estimated multivariate distributions) or created based on a mix of statistical techniques and expert judgment (*e.g.,* a 15% decline in market prices and 50% increase in volatility). These scenarios give OCC the ability to change the distribution and level of stress in ways necessary to produce an effective forward-looking stress testing methodology. OCC uses these pre-determined stress scenarios in stress tests, conducted on a daily basis, to determine OCC's risk exposure to each Clearing Member Group by simulating the profits and losses of the positions in their respective account portfolios under each such stress scenario.

Under the Policy and Methodology Description, OCC performs daily stress testing using a wide range of scenarios, both Hypothetical and Historical, designed to serve multiple purposes. OCC's proposed stress testing inventory contains scenarios designed to: (1) Determine whether the financial resources collected from all Clearing Members collectively are adequate to cover OCC's risk tolerance (''Adequacy Scenarios,'' and such scenarios collectively constituting ''Adequacy Stress Tests''); (2) establish the monthly size of the Clearing Fund necessary for OCC to maintain sufficient Pre-Funded Financial Resources to cover losses arising from the default of the two Clearing Member Groups that would potentially cause the largest aggregate credit exposure to OCC as a result of a 1-in-80 year hypothetical market event (''Sizing Scenarios,'' and such scenarios collectively constituting ''Sizing Stress Tests''); (3) measure the exposure of the Clearing Fund to the portfolios of individual Clearing Member Groups, and determine whether any such exposure is sufficiently large as to necessitate OCC calling for additional resources so that OCC continues to maintain sufficient financial resources to guard against potential losses under a wide range of stress scenarios, including extreme but plausible market conditions (''Sufficiency Scenarios,'' and such scenarios collectively constituting ''Sufficiency Stress Tests'');[8] and (4) monitor and assess the

[4] OCC also has filed a proposed rule change with the Commission in connection with the proposed changes. *See* SR–OCC–2019–009.

[5] OCC's By-Laws and Rules can be found on OCC's public website: *http://optionsclearing.com/about/publications/bylaws.jsp.*

[6] The Policy defines OCC's ''Pre-Funded Financial Resources'' to mean margin of the defaulted Clearing Member and the required Clearing Fund less any deficits, exclusive of OCC's assessment powers.

[7] On July 26, 2018, the Commission issued a Notice of No Objection to an advance notice by OCC concerning the adoption of a new stress testing and Clearing Fund methodology. *See* Securities Exchange Act Release No. 83714 (July 26, 2018), 83 FR 37570 (August 1, 2018) (SR–OCC–2018–803). On July 27, 2018, the Commission approved a proposed rule change by OCC concerning the same proposal. *See* Securities Exchange Act Release No. 83735 (July 27, 2018), 83 FR 37855 (August 2, 2018) (SR–OCC–2018–008).

[8] Under OCC Rule 609, the Policy, and the Methodology Description, if a Sufficiency Stress Test identifies exposures that exceed 75% of the current Clearing Fund requirement less deficits (the ''75% threshold'' or ''Sufficiency Stress Test Threshold 1''), OCC may require additional margin deposits from the Clearing Member Group(s) driving the breach. All such margin calls must be approved by a Vice President (or higher) of OCC's Financial Risk Management department (''FRM''); however, if the margin call imposed on an individual Clearing Member exceeds $500 million, OCC's Stress Testing and Liquidity Risk Management group (''STLRM'') must provide written notification to OCC's Executive Chairman, Chief Executive Officer, and Chief Operating Officer (collectively referred to as the ''Office of the Chief Executive Officer'' or ''OCEO''). Additionally, under Rule 1001(c) (and as described in the Policy and Methodology Description), if a Sufficiency Stress Test were to identify a Clearing Fund Draw for any one or two Clearing Member Groups that exceed 90% of the current Clearing Fund size (after subtracting any monies deposited as a result of a margin call in accordance with a breach of Sufficiency Stress Test Threshold 1), OCC has the authority to effect an intra-month resizing of the

Continued

size of OCC's Pre-Funded Financial Resources against a wide range of stress scenarios that may include extreme but implausible and reverse stress testing scenarios (''Informational Scenarios,'' and such scenarios collectively constituting ''Informational Stress Tests'').[9]

In addition, under the Rules, Policy, and Methodology Description, individual Clearing Members' Clearing Fund contribution requirements are determined using a risk-based allocation methodology of 70% ''total risk,'' 15% volume, and 15% open interest using a one-month look-back period. For purposes of allocating Clearing Fund contributions, ''total risk'' is defined to mean the margin requirement calculated and reported by OCC with respect to all accounts of a Clearing Member less the net asset value of the positions in such accounts aggregated across all such accounts.

Proposed Changes

OCC proposes to enhance its Clearing Fund and stress testing framework by: (1) Adopting a new set of stress scenarios to be used in the monthly sizing of OCC's Clearing Fund that are designed to capture the risks of extreme moves in individual or small subsets of securities (''Idiosyncratic Scenarios''); (2) improving its model for determining price shocks for futures on the Cboe Volatility Index (''VIX'') [10] (such futures contracts hereinafter referred to as ''VIX futures''); (3) modifying the methodology for allocating Clearing Fund contribution requirements to standardize the margin risk component of the allocation formula for all Clearing Members; (4) adopting an additional threshold for notifying senior management of certain intra-day margin calls based on Sufficiency Stress Test results; (5) correcting certain rules concerning OCC's cooling-off period and replenishment/assessment powers; and (6) making certain other clarifying and conforming changes to OCC's Rules, Policy, and Methodology Description. The proposed changes are described in detail below.

1. Introduction of Idiosyncratic Scenarios in Sizing Stress Tests

OCC proposes to revise its Policy and Methodology Description to incorporate into its inventory of Sizing Stress Tests a new set of Idiosyncratic Scenarios that are designed to capture the risks of extreme moves in individual or small subsets of securities. As noted above, OCC's Sizing Stress Tests are used to establish the monthly size of the Clearing Fund necessary for OCC to maintain sufficient Pre-Funded Financial Resources to cover losses arising from the default of the two Clearing Member Groups that would potentially cause the largest aggregate credit exposure to OCC in extreme but plausible market conditions. The proposed Idiosyncratic Scenarios would supplement OCC's current set of Sizing Scenarios (which are generally designed to estimate risk exposures arising from more broad-based market and systemic shocks (''Systemic Scenarios'') and would allow OCC to identify forward-looking, non-systemic market events that may impact its Pre-Funded Financial Resource requirements. Like other Sizing Scenarios, the proposed Idiosyncratic Scenarios may be used to determine the monthly size of Clearing Fund when projected exposures from the Idiosyncratic Scenarios are greater than OCC's other Sizing Scenarios.

The proposed Idiosyncratic Scenarios are designed to capture the risk of extreme non-systemic market moves on single-name securities through individual rally and decline shocks. Under the proposed methodology for Idiosyncratic Scenarios, every single-name equity (*i.e.,* excluding exchange-traded funds, exchange-traded notes, indices, and non-equity products) in a portfolio is shocked by a fixed extreme idiosyncratic up and down move. In order to determine these fixed shocks, single-name equities would be classified as either large or small capitalization (referred to herein as ''large cap'' and ''small cap,'' respectively) and the shocks would be constructed based on the market capitalization classification and direction of the price (*e.g.,* the four potential idiosyncratic moves would be large cap up, large cap down, small cap up, and small cap down. The fixed price shocks would be calibrated from historical price return data such that the probability of the idiosyncratic moves is comparable to OCC's Systemic Sizing Scenarios and the probability in all four scenarios would be approximately equal. The profit and loss (P/L) contribution for each name is then calculated for the portfolio using both up and down moves, and the worst loss from the two P/L moves is chosen as the direction of the idiosyncratic move for each name. Next, the four names with the worst P/L (along with the direction of extreme move) are chosen for the portfolio, providing the four names for every portfolio within a Clearing Member Group. Then the risk exposure (P/L) is aggregated at the Clearing Member Group-level using each set of four names. The worst shortfall generated is the idiosyncratic risk of the Clearing Member Group, and the largest two Clearing Member Group exposures are used to determine the Cover 2 Idiosyncratic Scenario Clearing Fund size.

OCC believes that implementing the proposed Idiosyncratic Scenarios would enhance OCC's stress testing methodology and overall resiliency by providing a more comprehensive suite of Sizing Stress Tests to ensure that OCC maintains an appropriate level of Pre-Funded Financial Resources to cover its credit exposures under scenarios addressing both systemic market risks and idiosyncratic risks.

2. Enhancements for Modeling Shocks on VIX Futures

OCC also proposes to enhance its methodology for modeling price shocks for VIX futures. Under OCC's current stress testing methodology, prices shocks for VIX futures are equivalent to the price shock for the underlying VIX index. OCC believes that this approach is unrealistic in that it produces a uniform shock across expirations of the VIX futures contract, which leads to an overestimation of VIX futures price shocks, particularly in market decline scenarios. Futures contracts for different expirations generally trade at different prices reflecting the differing future price expectations of the underlying asset.[11] Accordingly, OCC believes that the size of the price shocks produced by its stress testing methodology should vary based on the expiration of each contract as is more realistically observed in the market.

OCC proposes to enhance its stress testing methodology (and specifically, Section 3.4 of the Methodology Description) by using SPX at-the-money implied volatility shocks across different expirations to model forward volatility to generate shocks for VIX

Clearing Fund to ensure that it continues to maintain sufficient prefunded financial resources. *See supra* note 7.

[9] OCC notes that its Adequacy and Informational Stress Tests are not used to size the Clearing Fund or drive calls for additional financial resources.

[10] The VIX is an index designed to measure the 30-day expected volatility of the Standard & Poor's 500 index (''SPX'').

[11] When there is a large shock to the VIX it has consistently been observed that the change in price of near-term VIX future contracts is much larger than for further out expirations. For instance, on 2/5/2018 when the near-term VIX future contract expiring on 2/16/2018 increased by 113% the following standard expirations increased by less: 87% for 3/21/2018; 64% for 4/18/2018; 37% for 5/16/2018; and less than 30% for all further expirations. For all other days within the past 5 years with one-day VIX increases of over 45%, similar patterns were observed of a decreasing VIX future term structure of shocks (8/21/2015, 8/24/2015, 6/24/2016 and 5/17/2017).

futures contracts for the corresponding expirations. OCC believes the proposed model enhancements would produce more appropriate VIX futures price shocks in its stress scenarios because it would produce differing price shocks across the term structure as is generally observed in the market.[12] For example, OCC has observed that VIX futures price shocks obtained from the enhanced model for varying expirations is similar to the actual VIX futures market prices when tested on historical stress periods. Additionally, because VIX futures are used to calculate theoretical values for VIX options, OCC believes the proposed enhancement would improve the pricing of both VIX futures and VIX options in OCC's stress testing methodology.

3. Modifications to Clearing Fund Allocation Weighting Methodology

OCC proposes to modify its allocation methodology for determining individual Clearing Members' Clearing Fund requirements. As part of OCC's recently adopted stress testing and Clearing Fund methodology, OCC moved to a more risk-based method for allocating Clearing Fund requirements.[13] Clearing Fund allocations are currently based on a weighting of 70% margin risk, 15% open interest, and 15% cleared volume. The margin risk component of the allocation formula, known as ''total risk,'' is based on the total margin requirement calculated and reported by OCC with respect to all accounts of a Clearing Member less the net asset value of the positions in such accounts aggregated across all such accounts over a one-month look-back period compared to the aggregate of total risk across all Clearing Members.[14] While the majority of margin requirements used in the allocation formula are STANS-based margin requirements,[15] certain Clearing Members' accounts (and thus their allocations) are more heavily impacted by margin requirements calculated using the Standard Portfolio Analysis of Risk Margin Calculation System (''SPAN'') that reflects customer gross margining, which may result in higher risk charges than net margining with STANS for the same account.[16]

OCC proposes to standardize the margin or ''total risk'' component of its Clearing Fund allocation formula for all members by using only the STANS base amount, plus certain add-on charges [17] as may be determined by OCC pursuant to its policies and procedures. OCC believes it is more appropriate to use the same margin risk measurement for all Clearing Members/accounts when determining Clearing Fund allocations since this allows for a more equitable comparison across all accounts through the utilization of a consistent margin methodology. Accordingly, OCC proposes to modify the definition of ''total risk'' in Rule 1003(b)(i) to mean ''a risk measure aggregated across all accounts of a Clearing Member determined using the Corporation's margin methodology and such add-on charges as may be determined pursuant to the Corporation's policies and procedures.'' OCC also proposes to make conforming to changes to its Policy and Methodology Description to reflect the new definition of ''total risk.''

4. New Sufficiency Stress Test Notification Threshold

OCC also proposes to adopt a new internal notification threshold for intra-day margin calls resulting from its Sufficiency Stress Tests. Under existing Rule 609, the Policy, and the Methodology Description, if a Sufficiency Stress Test identifies a Clearing Fund Draw [18] for any one or two Clearing Member Groups that exceeds Sufficiency Stress Test Threshold 1, OCC is authorized to issue a margin call against the Clearing Member Group(s) and/or Clearing Member(s) causing the breach.[19] All Sufficiency Stress Test margin calls are required to be approved by a Vice President (or higher) of FRM; however, if the margin call imposed on an individual Clearing Member exceeds $500 million, the STLRM group must provide written notification to the Office of the CEO. If the margin call imposed on an individual Clearing Member would exceed 100% an individual Clearing Member's net capital, the issue is then escalated to the Office of the CEO, and each of the Executive Chairman, Chief Executive Officer, and Chief Operating Officer have the authority to determine whether OCC should continue calling for additional margin in excess of this amount.

OCC proposes to revise the Policy to require that STLRM provide written notification to the Office of the CEO whenever a Sufficiency Stress Test margin call imposed on an individual Clearing Member exceeds 75% of the Clearing Member's excess net capital (in addition to the current requirement to provide notification for any margin call exceeding $500 million). OCC believes that this additional notification requirement is appropriate because it will allow OCC's senior management to be informed as soon as practicable of, and to subsequently monitor, circumstances where a margin call may strain a particular Clearing Member's ability to meet such requirements based on its financial condition or the amount of collateral it has available to pledge when certain pre-identified thresholds have been exceeded.[20]

5. Correction of Cooling-Off Period and Replenishment/Assessment Power Rules

OCC proposes several corrections to its Rules and Policy concerning its

[12] *Id.*

[13] *See supra* note 7.

[14] *See* OCC Rule 1003(b)(i). OCC removes net asset value from the ''total risk'' component of the allocation formula because it does not reflect a risk measure but rather represents the value of contracts and collateral held in a Clearing Member's accounts.

[15] The System for Theoretical Analysis and Numerical Simulations (or ''STANS'') is OCC's proprietary risk management system for calculating Clearing Member margin requirements. *See* Securities Exchange Act Release No. 53322 (February 15, 2006), 71 FR 9403 (February 23, 2006) (SR–OCC–2004–20). A detailed description of the STANS methodology is available at *http://optionsclearing.com/risk-management/margins/.*

[16] Pursuant to OCC Rule 601(e)(1), in additions to STANS-based requirements, OCC calculates initial margin requirements for segregated futures accounts on a gross basis using SPAN. Commodity Futures Trading Commission (''CFTC'') Rule 39.13(g)(8), requires, in relevant part, that derivatives clearing organizations (''DCOs'') collect initial margin for customer segregated futures accounts on a gross basis. While OCC uses SPAN to calculate initial margin requirements for segregated futures accounts on a gross basis, OCC believes that margin requirements calculated on a net basis (*i.e.,* permitting offsets between different customers' positions held by a Clearing Member in a segregated futures account using STANS) affords OCC additional protections at the clearinghouse level against risks associated with liquidating a Clearing Member's segregated futures account. As a result, OCC calculates margin requirements for segregated futures accounts using both SPAN on a gross basis and STANS on a net basis, and if at any time OCC staff observes a segregated futures account where initial margin calculated pursuant to STANS on a net basis exceeds the initial margin calculated pursuant to SPAN on a gross basis, OCC collateralizes this risk exposure by applying an additional margin charge in the amount of such difference to the account. *See* Securities Exchange Act Release No. 72331 (June 5, 2014), 79 FR 33607 (June 11, 2014) (SR–OCC–2014–13). SPAN is a methodology developed by the Chicago Mercantile Exchange and used by many clearinghouses and exchanges around the world to calculate margin requirements on futures and options on futures.

[17] Under OCC's Margin Policy, OCC may collateralize certain exposures that may be modeled outside of STANS using add-on charges.

[18] The term ''Clearing Fund Draw'' refers to an estimated stress loss exposure in excess of margin requirements.

[19] *See supra* notes 7 and 8.

[20] For example, if a Sufficiency Stress Test margin call imposed on an individual Clearing Member exceeds 75% of the Clearing Member's excess net capital, and such Sufficiency Stress Test also results in Clearing Fund draws for any one or two Clearing Member Groups that exceed 90% of the current Clearing Fund size, OCC may choose to resize the Clearing Fund on an intra-month basis rather than continuing to call for additional margin from a Clearing Member whose ability to meet such a call may be strained. *See supra* notes 7 and 8.

cooling-off period and Clearing Fund replenishment/assessment powers. As part of OCC's recently approved filings to implement enhanced and new recovery tools (''Recovery Tools Filings''), OCC adopted a minimum 15-day ''cooling-off period'' with a cap on Clearing Fund assessments.[21] OCC Rule 1006(h) currently provides that the cooling-off period is triggered when any amount is paid out of the Clearing Fund as a result of a proportionate charge resulting from any of the events described in clauses (i) through (iv) of Rule 1006(a).[22] The actual intention of the Recovery Tools Filings, however, was to capture any proportionate charges related to the default of a Clearing Member,[23] which would also include any use of the Clearing Fund to make good losses or expenses suffered by OCC or as a result of a borrowing by OCC: (1) In connection with protective transactions effected for the account of OCC pursuant to Chapter XI of the Rules and (2) as a result of a failure of any Clearing Member to make any other required payment or render any other required performance (as provided in clauses (v) and (vi) of Rule 1006(a)). OCC therefore proposes to revise its Rules and Policy to more correctly reflect that the cooling-off period and associated assessment caps apply for any proportionate charge resulting from any of the events described in clauses (i) through (vi) of Rule 1006(a). The proposed rule change would ensure that all proportionate charges associated with a Clearing Member default are treated consistently as was originally intended with the adoption of the cooling-off period and modification of OCC's replenishment/assessment powers in the Recovery Tools Filings.

6. Other Clarifying and Conforming Changes

Finally, OCC proposes a number of clarifying, streamlining, and organizational changes to the Methodology Description that are not intended to change the substance of OCC's stress testing and Clearing Fund methodology, but that OCC believes would improve the clarity and readability of the document. The proposed changes to the Methodology Description are described below.

Proposed Changes to the Executive Summary

OCC proposes to revise the model scope discussion of the executive summary to provide a summary of the netting rules and positions sets used for stress testing and to break out different sections for the discussion of Systemic Scenarios and Idiosyncratic Scenarios. The executive summary would also be revised to provide additional information regarding the key assumptions of OCC's stress testing and Clearing Fund methodology. In addition, the Model Performance section of the executive summary would be revised to provide further information on supporting documentation for OCC's stress testing.

Proposed Changes to the Description of Stress Test Portfolio Construction

OCC also proposes to revise its Methodology Description to provide additional details regarding the construction of stress testing portfolios. For example, the proposed revisions would discuss OCC's process for creating the ''Synthetic Accounts'' used in stress testing. Clearing Member positions are initially held in ''Tier Accounts'' that have the same business type (*e.g.,* omnibus customer accounts, combined market maker accounts, firm accounts) and cross-margining relationship with other clearinghouses (if applicable). For the purpose of stress testing, OCC considers liquidation positions, where Tier Account level positions are further aggregated into Synthetic Accounts. The rules that govern the netting process and permissible offsets are based on account structures outlined in OCC's By-Laws and Rules.[24] The proposed revisions would also remove the discussion of ''marginable positions,'' which are used to calculate margin requirements, since marginable positions are not relevant to OCC's Clearing Fund and stress testing methodology requirements and OCC's various account structures and the manner in which such accounts are margined is covered in OCC's By-Laws, Rules, and Margin Policy. In addition, the proposed revisions would restate in descriptive terms the calculation for determining total credit loss shortfalls.

The proposed revisions would also provide further clarity and detail concerning the aggregation of account-level stress test results. A key aspect of the aggregation of business type accounts is that some accounts have a restricted lien, in which assets in that account can only be used to offset losses in that business type account, while other accounts have a general lien, in which assets or gains in that account can be used to offset losses in any business type account of the same Clearing Member. The Methodology Description would be revised to summarize OCC's process for determining if an account is a general lien account or restricted lien account and for ensuring that such accounts receive proper netting treatment.

Proposed Changes to the Description of OCC's Stress Testing Model

In addition, OCC proposes a number of changes to its Methodology Description to improve the description of the models used in OCC's stress testing and Clearing Fund methodology. For example, the Methodology Description would be revised to provide additional context around the types of scenarios (*e.g.,* Systemic Scenarios and Idiosyncratic Scenarios) that stress testing models are used to create. The proposed changes would also provide a more straightforward discussion around the use and selection of risk drivers used to represent risk factors in OCC's one-factor stress testing model.[25] OCC notes that under the current Methodology Description, risk drivers and their mappings are subject to periodic review and change by OCC's Stress Test Working Group (''STWG'').

[21] On August 23, 2018, the Commission issued a Notice of No Objection to an advance notice by OCC concerning changes to OCC's Rules and By-Laws to enhance OCC's existing tools to address the risks of liquidity shortfalls and credit losses and to establish new tools by which OCC could re-establish a matched book and, if necessary, allocate uncovered losses following the default of a Clearing Member as well as provide for additional financial resources. *See* Securities Exchange Act Release No. 83927 (August 23, 2018), 83 FR 44083 (August 29, 2018) (SR–OCC–2017–809). On August 23, 2018, the Commission approved a proposed rule change by OCC concerning the same proposal. *See* Securities Exchange Act Release No. 83916 (August 23, 2018), 83 FR 44076 (August 29, 2018) (SR–OCC–2017–020).

[22] These clauses include the following events: (i) Failure of any Clearing Member to discharge duly any obligation on or arising from any confirmed trade accepted by the Corporation; (ii) failure of any Clearing Member (including any Appointed Clearing Member) or of CDS to perform its obligations (including its obligations to the correspondent clearing corporation) under or arising from any exercised or assigned option contract or matured future or any other contract or obligation issued, undertaken, or guaranteed by the Corporation or in respect of which the Corporation is otherwise liable; (iii) failure of any Clearing Member to perform any of its obligations to the Corporation in respect of the stock loan and borrow positions of such Clearing Member; and (iv) any liquidation of a Clearing Member's open positions.

[23] *See e.g.,* Securities Exchange Act Release No. 83927 (August 23, 2018), 83 FR 44083, 44077 (August 29, 2018) (SR–OCC–2017–809) (providing that ''[t]he proposal would introduce a minimum fifteen calendar day 'cooling-off' period that automatically begins when OCC imposes a proportionate charge related to the default of a Clearing Member against non-defaulting Clearing Members' Clearing Fund contributions.'').

[24] *See e.g.,* OCC Rules 601, 602, 611.

[25] ''Risk factors'' refer broadly to all of the individual underlying securities (such as Google, IBM and Standard & Poor's Depositary Receipts (''SPDR''), S&P 500 Exchange Traded Funds (''SPY''), etc.) listed on a market. ''Risk drivers'' are a selected set of securities or market indices (*e.g.,* SPX or VIX) that are used to represent the main sources or drivers for the price changes of the risk factors.

The Methodology Description currently contains a non-exhaustive, sample set of risk drivers as of March 2018. OCC is proposing to replace the sample set of risk drivers with a more general list of risk drivers that may be used per risk factor type to ensure the ongoing accuracy and clarity of OCC's methodology documentation as the risk drivers change through the STWG governance process. The proposed revisions would also provide additional details around STWG's process for approving the addition, change or retiring of risk drivers. Changes to risk drivers may be based on, among other things: changing business needs, new product launches, open interest, or other changes in product mix. Moreover, when adding, changing, or retiring risk drivers, STWG would consider factors including, but not limited to: contract specifications (*e.g.* a derivative's underlying asset, the asset classification of a product), the relationship between proposed new products and existing risk drivers, the correlation between risk drivers and risk factors, and/or quality of available data. STWG may also approve the retirement and removal of a risk driver that has no risk factors mapped to it or if the risk driver itself is delisted. In addition, OCC would revise the methodology description to further clarify that, unlike annual recalibrations, the STWG would only approve quarterly recalibration of risk driver shocks when warranted (and not as a matter of course). OCC The Methodology Description would also be updated to note that risk drivers and their mappings are maintained by the STLRM group and are available in the stress testing system. OCC does not believe that these proposed changes constitute a material or substantive change in OCC's Methodology Description but rather more appropriately documents OCC's process for maintaining and updating risk drivers.[26]

In addition, OCC proposes to revise the Methodology Description to provide a more straightforward discussion of the modeling of risk factor returns and price shocks for Hypothetical and Historical Scenarios and for OCC's various cleared products. Specifically, OCC proposes clarifying, streamlining, and organizational changes to the description of its modeling of volatility shocks for risk factors with SPX as the risk driver and for non-SPX driven risk factors. The proposed changes would also provide additional details on OCC's volatility modeling for flexibly structured options (or ''flex options''),[27] for which shocked implied volatility is calculated from shocked implied volatilities of regular options.

OCC also proposes to replace a section specifically discussing price shocks for products where the underlying security is a basket of deliverable obligation securities with a more generalized discussion of OCC's approach to modeling price shocks for products with multiple risk factors as the underlying. In this case, the Methodology Description would describe how the underlyings are shocked by applying the one-factor model to each component risk factor. In addition, this proposed change would eliminate a restriction limiting the methodology to an ''all or none'' approach where price shocks are modeled using either all historical shocks or all shocks derived from OCC's beta methodology [28] to provide appropriate flexibility for OCC to determine price shocks on an individual risk factor basis depending on whether historical data is available. This allows for consistency between the shocks of the basket and the shocks used to price products on the basket's components. The Methodology Description would also be revised to describe how, in the case of a leveraged product, shocks are determined using a leverage ratio with respect to its tracking index used as the default beta. OCC believes the proposed changes are more generally aligned with the intended purpose of the Methodology Description, which is designed, in general, to provide a general description of the materials aspects of OCC's stress testing and Clearing Fund methodologies.

Additionally, OCC proposes to correct a reference to the use of log returns in the calculation of volatility shocks to more accurately state that these calculations are currently made using two-day arithmetic returns. OCC's stress testing methodology utilizes two-day arithmetic returns to calculate these shocks to align with OCC's two-day liquidation horizon assumption for its margin methodology and the arithmetic returns used in its dynamic VIX calibration process.[29]

OCC also proposes to clarify that implied volatility shocks for Systemic Scenarios are based on the expected risk, or ''variance,'' of the risk factor in a forward-looking period after the price shock as opposed to the ''standard deviation.'' OCC believes that using the terms ''variance'' or ''standard deviation'' are essentially equivalent ways to describe the equation; however, the term ''variance'' would more accurately reflect the terms of equation used in the document.

Proposed Changes to Description of Calibrations

OCC proposes to revise its Methodology Description to more correctly describe the approach for generating shocks for U.S. Treasuries and Canadian Government Bond by replacing the term ''covariance'' with ''correlation.'' While the calibration does use a covariance matrix, the inputs to the calibration are normalized by their standard deviation and so the resulting matrix actually contains correlations. The correlation matrix is then scaled by standard deviation terms to generate interest rate shocks.[30]

Proposed Changes to Description of Stress Test Scenarios

Finally, OCC proposes to revise the Methodology Description to provide additional clarity around the use and calibration of risk driver shocks in Hypothetical, Historical and Idiosyncratic Scenarios. OCC would also remove specific references to certain risk drivers and parameters that are subject to periodic review and change through its internal governance processes. OCC would also update the sample table of stress test scenarios in the document to: (1) Reflect the addition of the proposed Idiosyncratic Scenarios; (2) remove Informational Scenarios from the table, which do not drive financial resource determinations and are subject to periodic change; and (3) provide additional information on the type of price shock used for each scenario in

[26] OCC notes that the Methodology Description would continue to specify that SPX and VIX are the main risk drivers for shocks of equity risk factors as equity risk factors make up the vast majority of volume, open interest, and risk at OCC. Due to the nature of equity risk factors, OCC's stress testing methodology treats equity risk factors in a standard and consistent fashion with respect to the mapping of risk drivers. Non-equity products, such as commodity futures and certain exchange-traded products (*e.g.,* ETFs and ETNs), may have different risk drivers or risk drivers may change due to the evolving nature of the securities markets and the products OCC clears. Consequently, OCC believes it is necessary to maintain appropriate flexibility to adjust risk drivers as evolving circumstances warrant through the established STWG governance process.

[27] Flex options are options that give investors the ability to customize basic option features including size, expiration date, exercise style, and certain exercise prices that do not correspond to the terms of any series of non-flexibly structured options previously opened for trading on an Exchange. *See* OCC By-Laws, Article I., Section 1.F.(8).

[28] The ''beta'' is the sensitivity of a security with respect to its corresponding risk driver (*i.e.,* the sensitivity of the price of the security relative to the price of the risk driver).

[29] *See supra* note 7.

[30] OCC notes that this is a standard practice. *See* Litterman, Robert and Sheinkman, Jose, ''Common Factors Affecting Bond Returns,'' *Journal of Fixed Income,* 1991.

the table. In addition, OCC proposes to remove certain language from the document that provides qualitative justification for OCC's Clearing Fund allocation methodology but does not have any relevance to the actual calculation of Clearing Fund allocations.

Clearing Member Outreach

To inform Clearing Members of the proposed changes, OCC has provided an overview of the proposed changes to the Financial Risk Advisory Council (''FRAC''), a working group comprised of exchanges, Clearing Members and indirect participants of OCC. OCC has also performed direct outreach to Clearing Members that would be most impacted by the proposed changes. To-date, OCC has not received any material objections or concerns in response to this outreach.

Implementation Timing

OCC expects to implement the proposed changes within sixty (60) days after the date that OCC receives all necessary regulatory approvals for the proposed changes. OCC will announce the implementation date of the proposed change by an Information Memorandum posted to its public website at least two (2) weeks prior to implementation.[31]

Expected Effect on and Management of Risk

OCC believes the proposed changes are designed to enhance OCC's overall framework for managing credit risk. The introduction of the proposed Idiosyncratic Scenarios would enhance OCC's stress testing methodology and overall resiliency by providing a more comprehensive suite of Sizing Stress Tests to ensure that OCC maintains an appropriate level of Pre-Funded Financial Resources to cover its credit exposures under scenarios addressing both systemic market risks and idiosyncratic risks. As noted above, OCC's Sizing Stress Tests are used to establish the monthly size of the Clearing Fund necessary for OCC to maintain sufficient Pre-Funded Financial Resources to cover losses arising from the default of the two Clearing Member Groups that would potentially cause the largest aggregate credit exposure to OCC in extreme but plausible market conditions. The proposed Idiosyncratic Scenarios would supplement OCC's current set of Sizing Scenarios (which are generally designed to estimate risk exposures arising from more broad-based market and systemic shocks reflected in OCC's Systemic Scenarios) by enabling OCC to appropriately consider the risks of extreme moves in individual or small subsets of securities. OCC therefore believes that the proposed rule change would enhance OCC's overall framework for managing credit risks and reduce the risk that its Pre-Funded Financial Resources would be insufficient in the event of a Clearing Member default.

In addition, OCC proposes to enhance its stress testing methodology to more accurately and appropriately model price shocks for VIX futures. Under OCC's current stress testing methodology, prices shocks for VIX futures are equivalent to the price shock for the underlying VIX index. OCC believes that this approach is unrealistic in that it produces a uniform shock across expirations of the VIX futures contract, which leads to an overestimation of VIX futures price shocks, particularly in market decline scenarios. OCC therefore proposes to enhance its stress testing methodology to produce more appropriate VIX futures price shocks that would vary based on the expiration of contracts as is more realistically observed in the market.[32] OCC believes the proposed changes would enhance OCC's framework for managing credit risk because it would result in more accurate and realistic stress testing results.

OCC also proposes to revise the Policy to require that STLRM provide written notification to the Office of the CEO whenever a Sufficiency Stress Test margin call imposed on an individual Clearing Member exceeds 75% of the Clearing Member's excess net capital. The proposed change would allow OCC's senior management to be informed of, and to subsequently monitor, circumstances where a margin call may strain a particular Clearing Member's ability to meet such requirements based on its financial condition or the amount of collateral it has available to pledge when certain pre-identified thresholds have been exceeded. OCC believes the proposed rule change would improve its process for monitoring and managing credit risk, particularly those risks that may be identified in the Sufficiency Stress Test margin call process, and allow OCC to take steps to reduce potential default risks for its Clearing Members.

OCC proposes to standardize the margin risk component of its Clearing Fund allocation formula by using only STANS-based margin requirements for all Clearing Members. OCC believes it is appropriate to use the same margin risk measurement for all Clearing Members/accounts when determining Clearing Fund allocations since this allows for a more equitable comparison across all accounts through the utilization of a consistent margin methodology. OCC believes that the proposed changes would result in an allocation formula that determines Clearing Member contribution requirements that are commensurate to the risks posed by each Clearing Member.

Consistency With the Payment, Clearing and Settlement Supervision Act

The stated purpose of the Clearing Supervision Act is to mitigate systemic risk in the financial system and promote financial stability by, among other things, promoting uniform risk management standards for systemically important financial market utilities and strengthening the liquidity of systemically important financial market utilities.[33] Section 805(a)(2) of the Clearing Supervision Act[34] also authorizes the Commission to prescribe risk management standards for the payment, clearing and settlement activities of designated clearing entities, like OCC, for which the Commission is the supervisory agency. Section 805(b) of the Clearing Supervision Act[35] states that the objectives and principles for risk management standards prescribed under Section 805(a) shall be to:

- Promote robust risk management;
- promote safety and soundness;
- reduce systemic risks; and
- support the stability of the broader financial system.

OCC believes that the proposed changes described herein are consistent with the objectives and principles of Section 805(b) of the Clearing Supervision Act[36] and the risk management standards adopted by the Commission in Rule 17Ad–22 under the Act for the reasons set forth below.[37]

[31] OCC notes that the impact of certain changes, such as the proposed changes to the Clearing Fund allocation formula and potential for a new Idiosyncratic Scenario to set the size of the Clearing Fund, will not occur until the first monthly resizing of the Clearing Fund following the announced implementation date.

[32] Additionally, because VIX futures are used to calculate theoretical values for VIX options, the proposed enhancement would improve the pricing of both VIX futures and VIX options in OCC's stress testing methodology.

[33] 12 U.S.C. 5461(b).

[34] 12 U.S.C. 5464(a)(2).

[35] 12 U.S.C. 5464(b).

[36] *Id.*

[37] 17 CFR 240.17Ad–22. *See* Securities Exchange Act Release Nos. 68080 (October 22, 2012), 77 FR 66220 (November 2, 2012) (S7–08–11) (''Clearing Agency Standards''); 78961 (September 28, 2016), 81 FR 70786 (October 13, 2016) (S7–03–14) (''Standards for Covered Clearing Agencies''). OCC is a ''covered clearing agency'' as defined in Rule 17Ad–22(a)(5) and therefore must comply with the requirements of Rule 17Ad–22(e).

OCC believes the proposed changes are consistent with the objectives and principles of Section 805(b) of the Clearing Supervision Act.[38] The proposed changes are designed to enhance OCC's overall framework for managing credit risk. The proposed changes would introduce new Idiosyncratic Scenarios to provide for a more comprehensive suite of Sizing Stress Tests and ensure that OCC maintains an appropriate level of Pre-Funded Financial Resources to cover its credit exposures under scenarios addressing both systemic market risks and idiosyncratic risks. OCC also proposes to enhance its stress testing methodology to more accurately and appropriately model price shocks for VIX futures. Additionally, OCC proposes to standardize the margin risk component of its Clearing Fund allocation formula by using only STANS-based margin requirements for all Clearing Members, which would allow for a more equitable comparison across all accounts through the utilization of a consistent margin methodology, and result in an allocation formula that determines Clearing Member contribution requirements that are commensurate to the risks posed by each Clearing Member. Moreover, OCC proposes to enhance its process for monitoring and managing credit risk, particularly those risks that may be identified in the Sufficiency Stress Test margin call process, and allow OCC to take steps to reduce potential default risks for its Clearing Members. OCC believes the proposed changes are generally designed to promote robust risk management, promote safety and soundness, reduce systemic risks, and support the stability of the broader financial system in accordance with the objectives and principles of Section 805(b) of the Clearing Supervision Act.[39]

OCC also believes the proposed changes are consistent with the risk management standards adopted by the Commission in Rule 17Ad–22 under the Act. Rule 17Ad–22(b)(3)[40] requires a registered clearing agency that performs central counterparty services to establish, implement, maintain and enforce written policies and procedures reasonably designed to maintain sufficient financial resources to withstand, at a minimum, a default by the participant family to which it has the largest exposure in extreme but plausible market conditions. Rules 17Ad–22(e)(4)(iii) and (iv)[41] further require, in part, that a covered clearing agency establish, implement, maintain and enforce written policies and procedures reasonably designed to effectively identify, measure, monitor, and manage its credit exposures to participants and those arising from its payment, clearing, and settlement processes, including by maintaining additional financial resources (beyond those collected as margin or otherwise maintained to meet the requirements of Rule 17Ad–22(e)(4)(i))[42] at the minimum to enable it to cover a wide range of foreseeable stress scenarios that include, but are not limited to, the default of the participant family that would potentially cause the largest aggregate credit exposure for the covered clearing agency in extreme but plausible market conditions and do so exclusive of assessments for additional guaranty fund contributions or other resources that are not prefunded.

The proposed rule change would enhance OCC's stress testing methodology and overall resiliency by providing a more comprehensive suite of Sizing Stress Tests to ensure that OCC maintains appropriate level of Pre-Funded Financial Resources to cover its credit exposures under scenarios addressing both systemic market risks and idiosyncratic risks. The proposed Idiosyncratic Scenarios would supplement OCC's current set of Sizing Scenarios, which are generally designed to estimate risk exposures arising from more broad-based market and systemic shocks reflected in OCC's Systemic Scenarios, by enabling OCC to appropriately consider the risks of extreme moves in individual or small subsets of securities. OCC therefore believes that the proposed rule change would enhance OCC's overall framework for managing credit risks and reduce the risk that its Pre-Funded Financial Resources would be insufficient in an actual default.

In addition, OCC proposes to enhance its stress testing methodology by using SPX at-the-money implied volatility shocks across different expirations to model price shocks for VIX futures contracts for corresponding expirations as opposed to using a uniform shock for all expirations. The proposed rule change is designed to more accurately measure OCC's credit exposure in its stress scenarios by producing price shocks for VIX futures that would vary based on the expiration as is more realistically observed in the market.

Taken together, OCC believes the proposed changes are reasonably designed so that OCC can measure its credit exposures to its participants and manage such exposures by maintaining sufficient financial resources at a minimum to enable it to cover a wide range of foreseeable stress scenarios that include, but are not limited to, the default of the participant family that would potentially cause the largest aggregate credit exposure for OCC in extreme but plausible market conditions (and do so exclusive of assessments for additional Clearing Fund contributions or other resources that are not prefunded). For these reasons, OCC believes the proposed changes are consistent with Rule 17Ad–22(b)(3) and Rules 17Ad–22(e)(4)(iii) and (iv).[43]

Furthermore, Rule 17Ad–22(e)(4)[44] generally requires that a covered clearing agency establish, implement, maintain and enforce written policies and procedures reasonably designed to effectively identify, measure, monitor, and manage its credit exposures to participants and those arising from its payment, clearing, and settlement processes. OCC believes the proposed changes to its Sufficiency Stress Test monitoring process would improve its overall processes for monitoring and managing credit risk. OCC would revise the Policy to require that STLRM provide written notification to the Office of the CEO whenever a Sufficiency Stress Test margin call imposed on an individual Clearing Member exceeds 75% of the Clearing Member's excess net capital (in addition to the current requirement to provide notification for any margin call exceeding $500 million). The proposed change would allow OCC's senior management to be informed of, and to subsequently monitor, circumstances where a margin call may strain a particular Clearing Member's ability to meet such requirements based on its financial condition or the amount of collateral it has available to pledge when certain pre-identified thresholds have been exceeded. OCC therefore believes the proposed rule change is reasonably designed to help OCC identify, measure, and monitor its credit exposures to participants, particularly those identified through Sufficiency Stress Test margin calls, consistent with Rule 17Ad–22(e)(4).[45]

[38] 12 U.S.C. 5464(b).

[39] *Id.*

[40] 17 CFR 240.17Ad–22(b)(3).

[41] 17 CFR 240.17Ad–22(e)(4)(iii) and (iv).

[42] 17 CFR 240.17Ad–22(e)(4)(i).

[43] 17 CFR 240.17Ad–22(b)(3) and (e)(4)(iii) and (iv).

[44] 17 CFR 240. 17Ad–22(e)(4).

[45] *Id.* OCC also believes that the proposed change to the Policy would: (1) Provide for governance arrangements that specify clear and direct lines of responsibility consistent with the requirements of

Continued

OCC also believes that the proposed changes to standardize the margin risk component of its Clearing Fund allocation formula by using only STANS-based margin requirements for all Clearing Members are reasonably designed to measure and manage its credit exposures to participants. With respect to the use of Clearing Funds and the requirements of Rule 17Ad–22(e)(4),[46] the Commission has noted that, to the extent that a clearing agency uses guaranty or clearing fund contributions to mutualize risk across participants, the clearing agency generally should value margin and guaranty fund contributions so that the contributions are commensurate to the risks posed by the participants' activity.[47] OCC believes it is appropriate to use the same margin risk measurement for all Clearing Members/accounts when determining Clearing Fund allocations since this allows for a more equitable comparison across all accounts and would result in contribution requirements that are commensurate to the risks posed by each Clearing Member. As a result, OCC believes the proposed changes are reasonably designed to comply with the requirements of Rule 17Ad–22(e)(4).[48]

Rule 17Ad–22(e)(4)(ix)[49] requires that a covered clearing agency establish, implement, maintain and enforce written policies and procedures reasonably designed to effectively identify, measure, monitor, and manage its credit exposures to participants and those arising from its payment, clearing, and settlement processes, including by describing its process to replenish any financial resources it may use following a default or other event in which use of such resources is contemplated. OCC believes the proposed changes to its cooling-off period and associated assessment cap Rules would ensure that the cooling-off period and associated assessment caps are consistently applied for any proportionate charge resulting from any of the events described in clauses (i) through (vi) of Rule 1006(a) and thereby ensure that OCC can fully access, utilize, and replenish its Clearing Fund resources to address any losses chargeable against the Clearing Fund and manage its credit exposures to participants and those arising from its payment, clearing, and settlement processes in a manner consistent with Rule 17Ad–22(e)(4)(ix).[50]

Finally, OCC believes the proposed clarifying, organizational, and streamlining changes to its Rules, Policy, and Methodology Description would improve the clarity and readability of its stress testing and Clearing Fund-related rules and policies are therefore consistent with the Rule 17Ad–22(e)(4)[51] requirement that OCC maintain policies and procedures that are reasonably designed to effectively identify, measure, monitor, and manage its credit exposures to participants and those arising from its payment, clearing, and settlement processes.

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 the proposed change was filed with the Commission or (ii) the date any additional information requested by the Commission is received. OCC 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.

OCC 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–OCC–2019–806 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–OCC–2019–806. 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 office of the self-regulatory organization.

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–2019–806 and should be submitted on or before November 27, 2019.

By the Commission.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–24548 Filed 11–8–19; 8:45 am]

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Rule 17Ad–22(e)(2)(v) and (2) contribute to a sound risk management framework for identifying, measuring, monitoring and managing credit and other risks that arise in or are borne by OCC in furtherance of the requirements of Rule 17Ad–22(e)(3)(i). *See* 17 CFR 240.17Ad–22(e)(2)(v) and 17 CFR 240.17Ad–22(e)(3)(i).

[46] *Id.*

[47] *See* Securities Exchange Act Release No. 78961 (September 28, 2016), 81 FR 70786 (October 13, 2016) (S7–03–14) (''Standards for Covered Clearing Agencies'') at 70813.

[48] *Id.*

[49] 17 CFR 240. 17Ad–22(e)(4).

[50] *Id.*

[51] 17 CFR 240. 17Ad–22(e)(4).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87463; File No. SR–C2–2019–023]

Self-Regulatory Organizations; Cboe C2 Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Introduce a New Data Product To Be Known as Open-Close Data and To Adopt Fees for Such Product

November 5, 2019.

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 October 29, 2019, Cboe C2 Exchange, Inc. (the ''Exchange'' or ''C2'') 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 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 C2 Exchange, Inc. (the ''Exchange'' or ''C2'') is filing with the Securities and Exchange Commission (''Commission'') a proposed rule change to introduce a new data product to be known as Open-Close Data and to adopt fees for such product. The text of the proposed rule change is provided bin [sic] 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/ctwo/*), 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 introduce a new data product on C2 to be known as Open-Close Data, which will be available for purchase to C2 Trading Permit Holders (''TPHS'') and non-TPHs and also adopt fees for Open-Close Data. Cboe LiveVol, LLC (''LiveVol''), a wholly owned subsidiary of the Exchange's parent company, Cboe Global Markets, Inc., will make the Open-Close Data available for purchase to TPHs and non-TPHs on the LiveVol DataShop website (*datashop.cboe.com*).[5]

More specifically, Open-Close Data is a volume summary file for trading activity on C2 Options. The Exchange notes it is proprietary C2 trade data and does not include trade data from any other exchanges. It is also a historical data product and not a real time data feed. The Open-Close Data summarizes and buckets the volume by origin (customer, professional customer, broker-dealer, and market maker), buying/selling, and opening/closing criteria. The customer and professional customer volume is further broken down into trade size buckets (less than 100 contracts, 100–199 contracts, greater than 199 contracts). The data currently goes back to January 2018 and contains all series in an underlying security if it has volume.[6] The Exchange anticipates a wide variety of market participants to purchase Open-Close Data, including, but not limited to, individual customers, buy-side investors, investment banks and academic institutions. For example, the Exchange notes that academic institutions may utilize the proposed Open-Close Data and as a result promote research and studies of the options industry to the benefit of all market participants. The Exchange believes the proposed Open-Close Data product may also provide helpful trading information regarding investor sentiment and may be used to create and test trading models and analytical strategies and provides comprehensive insight into trading on C2. It is a completely voluntary product, in that the Exchange is not required by any rule or regulation to make this data available and that potential subscribers may purchase it only if they voluntarily choose to do so. The Exchange notes that its affiliate, Cboe Exchange, Inc. (''Cboe Options''), as well as other exchanges, offer a similar data product.[7]

The Exchange proposes to provide in its Fee Schedule that TPHs and non-TPHs may purchase Open-Close Data on a subscription basis (end of day file) or by ad hoc request for a specified month (historical file). The Exchange proposes to assess a monthly fee of $500 for subscribing to a daily update which will consist of Open/Close data covering all Exchange-listed securities. TPHs and non-TPHs purchasing Open/Close data on a subscription basis will receive access to a daily data file. The Exchange proposes to assess a fee of $400 per request per month for an ad-hoc request of historical Open/Close data covering all Exchange-listed securities. An ad-hoc request can be for any number of months beginning with January 2018 for which the data is available.[8] The proposed subscription and ad-hoc fees will apply both to TPHs or non-TPHs. The Exchange notes that other exchanges, including its affiliate Exchange Cboe Exchange, Inc. (''Cboe Options'') provide similar data products that may be purchased on both a subscription and ad-hoc basis and are similarly priced.[9]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[10] in general, and furthers the objectives of Section 6(b)(5) of the Act,[11] 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 to protect investors and the

[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).

[5] The Exchange initially filed the proposed fee changes on business date August 30, 2019 (SR–C2–2019–019). On business date October 29, 2019, the Exchange withdrew that filing and submitted this filing.

[6] The Open-Close data file format specifications can be found at *https://datashop.cboe.com/Themes/Livevol/Content/static/OpenCloseSpecification.pdf*

[7] *See* Securities Exchange Act Release No. 55062 (January 8, 2007), 72 FR 2048 (January 17, 2007) (approving SR–CBOE–2006–88); *See also* Securities Exchange Act Release No. 56254 (August 15, 2007), 72 FR 47104 (August 22, 2007) (SR–ISE–2007–70).

[8] For example, a TPH or non-TPH that requests historical Open/Close Data for the months of October 2018 and November 2018, would be assessed a total of $800. The Exchange notes that it may make historical data prior to January 2018 available in the future and that such historical data would be available to all TPHs or non-TPHs.

[9] *See e.g.,* Cboe Options Fees Schedule, Livevol Fees, Open-Close Data. *See also* Nasdaq ISE Options 7 Pricing Schedule, Section 10.A.

[10] 15 U.S.C. 78f.

[11] 15 U.S.C. 78f(b)(5).

public interest, and that it is not designed to permit unfair discrimination among customers, brokers, or dealers. The Exchange also believes that its proposal to adopt fees for Open-Close Data is consistent with Section 6(b) of the Act in general, and furthers the objectives of Section 6(b)(4) of the Act [12] in particular, in that it is an equitable allocation of dues, fees and other charges among its members and other recipients of Exchange data.

In adopting Regulation NMS, the Commission granted self-regulatory organizations (''SROs'') 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. The Exchange believes that the proposed Open-Close Data would further broaden the availability of U.S. option market data to investors consistent with the principles of Regulation NMS. The proposal also promotes increased transparency through the dissemination of Open-Close Data. The proposed rule change would benefit investors by providing access to the Open-Close Data, which as noted above, may promote better informed trading, as well as research and studies of the options industry. Particularly, information regarding opening and closing activity across different option series may indicate investor sentiment, which can be helpful research and/or trading information. Subscribers to the data may be able to enhance their ability to analyze option trade and volume data, and create and test trading models and analytical strategies. The Exchange believes Open-Close Data provides a valuable tool that subscribers can use to gain comprehensive insight into the trading activity in a particular series, but also emphasizes such data is not necessary for trading. Moreover, the Exchange's affiliate Cboe Options, along with other exchanges, also offer a similar data product.[13]

The Exchange operates in a highly competitive environment. Indeed, there are currently 16 registered options exchanges that trade options. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Particularly, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [14] Making similar data products available to market participants fosters competition in the marketplace, and constrains the ability of exchanges to charge supracompetitive fees. In the event that a market participant views one exchange's data product as more or less attractive than the competition they can and do switch between similar products. The proposed fees are a result of the competitive environment, as the Exchange seeks to adopt fees to attract purchasers of the proposed Open-Close Data product.

The Exchange believes the proposed fees are reasonable as the proposed fees are both modest and similar to, or even lower than, the fees assessed by other exchanges that provide similar data products.[15] Indeed, proposing fees that are excessively higher than established fees for similar data products would simply serve to reduce demand for the Exchange's data product, which as noted, is entirely optional. Like the Exchange's proposed Open-Close Data product, other exchanges offer similar data products that each provide insight into trading on those markets and may likewise aid in assessing investor sentiment. Although each of these similar open-close data products provide only proprietary trade data and not trade data from other exchanges, it's possible investors are still able to gauge overall investor sentiment across different option series based on open and closing interest on any one exchange.[16] Similarly, market participants may be able to analyze option trade and volume data, and create and test trading models and analytical strategies using only open-close data relating to trading activity on one or more of the other markets that provide similar data products. As such, if a market participant views another exchange's open-close data as more attractive than its proposed open-close data product, then such market participant can merely choose not to purchase the Exchange's Open-Close Data and instead purchase another exchange's open-close data product, which offer similar data points, albeit based on that other market's trading activity.

The Exchange also believes the proposed fees are reasonable as they would support the introduction of a new market data product that is designed to aid investors by providing insight into trading on C2 Options. The proposed Open-Close Data would provide options market participants with valuable information about opening and closing transactions executed on the Exchange, similar to other historical trade data products offered by competing options exchanges. In turn, this data would assist market participants in gauging investor sentiment and trading activity, resulting in potentially better informed trading decisions. As noted above, users may also use such data to create and test trading models and analytical strategies.

Selling historical market data, such as Open-Close Data, is also a means by which exchanges compete to attract business. To the extent that the Exchange is successful in attracting subscribers for the Open-Close Data, it may earn trading revenues and further enhance the value of its data products. If the market deems the proposed fees to be unfair or inequitable, firms can diminish or discontinue their use of the data and/or avail themselves of similar products offered by other exchanges.[17] The Exchange therefore believes that the proposed fees for Open-Close Data reflect the competitive environment and would be properly assessed on TPH or non-TPH users. The Exchange also believes the proposed fees are equitable and not unfairly discriminatory as the fees would apply equally to all users who choose to purchase such data. The Exchange's proposed fees would not differentiate between subscribers that purchase Open-Close Data, and are set at a modest level that would allow any interested TPH or non-TPH to purchase such data based on their business needs.

As noted above, the Exchange anticipates a wide variety of market participants to purchase Open-Close Data, including but not limited to individual customers, buy-side investors, investment banks and academic institutions. For example, on its affiliate exchange Cboe Options, which also offers an Open-Close Data

[12] 15 U.S.C. 78f(b)(4).

[13] *See* Securities Exchange Act Release No. 55062 (January 8, 2007), 72 FR 2048 (January 17, 2007) (approving SR–CBOE–2006–088); *See also* Securities Exchange Act Release No. 56254 (August 15, 2007), 72 FR 47104 (August 22, 2007) (SR–ISE–2007–70).

[14] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (''Regulation NMS Adopting Release'').

[15] *See e.g.,* Cboe Options Fees Schedule, Livevol Fees, Open-Close Data. *See also* Nasdaq ISE Options 7 Pricing Schedule, Section 10.A.

[16] The exchange notes that its open-close data product does not include data on any exclusive, singly-listed option series.

[17] *See e.g.,* Cboe Options Fees Schedule, Livevol Fees, Open-Close Data. *See also* Nasdaq ISE Options 7 Pricing Schedule, Section 10.A.

product, approximately 38% of purchases of historical ad hoc Open-Close Data files are individuals, 33% are buy-side investors or investment banks and 25% are academic institutions. Accordingly, the Exchange anticipates that open-close data may be used not just for commercial or monetizing purposes, but also for educational use and research. The Exchange reiterates that the decision as to whether or not to purchase the Open-Close Data is entirely optional for all potential subscribers. Indeed, no market participant is required to purchase the Open-Close Data, and the Exchange is not required to make the Open-Close Data available to all investors. Rather, the Exchange is voluntarily making historical Open-Close Data available, as requested by customers, and market participants may choose to receive (and pay for) this data based on their own business needs. Potential purchasers may request the data at any time if they believe it to be valuable, or may decline to purchase such data.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange 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. Rather, the Exchange believes that the proposal will promote competition by permitting the Exchange to introduce and sell a data product similar to those offered by other competitor options exchanges.[18] The Exchange is proposing to introduce Open-Close Data in order to keep pace with changes in the industry and evolving customer needs, and believes this proposed rule change would contribute to robust competition among national securities exchanges. As noted, at least three other U.S. options exchanges offer a market data product that is substantially similar to the Open-Close Data. As a result, the Exchange believes this proposed rule change permits fair competition among national securities exchanges.

Furthermore, the Exchange operates in a highly competitive environment, and its ability to price the proposed data product is constrained by competition among exchanges that offer similar data products to their customers. As discussed, there are currently a number of similar products available to market participants and investors. At least three other U.S. options exchanges offer a market data product that is substantially similar to the Open-Close Data, which the Exchange must consider in its pricing discipline in order to compete for the market data.[19] For example, proposing fees that are excessively higher than established fees for similar data products would simply serve to reduce demand for the Exchange's data product, which as discussed, market participants are under no obligation to utilize. In this competitive environment, potential purchasers are free to choose which, if any, similar product to purchase to satisfy their need for market information. As a result, the Exchange believes this proposed rule change permits fair competition among national securities exchanges.

The Exchange also does not believe the proposed fees would cause any unnecessary or inappropriate burden on intermarket competition as other exchanges are free to introduce their own comparable data product and lower their prices to better compete with the Exchange's offering. The Exchange does not believe the proposed rule change would cause any unnecessary or inappropriate burden on intramarket competition. Particularly, the proposed product and fees apply uniformly to any purchaser, in that it does not differentiate between subscribers that purchase Open-Close Data. The proposed fees are set at a modest level that would allow any interested TPH or non-TPH to purchase such data based on their business needs.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act[20] and Rule 19b–4(f)(6)[21] thereunder. 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[22] and Rule 19b–4(f)(6)[23] thereunder.

A proposed rule change filed under Rule 19b–4(f)(6)[24] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[25] the Commission may designate a shorter time if such action is consistent with protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay to permit the Exchange to provide Open-Close Data to its three subscribers on an uninterrupted basis.[26] According to the Exchange, other exchanges offer a similar data product at similar prices, and the proposed rule change presents no new or novel issues. The Commission believes that waving the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission designates the proposed rule change to be 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 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,

[18] *Id.*

[19] *See e.g.,* Cboe Options Fees Schedule, Livevol Fees, Open-Close Data. *See also* Nasdaq ISE Options 7 Pricing Schedule, Section 10.A and Nasdaq PHLX Options 7 Pricing Schedule, Section 10, PHLX Options Trade Outline (''PHOTO'').

[20] 15 U.S.C. 78(b)(3)(A).

[21] 17 CFR 240.19b–4(f)(6).

[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 the Exchange to give the Commission written notice of the Exchange's 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] 17 CFR 240.19b–4(f)(6).

[25] 17 CFR 240.19b–4(f)(6).

[26] As noted above, the Exchange previously filed proposed fees for the Open-Close Data product on August 30, 2019, as effective immediately. *See supra,* note 5, and Securities Exchange Act Release 86928 (September 11, 2019), 84 FR 48968 (September 17, 2019) (noticing C2–2019–019). The Commission received only one comment letter on the proposed rule change from C2 withdrawing the filing. *See* Letter from Corinne Klott, Assistant General Counsel, C2, dated October 29, 2019. This filing withdrew and replaced the earlier filing.

[27] For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

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–C2–2019–023 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–C2–2019–023. 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–C2–2019–023 and should be submitted on or before December 3, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[28]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–24497 Filed 11–8–19; 8:45 am]

BILLING CODE 8011–01–P

[28] 17 CFR 200.30–3(a)(12)

SMALL BUSINESS ADMINISTRATION

[License No. 07/77–0197]

AAVIN Equity Partners I, L.P.; Surrender of License of Small Business Investment Company

Pursuant to the authority granted to the United States Small Business Administration under the Small Business Investment Act of 1958, as amended, under Section 309 of the Act and Section 107.1900 of the Small Business Administration Rules and Regulations (13 CFR 107.1900) to function as a small business investment company under the Small Business Investment Company License No. 07/77–0107 issued to AAVIN Equity Partners I, LP said license is hereby declared null and void.

A. Joseph Shepard,

Associate Administrator for Office of Investment and Innovation.

[FR Doc. 2019–24463 Filed 11–8–19; 8:45 am]

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DEPARTMENT OF STATE

[Public Notice:10941]

Notice of Determinations; Culturally Significant Objects Imported for Exhibition—Determinations: "Fiji: Art & Life in the Pacific" Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects to be included in the exhibition ''Fiji: Art & Life in the Pacific,'' imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at the Los Angeles County Museum of Art, Los Angeles, California, from on or about December 15, 2019, until on or about July 19, 2020; at the Peabody Essex Museum, Salem, Massachusetts, from on or about September 12, 2020, until on or about January 3, 2021; and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Chi D. Tran, Paralegal Specialist, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, and Delegation of Authority No. 236–3 of August 28, 2000.

Marie Therese Porter Royce,

Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2019–24656 Filed 11–8–19; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Transportation Project in Washington State

AGENCY: Federal Highway Administration (FHWA), Department of Transportation (DOT).

ACTION: Notice of Limitation on Claims for Judicial Review of Actions by FHWA.

SUMMARY: This notice announces actions taken by the FHWA that are final. The action relates to the creation of a reversible north-south transit and high occupancy vehicle lane connecting Mercer Street and SR 520 along the I–5 express lanes and other associated design refinements associated with SR 520, I–5 to Medina construction in the City of Seattle, King County, State of Washington.

DATES: A claim seeking judicial review of the Federal agency actions on the listed highway project will be barred unless the claim is filed on or before April 10, 2020. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: Susan Wimberly, Field Operations Team Leader, Federal Highway Administration, 711 S. Capitol Way, Suite 501, Olympia, WA 98501–1284, 360–753–9480, or *Washington.FHWA@dot.gov*; or Margaret Kucharski, Megaprograms Environmental Manager, Washington State Department of Transportation, 999 3rd Ave, Suite 2200, Seattle, WA 98104, 206–770–3500, or *Margaret.Kucharski@wsdot.wa.gov*.

SUPPLEMENTARY INFORMATION: On September 7, 2011, FHWA published a ''Notice of Final Federal Agency Actions on Proposed Highway in Washington'' in the **Federal Register** at 76 FR 55459 for the SR 520, I–5 to Medina: Bridge Replacement and HOV Project. Notice is hereby given that, subsequent to the earlier FHWA notice, FHWA has taken final agency actions within the meaning of 23 U.S.C. 139(l)(1) by issuing a NEPA re-evaluation for the SR 520 SR 520, I–5 to Medina: Bridge Replacement and HOV Project: I–5 Design Refinements (hereafter ''re-evaluation''). The action(s) by FHWA and the laws under which such actions were taken, are described in the re-evaluation and the associated agency records. That information is available by contacting FHWA at the addresses provided above.

The project proposed to improve safety and mobility for people and goods across Lake Washington by replacing the SR 520 Portage Bay and Evergreen Point bridges and improve existing roadway between Interstate 5 (I–5) in Seattle and Evergreen Point Road in Medina spanning 5.2 miles. The Final Environmental Impact Statement (EIS) for the project was published in January 2011 and the Record of Decision (ROD) was issued in August 2011.

Since issuance of the FHWA ROD, the design and construction approach has been refined such that a reversible north-south transit and high occupancy vehicle lane connecting Mercer Street and SR 520 along the I–5 express lanes would be constructed; and additional design changes would be implemented, including stormwater treatment improvement, revisions to the heights of proposed retaining walls, and replacement of fiber optic cable within the I–5 right-of-way. The re-evaluation considering these refinements was prepared in October 2019. It identifies and documents potential effects associated with the refinement. This notice only applies to the re-evaluation.

Information about the re-evaluation and associated records are available from FHWA and WSDOT at the addresses provided above and can be found at: *https://www.wsdot.wa.gov/Projects/SR520Bridge/Library/I5Medina.htm*. This notice applies to all Federal agency decisions related to the re-evaluation as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. *General:* National Environmental Policy Act (NEPA) [42 U.S.C. 4321–4347]; Federal-Aid Highway Act [23 U.S.C. 109].
2. *Air:* Clean Air Act, as amended [42 U.S.C. 7401–7671(q)].
3. *Land*: Section 6(f) of the Land and Water Conservation Fund Act of 1965 [16 U.S.C. 4601]; Section 4(f) of the Department of Transportation Act of 1966 [49 U.S.C. 303].
4. *Wildlife:* Anadromous Fish Conservation Act [16 U.S.C. 757(a–757(g)); Fish and Wildlife Coordination Act [16 U.S.C. 661–667(d)]; Magnuson-Stevens Fishery Conservation and Management Act of 1976, as amended [16 U.S.C. 1801 *et seq.*].
5. *Historic and Cultural Resources:* Section 106 of the National Historic Preservation Act of 1966, as amended [16 U.S.C. 470(f) *et seq.*]; Archaeological and Historic Preservation Act [16 U.S.C. 469–469(c)]; Native American Grave Protection and Repatriation Act (25 U.S.C. 3001–3013).
6. *Wetlands and Water Resources:* Clean Water Act, (Section 319 [33 U.S.C. 329]); Safe Drinking Water Act [42 U.S.C. 300(f)–300(j)(6)].
7. *Navigation:* Rivers and Harbors Act of 1899 [33 U.S.C. 403]; General Bridge Act of 1946 [33 U.S.C. 9 and 11].
8. *Executive Orders:* E.O. 11990 Protection of Wetlands; E.O. 11988 Floodplain Management; E.O. 12898 Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations; E.O. 11593 Protection and Enhancement of Cultural Resources; E.O. 13007 Indian Sacred Sites; E.O. 13287 Preserve America; E.O. 13175 Consultation and Coordination with Indian Tribal Governments; E.O. 11514 Protection and Enhancement of Environmental Quality; E.O. 13112 Invasive Species.

Authority: 23 U.S.C. 139(l)(1), as amended by Moving Ahead for Progress in the 21st Century Act, (Pub. L. 112–141, 126 Stat. 405).

Issued on: November 4, 2019.

Daniel M. Mathis,

FHWA Division Administrator, Olympia, WA.

[FR Doc. 2019–24571 Filed 11–8–19; 8:45 am]

BILLING CODE 4910–RY–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2018–0246]

Hours of Service of Drivers: HEPACO, LLC; Heritage Environmental Services, LLC; Lewis Environmental, Inc.; and Moran Environmental Recovery, LLC; Application for Exemption

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to deny the joint application from HEPACO, LLC; Heritage Environmental Services, LLC; Lewis Environmental, Inc.; and Moran Environmental Recovery, LLC, for exemption from the hours-of-service (HOS) regulations for drivers engaged in providing direct assistance in actual and potential environmental emergencies. FMCSA analyzed the exemption application and the public comments received in response to the Agency's August 9, 2018, notice announcing receipt of the request. The Agency has concluded there is no basis for determining that the terms and conditions of an exemption would achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption.

DATES: This decision is effective November 12, 2019.

FOR FURTHER INFORMATION CONTACT: Mr. Richard Clemente, FMCSA Driver and Carrier Operations Division; Telephone: (202) 366–2722; email: *MCPSD@dot.gov.* If you have questions on viewing or submitting material to the docket, contact Docket Services, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *www.regulations.gov* and insert the docket number, FMCSA–2018–0246 in the ''Keyword'' box and click ''Search.'' Next, click the ''Open Docket Folder'' button and choose the document to review. If you do not have access to the internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315 to grant exemptions from certain Federal Motor Carrier Safety Regulations (FMCSRs). FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted. The Agency must provide an opportunity for public comment on the request.

The Agency reviews the safety analyses and public comments submitted and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305). The decision of the Agency must be published in the **Federal Register** (49 CFR 381.315(b)) with the reasons for denying or granting the application and, if granted, the name of the person or class of persons receiving the exemption, and the regulatory provision from which the exemption is granted. The notice must specify the effective period (up to 5 years) and explain its terms and conditions. The exemption may be renewed (49 CFR 381.300(b)).

III. Request for Exemption

The following companies applied for this exemption: HEPACO, LLC; Heritage Environmental Services, LLC; Lewis Environmental, Inc. and Moran Environmental Recovery, LLC. They all are members of the Spill Control Association of America (SCAA), which filed the exemption application on their behalf. Together, the four companies have 758 commercial driver's license holders and 840 commercial motor vehicles (CMVs). In responding to emergency incidents, these companies work alongside a mix of both private industry and public agencies. Often, their work often has a direct impact on protecting both public safety and the environment. They are required contractually to provide direct assistance to responsible parties who are experiencing actual or potential environmental emergencies, defined as a sudden threat to the public health or the well-being of the environment, arising from the release of oil, radioactive materials, or hazardous chemicals into the air, land or water. Their employees are hybrid driver/operator/technicians, whose work challenges the limits on total on-duty time, especially after hours. In addition, the applicant references the current driver shortage and argues that obtaining drivers with the necessary additional skills and experience is problematic.

The applicants requested relief from 49 CFR 395.3(a)(2), commonly known as the ''14-hour rule.'' The applicants state that the HOS limitations have always been an issue for emergency response companies. They request this exemption to allow these four companies to respond to a release or threat of a release of oil and other hazardous materials, subject to the following conditions for each driver:

- The on-duty period may not exceed 4.5 additional hours for a total of 18.5 hours of non-consecutive on-duty time before the required reset;
- Driving time for drivers who exceed the 14-hour period may not exceed 8 hours;
- Driving is not permitted after 70 hours on duty in 8 days;
- Drivers must take 10 hours off duty following the duty day; and
- All drivers must comply with the electronic logging device rule.

According to the applicants, the initial response hours are the most critical in an environmental emergency and the ability to quickly respond is vital. These companies' drivers typically drive 1–2 hours each way to and from the incident. In no case, would these companies' drivers exceed 8 hours of drive time per incident. SCAA states that if the exemption is not granted, there could be a disruption of national/regional commerce, including delays in power restoration and protection of interstate commerce and infrastructure.

The applicants believe that the proposed relief, and the parameters in which their drivers operate, would continue to provide the highest level of safety and compliance, while prudently responding to incidents that threaten public safety and the environment. A copy of the application for exemption is available for review in the docket for this notice.

IV. Public Comments

On August 9, 2018, FMCSA published notice of this application and requested public comment (83 FR 39498). The Agency received six comments—two from spill response contractors and four from individuals. Three individuals and both spill response contractors support the proposed exemption.

One commenter opposed the application, stating ''[p]lease do not allow this exemption. This is a wonderful opportunity to hire more employees, should they need to work more than 14 hours in a day. This has been in effect for many years, and for safety no driver should be allowed to work more than 14 hours.''

V. FMCSA Decision

FMCSA has evaluated SCAA's application and the public comments submitted and hereby denies the exemption. When the Agency established the rules mandating HOS, it relied upon research indicating that the rules improve CMV safety. These regulations put limits in place for when and how long an individual may drive to ensure that drivers stay awake and alert while driving and to reduce the possibility of driver fatigue.

Based on the body of research underlying the HOS requirements, there is no basis for granting an exemption that would allow an individual to drive after the 18th hour of coming on duty. Although SCAA explained that drivers would not exceed 8 hours of driving time during a work shift, the Agency does not believe there is a basis for concluding that the 8-hour limit on driving time offsets the potential increase in safety risks associated with an 18.5 hour driving window.

Except for the limit on driving time, the applicants would comply with all the other applicable HOS requirements, including using electronic logging devices and requiring drivers to take 10 consecutive hours off-duty at the end of the work shift. The applicants are essentially requesting that the 14-hour rule be extended by 4.5 hours in exchange for a 3-hour reduction in the driving time limit. The Agency does not find this safety tradeoff to be persuasive.

The SCAA application does not analyze the safety impacts the exemption may cause nor does it provide countermeasures to ensure that the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulations. Furthermore, the applicant did not clearly define the conditions that would trigger the exemption.

Issued on: November 5, 2019.

Jim Mullen,

Deputy Administrator.

[FR Doc. 2019–24526 Filed 11–8–19; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2019–0066]

Petition for Waiver of Compliance and Notice of Public Hearing

Under part 211 of title 49 Code of Federal Regulations (CFR), this document provides the public notice that by a letter dated April 23, 2019, the National Railroad Passenger Corporation (Amtrak) petitioned the Federal Railroad Administration (FRA) for an exemption from certain requirements of chapter 203, title 49 of the United States Code (U.S.C.). FRA assigned the petition Docket Number FRA–2019–0066.

Amtrak's request for relief relates to its planned operation of new high-speed trainsets built to Tier III passenger equipment safety standards (49 CFR part

238, subpart H) and intended to be operated at speeds above 125 miles per hour. This equipment is the subject of a separate FRA waiver proceeding in Docket Number FRA–2014–0124.

In its April 23, 2019, request, Amtrak asks FRA to exercise its authority under 49 U.S.C. 20306 to exempt this new passenger equipment from the requirements of 49 U.S.C. 20302, mandating that railroad vehicles be equipped with (1) secure sill steps and efficient hand brakes; (2) secure grab irons or handholds on vehicle ends and sides for greater security to individuals coupling and uncoupling vehicles; and (3) the standard height of drawbars. *See* 49 U.S.C. 20302(a)(1)(B), (a)(2), and (a)(3).

In support of its request for relief, Amtrak notes that in lieu of handbrakes, the trainsets will be equipped with spring actuated parking brake technology that can be manually set or released from the engineer's control stand from an active cab and automatically applied when there is no active cab in the train or there is a loss of trainline brake continuity. Amtrak further notes that grab irons and handholds on the ends and sides of the subject equipment are not required for the security or safety of individuals coupling and uncoupling the vehicles because by design, the individual passenger vehicles and power cars can only be disconnected from each other in repair facilities where personnel can work on, under, or between units under protections afforded by 49 CFR part 218, subpart B. In addition, Amtrak asserts that side steps, end handholds, and side handholds are not required at the leading and trailing ends of high-speed trainsets because the trainsets are equipment with technology for the safe coupling of one trainset to another (*i.e.,* each end will have automatic self-centering couplers that couple to other trainsets on impact and uncouple by mechanisms that do not require a person to go between trainsets or the activation of a traditional uncoupling lever). Finally, Amtrak asserts that because the equipment is a fixed train consist in which individual vehicles are semi-permanently coupled and, as noted above, individual vehicles can only be disconnected in repair facilities where personnel can work on, under, or between units under protections afforded by 49 CFR part 218, subpart B, having drawbars at the statutorily-prescribed height is unnecessary. Further, as this technology is intended to operate at high-speeds, the inclusion of these appurtenances would have a significant and detrimental impact on the aerodynamics of the trainset. This increase in the aerodynamic footprint would negatively impact both efficiency and aerodynamic noise emissions. In sum, Amtrak asserts that requiring compliance with the identified statutory requirements would ''serve as an impediment to the introduction of the advanced technology represented by the trainset design.''

Under 49 U.S.C. 20306, FRA may exempt Amtrak from the above-identified statutory requirements based on evidence received and findings developed at a hearing demonstrating that the statutory requirements ''preclude the development or implementation of more efficient railroad transportation equipment or other transportation innovations under existing law.'' Accordingly, to receive evidence and develop findings to determine whether FRA should invoke its discretionary authority under 49 U.S.C. 20306 in this instance, a public hearing is scheduled for December 11, 2019, at 9 a.m., at the National Association of Home Builders, 1201 15th St. NW, Washington, DC 20005. Interested parties are invited to present oral statements at the hearing.

For information on facilities or services for persons with disabilities or to request special assistance at the hearing, contact FRA Staff Director, Motive Power and Equipment Division, Gary Fairbanks, by telephone, email or in writing, at least five business days before the date of the hearing. Mr. Fairbanks' contact information is as follows: FRA, Office of Railroad Safety, 1200 New Jersey Ave. SE, Washington, DC 20590; telephone 202–493–6322; email *Gary.Fairbanks@dot.gov.*

The hearing will be informal and will be conducted by a representative designated by FRA in accordance with FRA's Rules of Practice (49 CFR 211.25). The hearing will be a non-adversarial proceeding; therefore, there will be no cross examination of persons presenting statements. The FRA representative will make an opening statement outlining the scope of the hearing. After all initial statements have been completed, those persons wishing to make a brief rebuttal will be given the opportunity to do so in the same order in which initial statements were made. Additional procedures, as necessary for the conduct of the hearing, will be announced at the hearing.

The petitioner should be present at the hearing and prepared to present evidence that any requirements of chapter 203, title 49, U.S.C., for which exemption is sought ''preclude the development or implementation of more efficient railroad transportation equipment or other transportation innovations under existing law.''

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov* and in person at the U.S. Department of Transportation's (DOT) Docket Operations Facility, 1200 New Jersey Ave. SE, W12–140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

Interested parties are invited to participate in these proceedings by participating in the hearing and/or submitting written views, data, or comments to the FRA docket identified above.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

- *Website: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Ave. SE, W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Ave. SE, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Communications received by December 26, 2019 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable.

Anyone can search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. 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 *https://www.transportation.gov/privacy.* See also *https://www.regulations.gov/privacyNotice* for the privacy notice of *regulations.gov.*

Issued in Washington, DC.

John Karl Alexy,

Associate Administrator for Railroad Safety, Chief Safety Officer.

[FR Doc. 2019–24537 Filed 11–8–19; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF THE TREASURY

Fiscal Service

Bureau of the Fiscal Service

Notice of Rate To Be Used for Federal Debt Collection, and Discount and Rebate Evaluation

AGENCY: Bureau of the Fiscal Service, Fiscal Service, Treasury.

ACTION: Notice of rate to be used for Federal debt collection, and discount and rebate evaluation.

SUMMARY: The Secretary of the Treasury is responsible for computing and publishing the percentage rate that is used in assessing interest charges for outstanding debts owed to the Government (The Debt Collection Act of 1982, as amended). This rate is also used by agencies as a comparison point in evaluating the cost-effectiveness of a cash discount. In addition, this rate is used in determining when agencies should pay purchase card invoices when the card issuer offers a rebate. Notice is hereby given that the applicable rate for calendar year 2020 is 2.00 percent.

DATES: January 1, 2020 through December 31, 2020.

FOR FURTHER INFORMATION CONTACT: Department of the Treasury, Bureau of the Fiscal Service, Payment Management, E-Commerce Division (LC–RM 349B), 3201 Pennsy Drive, Building E, Landover, MD 20785 (Telephone: 202–874–9428).

SUPPLEMENTARY INFORMATION: The rate reflects the current value of funds to the Treasury for use in connection with Federal Cash Management systems and is based on investment rates set for purposes of Public Law 95–147, 91 Stat. 1227 (October 28, 1977). Computed each year by averaging Treasury Tax and Loan (TT&L) investment rates for the 12-month period ending every September 30, rounded to the nearest whole percentage, for applicability effective each January 1. Quarterly revisions are made if the annual average, on a moving basis, changes by 2 percentage points. The rate for calendar year 2020 reflects the average investment rates for the 12-month period that ended September 30, 2019.

This percentage rate is used in assessing interest charges for outstanding debts owed to the Government, pursuant to the Debt Collection Act of 1982, as amended (31 U.S.C. 3717). This rate is also used by agencies as a comparison point in evaluating the cost-effectiveness of a cash discount. In addition, this rate is used in determining when agencies should pay purchase card invoices when the card issuer offers a rebate (see 5 CFR 1315.8). Notice is hereby given that the applicable rate for calendar year 2020 is 2.00 percent.

(Authority: 31 U.S.C. Section 3717).

Ronda L. Kent,

Assistant Commissioner, Payment Management and Chief Disbursing Officer.

[FR Doc. 2019–24534 Filed 11–8–19; 8:45 am]

BILLING CODE 4810–AS–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 effective 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; or 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 November 4, 2019, 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

1. GOLPAYEGANI, Mohammad Mohammadi, Iran; DOB 1943; POB Golpayegan, Iran; Additional Sanctions Information—Subject to Secondary Sanctions; Gender Male (individual) [IRAN–EO13876].

Designated pursuant to section 1(a)(ii)(D) of E.O. 13876 for having acted or purported to act for or on behalf of, directly or indirectly, the SUPREME LEADER'S OFFICE, a person whose property and interests in property are blocked pursuant to E.O. 13876.

2. VELAYATI, Ali Akbar, Iran; DOB 25 Jun 1945; POB Shemiran, Tehran, Iran; Additional Sanctions Information—Subject to Secondary Sanctions; Gender Male (individual) [IRAN–EO13876].

Designated pursuant to section 1(a)(ii)(D) of E.O. 13876 for having acted or purported to act for or on behalf of, directly or indirectly, the SUPREME LEADER OF IRAN, a person whose property and interests in property are blocked pursuant to E.O. 13876.

3. RAISI, Ebrahim (a.k.a. RA'EESI, Sayyid Ibrahim; a.k.a. RAISOL–SADATI, Seyyid Ebrahim; a.k.a. RAIS–O–SADAT, Sayyid Ebrahim), Iran; DOB 14 Dec 1960; alt. DOB 01 Nov 1960 to 30 Nov 1960; alt. DOB 01 Dec 1960 to 31 Dec 1960; POB Masshad, Iran; nationality Iran; Additional Sanctions Information—Subject to Secondary Sanctions; Gender Male (individual) [IRAN–EO13876].

Designated pursuant to section 1(a)(ii)(B) of E.O. 13876 for being a person appointed to a position as a state official of Iran by the SUPREME LEADER OF IRAN, a person whose property and interests in property are blocked pursuant to E.O. 13876.

4. DEHGHAN, Hossein (a.k.a. DEHGHAN POUDEH, Hossein), Iran; DOB 1957; POB Poudeh, Isfahan, Iran; nationality Iran; Additional Sanctions Information—Subject to Secondary Sanctions; Gender Male (individual) [IRAN–EO13876].

Designated pursuant to section 1(a)(ii)(B) of E.O. 13876 for being a person appointed to a position as a state official of Iran by the SUPREME LEADER OF IRAN, a person whose property and interests in property are blocked pursuant to E.O. 13876.

5. HAGHANIAN, Vahid, Iran; DOB 01 Jan 1961 to 31 Dec 1962; POB Iran; nationality Iran; Additional Sanctions Information—Subject to Secondary Sanctions; Gender Male (individual) [IRAN–EO13876].

Designated pursuant to section 1(a)(ii)(D) of E.O. 13876 for having acted or purported to act for or on behalf of, directly or indirectly, the SUPREME LEADER OF IRAN, a person whose property and interests in property are blocked pursuant to E.O. 13876.

6. HADDAD–ADEL, Gholamali (a.k.a. HADDAD ADEL, Gholamali; a.k.a. HADDAD ADEL, Gholam-Ali; a.k.a. HADDADADEL, Gholam-Ali), Iran; DOB 1945; POB Tehran, Iran; nationality Iran; Additional Sanctions Information—Subject to Secondary Sanctions; Gender Male (individual) [IRAN–EO13876].

Designated pursuant to section 1(a)(ii)(D) of E.O. 13876 for having acted or purported to act for or on behalf of, directly or indirectly, the SUPREME LEADER OF IRAN, a person whose property and interests in property are blocked pursuant to E.O. 13876.

7. KHAMENEI, Mojtaba (a.k.a. KHAMENEI, Sayyed Mojtaba Hosseini), Iran; DOB 1969; POB Mashhad, Iran; nationality Iran; Additional Sanctions Information—Subject to Secondary Sanctions; Gender Male (individual) [IRAN–EO13876].

Designated pursuant to section 1(a)(ii)(D) of E.O. 13876 for having acted or purported to act for or on behalf of, directly or indirectly, the SUPREME LEADER OF IRAN, a person whose property and interests in property are blocked pursuant to E.O. 13876.

8. BAGHERI, Mohammad (a.k.a. BAGHERI AFSHORDI, Mohammad; a.k.a. BAGHERI, Mohammed; a.k.a. BAQERI, Mohammad Hossein), Iran; DOB 01 Jan 1960 to 31 Dec 1960; POB Tehran, Iran; nationality Iran; Additional Sanctions Information—Subject to Secondary Sanctions; Gender Male (individual) [IRAN–EO13876].

Designated pursuant to section 1(a)(ii)(B) of E.O. 13876 for being a person appointed to a position as a state official of Iran by the SUPREME LEADER OF IRAN, a person whose property and interests in property are blocked pursuant to E.O. 13876.

9. RASHID, Gholam Ali (a.k.a. RASHID, Gholamali), Iran; DOB 01 Jan 1953 to 31 Dec 1954; POB Dezful, Iran; nationality Iran; Additional Sanctions Information—Subject to Secondary Sanctions; Gender Male (individual) [IRAN–EO13876].

Designated pursuant to section 1(a)(ii)(B) of E.O. 13876 for being a person appointed to a position as a state official of Iran by the SUPREME LEADER OF IRAN, a person whose property and interests in property are blocked pursuant to E.O. 13876.

Entity

1. ARMED FORCES GENERAL STAFF (a.k.a. GENERAL STAFF OF IRANIAN ARMED FORCES; a.k.a. ''AFGS''), Iran; Additional Sanctions Information—Subject to Secondary Sanctions [IRAN–EO13876].

Designated pursuant to section 1(a)(ii)(D) of E.O. 13876 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, the SUPREME LEADER OF IRAN, a person whose property and interests in property are blocked pursuant to E.O. 13876.

Dated: November 4, 2019.

Andrea M. Gacki,

Director, Office of Foreign Assets Control.

[FR Doc. 2019–24613 Filed 11–8–19; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Extension of Information Collection Request Submitted for Public Comment; Comment Request on Requirements for Investment in Qualified Caribbean Basin Countries

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the 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. Currently, the IRS is soliciting comments concerning the collection of information related to the requirements for investments to qualify under section 936(d)(4) as investments in Qualified Caribbean Basin countries.

DATES: Written comments should be received on or before January 13, 2020 to be assured of consideration.

ADDRESSES: Direct all written comments to Philippe Thomas, Internal Revenue Service, Room 6529, 1111 Constitution Avenue NW, Washington, DC 20224. Requests for additional information or copies of the regulations should be directed to R. Joseph Durbala, at Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet, at *RJoseph.Durbala@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Requirements for Investments to Qualify under Section 936(d)(4) as Investments in Qualified Caribbean Basin Countries.

OMB Number: 1545–1138.

Regulatory Number: TD 8350.

Abstract: This document contains final regulations that provide guidance relating to the requirements that must be met for an investment to qualify under Internal Revenue code section 936(d)(4) as an investment in qualified Caribbean Basin countries. The collection of information is required by the Internal Revenue Service to verify that an investment qualifies under IRC section 936(d)(4). The respondents will be possession corporations, certain financial institutions located in Puerto Rico, and borrowers of funds covered by this regulation.

Current Actions: There is no change to the burden previously approved by OMB. This form is being submitted for renewal purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 50.

Estimated Time per Respondent: 30 hrs.

Estimated Total Annual Burden Hours: 1,500.

The following paragraph applies to all the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number.

Books or records relating to a collection of information must be retained if their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Desired Focus of Comments: The Internal Revenue Service (IRS) is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* by permitting electronic submissions of responses.

Comments submitted in response to this notice will be summarized and/or included in the ICR for OMB approval of the extension of the information collection; they will also become a matter of public record.

Approved: November 5, 2019.

R. Joseph Durbala,

IRS Tax Analyst.

[FR Doc. 2019–24456 Filed 11–8–19; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Quarterly Publication of Individuals, Who Have Chosen To Expatriate, as Required by Section 6039G

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice.

SUMMARY: This notice is provided in accordance with IRC section 6039G of the Health Insurance Portability and Accountability Act (HIPPA) of 1996, as amended. This listing contains the name of each individual losing United States citizenship (within the meaning of section 877(a) or 877A) with respect to whom the Secretary received information during the quarter ending September 30, 2019. For purposes of

this listing, long-term residents, as defined in section 877(e)(2), are treated as if they were citizens of the United States who lost citizenship.

Last name	First name	Middle name/initials
AHTI	RITVA	I.
AKAI	FUMIKO	
AKAI	NAOTAKE	
ASAHINA	HIROE	
BAARS	HEIKE	
BAJAJ	KAMLESH	KUMAR.
BAUDREXL	RAINER	M.
BAUER	HEINRICH	
BAY	ELIZABETH	
BELL	LINDA	S.
BIERBAUM	MAIKE	ROSA.
BOS	JUDITH	S.
BRADYZUCCHELLI (SP?)	VIVIANA	P.
BRYCE	JASON	E.
BRYCE	PATRICIA	
CAI	GUANGSHUN	
CASTEJON	MARIO	F.
CHANDRASEKARAN	SHOBHA	
CHANG	MU-LI	
CHIMKO	TRUDY	N.
CHOE	ARAM	
CLAPHAM	PAUL	RICHARD.
CLAPHAM	VALERIE	ANN.
CLARKE	DAVID	M.
CLARKE	LORRAINE	M.
CLARKE-LING	PHILIPPA	R.
COOPER	ANDREA	MAY.
CORSINI	BENEDETTA	
CULVERWELL	ELIZABETH	
CULVERWELL	JAMES	N.
DATLA	GOPI	K.
DELANSAY	PHILIPPE	
DEVINO	WENDY	
DOSHI	PANKAJ	BHUPATRAI.
DOSHI	SANGITA	PANKAJ.
DROLET	JEAN-JACQUES	P.
DYMA	CAROLYN	E.
FISHER	CAROL	
FISHER	RONALD	
FROMSON	KAREN	
FROMSON	LEE	S.
GAMBS	DANIEL	
GARCIA	ZENAIDA	R.
GOPALAKRISHNA	VIDYA	B.
GREENE	CHARLES	J.
GREGORY	CHRISTINE	
GREGORY	DAVID	A.
GUNTURI	PRASANNA	
GUNTURI	SIVARAMA	
HAGGAI	OREN	
HAINER	KIRSTIN	L.
HANKS	BRIAN	
HANSEN	JUDITH	
HANSEN	MICHAEL	
HARGREAVES	ANDREW	
HARGREAVES	PAULINE	E.
HARRISON	RICHARD	C.
HEDBERG	LARS	JOHAN.
HEPPNER	HENNING	
HEWSON	WILLIAM	
HINDERBERGER	GABRIELE	C.
HVATUM	EVAN	A.
HWANG	EU JIN	B.
IMAI	TAKUMI	
INOUE	KUMIKO	
JACKSON	SUSAN	J.
JANZEN	FRANK	H.
JANZEN	MARIE	
JIN	YILUN	
JOHNSTON (SP?)	ROBERT	W.
JOHNSTONE	SHEILA	C.

Last name	First name	Middle name/initials
JOUNG	SUMI	
JUHL	NIAMH	
KANEKO	AYAKA	
KANOST	DAWN	
KATO	KENJI	
KATO	YUKARI	
KAUFMAN	DEAN	V.
KAWASHIMA	AYA	
KIM	EUNHA	
KIM	JUNGHWA	
KNIGHT	ANJA	E.
KOBAYASHI	MASAFUMI	
KOBAYASHI	NATSUKO	
KOHAMA	KEISUKE	
KOHAMA	NOBUKO	
KOO	PILJU	
KRUGER	JACO	
LANDRE-SMITH	CAROLINE	C.
LAVY	HADAS	
LAVY	HANAN	
LAWRENCE	DANNY	
LEE	LI-CHEN	
LIAO	KEN-CHUNG	
LINNEGAR	MYRENE	LILIAN.
LUCAS	CLIVE	A.
LUCAS	SALLY	A.
LUNDERSTEDT	AVRIL	
LUNDERSTEDT	DAVID	B.
LUROSS	JEFFREY	A.
LUU	TRANG	
MANSSON	BEATRICE	
MANSSON	FABIAN	
MANSSON	MAYA	
MANSSON	NIKKI	
MCCAIN	SHARON	K.
MCKILLOP	BARBARA	
MEHTA	JAGRUTI	P.
MELKA	ALFRED	G.
MORA	FREDERIC	
MORIN	ODETTE	L.
MORISAKI	RYUSEI	
MOTOYOSHI	KEIKO	
MOTOYOSHI	KOJI	
MUTEKI	KOJI	
NAKAE	ERI	
NARCE	MELITA	
NARITA-PANTUSO	AKIKO	
OKAMOTO	HISAE	
OKAMOTO	KOJI	
OMAR	NAZISH	ZAFA.
OTSUKA	FUMIHIKO	
OTT	JENNA	K.
OTZ	INES	
OTZ	MARTIN	H.
PANDO	ROBERT	M.
PARTON	SAMANTHA	E.
PICKRAHN	STEPHEN	
POND	ALEXANDRA	
RAJAN	MRIDULA	
RAMUS	SUSAN	J.
RASMUSSEN	MICHAEL	
RIVAS	ORLANDO	J.
ROTH	NADINE	D.
RUSTAT	OLIVIER	
SA	WENJUAN	
SAKAKIBARA	KAZUHIRO	
SAN	BRIGID	
SCHAAF	CHRISTIAN	
SCHAAF	KATHRIN	
SHEPHERD	KEIKO	
SHIMONO	YOSHIKO	
SHIN	DONGIN	
SHINDO	MASAO	
SHIRAI	CHISEKO	

Last name	First name	Middle name/initials
SHU	TAO-YI	
SIERSBAEK	RIKKE	
SMITH	GRAHAM	F.
SNOOK	EDWARD	C.
STAMOS	TOMEKO	
STOCK	CLAUDE	
STOKES	BARBARA	A.
STRUNK	DOROTHEA	GISELA.
TAGG	HEATHER	S.
TAGG	ROGER	J.
TAKAHASHI	KAZUKO	
TAKAYAMA	YURIKO	
TEDJA	ANDRIANA	
THURSTON	KATIE	J.L.
TRAMUTTOLA	MARIA	
TREMEL	VERENA	M.
TSUCHIDA	YOSHIKO	
TZAVIDAS	STAVROS	
VIETTI	YURIKO	OSONO.
VON NIESSEN-SILVA	LIESELOTTE	
WANG	JUNHONG	
WATANABE	NOZOMI	
WATANABE	RYUJI	
WATHEN	MELITA	H.
WEST	MATTHEW	
WHITELAW	PHILLIPA	F.
WILLIS	CARMEL	A.
WILSON	ELIZABETH	D.
WILSON	JANE	L.
WILSON	MICHAEL	G.
WONG	MICHAEL	S.
WOZNIAK	GRAZYNA	BARBARA.
WOZNIAK	WLADYSLAW	
WRIGHT	LINDA	
YAGIL	YORAM	
YAMAMOTO	MASAHIRO	
ZENG	QING	
ZHOU	XUEMEI	

Dated: October 30, 2019.

Diane Costello,

Manager Classification Team 82413, Examinations Operations—Philadelphia Compliance Services.

[FR Doc. 2019–24474 Filed 11–8–19; 8:45 am]

BILLING CODE 4830–01–P

FEDERAL REGISTER

Vol. 84 Tuesday,

No. 218 November 12, 2019

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 412, et al.

Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Revisions of Organ Procurement Organizations Conditions of Coverage; Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Changes to Grandfathered Children's Hospitals-Within-Hospitals; Notice of Closure of Two Teaching Hospitals and Opportunity To Apply for Available Slots; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 412, 414, 416, 419, and 486

[CMS–1717–FC]

RIN 0938–AT74

Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Revisions of Organ Procurement Organizations Conditions of Coverage; Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Changes to Grandfathered Children's Hospitals-Within-Hospitals; Notice of Closure of Two Teaching Hospitals and Opportunity To Apply for Available Slots

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

ACTION: 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 2020 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 a process and requirements for prior authorization for certain covered outpatient department services; revise the conditions for coverage of organ procurement organizations; and revise the regulations to allow grandfathered children's hospitals-within-hospitals to increase the number of beds without resulting in the loss of grandfathered status; and 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.

DATES:

Effective date: This final rule is effective on January 1, 2020.

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 must be received at one of the addresses provided in the **ADDRESSES** section no later than 5 p.m. EST on December 2, 2019.

ADDRESSES: In commenting, please refer to file code CMS–1717–FC when commenting on the issues in this 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–1717–FC, P.O. Box 8013, 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–1717–FC, 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:

2–Midnight Rule (Short Inpatient Hospital Stays), contact Lela Strong-Holloway via email *Lela.Strong@cms.hhs.gov* or at 410–786–3213.

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 at 410–786–4142 or Mitali Dayal via email *Mitali.Dayal2@cms.hhs.gov* or at 410–786–4329.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program Administration, Validation, and Reconsideration Issues, contact Anita Bhatia via email *Anita.Bhatia@cms.hhs.gov* or at 410–786–7236.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program Measures, contact Nicole Hewitt via email *Nicole.Hewitt@cms.hhs.gov* or at 410–786–7778.

Blood and Blood Products, contact Josh McFeeters via email *Joshua.McFeeters@cms.hhs.gov* or at 410–786–9732.

Cancer Hospital Payments, contact Scott Talaga via email *Scott.Talaga@cms.hhs.gov* or at 410–786–4142.

CMS Web Posting of the OPPS and ASC Payment Files, contact Chuck Braver via email *Chuck.Braver@cms.hhs.gov* or at 410–786–6719.

Control for Unnecessary Increases in Volume of Outpatient Services, contact Elise Barringer via email *Elise.Barringer@cms.hhs.gov* or at 410–786–9222.

Composite APCs (Low Dose Brachytherapy and Multiple Imaging), contact Elise Barringer via email *Elise.Barringer@cms.hhs.gov* or at 410–786–9222.

Comprehensive APCs (C–APCs), contact Lela Strong-Holloway via email *Lela.Strong@cms.hhs.gov* or at 410–786–3213, or Mitali Dayal via email at *Mitali.Dayal2@cms.hhs.gov* or at 410–786–4329.

CPT and Level II HCPCS Codes, contact Marjorie Baldo via email *Marjorie.Baldo@cms.hhs.gov* or at 410–786–4617.

Grandfathered Children's Hospitals-within-Hospitals, contact Michele Hudson via email *Michele.Hudson@cms.hhs.gov* or 410–786–4487.

Hospital Cost Reporting and Chargemaster Comment Solicitation, contact Dr. Terri Postma at 410–786–4169.

Hospital Outpatient Quality Reporting (OQR) Program Administration, Validation, and Reconsideration Issues, contact Anita Bhatia via email *Anita.Bhatia@cms.hhs.gov* or at 410–786–7236.

Hospital Outpatient Quality Reporting (OQR) Program Measures, contact Vinitha Meyyur via email *Vinitha.Meyyur@cms.hhs.gov* or at 410–786–8819.

Hospital Outpatient Visits (Emergency Department Visits and Critical Care Visits), contact Elise Barringer via email

Elise.Barringer@cms.hhs.gov or at 410–786–9222.

Inpatient Only (IPO) Procedures List, contact Lela Strong-Holloway via email *Lela.Strong@cms.hhs.gov* or at 410–786–3213, or Au'Sha Washington via email at *Ausha.Washington@cms.hhs.gov* or at 410–786–3736.

New Technology Intraocular Lenses (NTIOLs), contact Scott Talaga via email *Scott.Talaga@cms.hhs.gov* or at 410–786–4142.

No Cost/Full Credit and Partial Credit Devices, contact Scott Talaga via email *Scott.Talaga@cms.hhs.gov* or at 410–786–4142.

Notice of Closure of Two Teaching Hospitals and Opportunity to Apply for Available Slots, contact Michele Hudson via email *Michele.Hudson@cms.hhs.gov* or 410–786–4487.

OPPS Brachytherapy, contact Scott Talaga via email *Scott.Talaga@cms.hhs.gov* or at 410–786–4142.

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 at 410–786–1816, or Scott Talaga via email *Scott.Talaga@cms.hhs.gov* or at 410–786–4142, or Josh McFeeters via email at *Joshua.McFeeters@cms.hhs.gov* or at 410–786–9732.

OPPS Drugs, Radiopharmaceuticals, Biologicals, and Biosimilar Products, contact Josh McFeeters via email *Joshua.McFeeters@cms.hhs.gov* or at 410–786–9732.

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 at 410–786–3213, or Mitali Dayal via email at *Mitali.Dayal2@cms.hhs.gov* or at 410–786–4329.

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* or at 410–786–2682.

Organ Procurement Organization (OPO) Conditions for Coverage (CfCs), contact Alpha-Banu Wilson via email at *AlphaBanu.Wilson@cms.hhs.gov* or at 410–786–8687, or Diane Corning via email at *Diane.Corning@cms.hhs.gov* or at 410–786–8486.

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 Hospital Outpatient Department Services, contact Thomas Kessler via email at *Thomas.Kessler@cms.hhs.gov* or at 410–786–1991.

Rural Hospital Payments, contact Josh McFeeters via email at *Joshua.McFeeters@cms.hhs.gov* or at 410–786–9732.

Skin Substitutes, contact Josh McFeeters via email *Joshua.McFeeters@cms.hhs.gov* or at 410–786–9732.

Supervision of Outpatient Therapeutic Services in Hospitals and CAHs, contact Josh McFeeters via email *Joshua.McFeeters@cms.hhs.gov* or at 410–786–9732.

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.

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.

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/index.html.* The Addenda relating to the ASC payment system are available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

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 2018 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, 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, 2020. 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 technologies, and the addition of new services, new cost data, and other relevant information and factors. In addition, under section 1833(i) 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. 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.

In this final rule with comment period, we establish a process and requirements for prior authorization for certain covered outpatient department services; revise the conditions for coverage for organ procurement organizations; and revise the regulations to allow grandfathered children's hospitals-within-hospitals to increase

the number of beds without resulting in the loss of grandfathered status.

2. Summary of the Major Provisions

• *OPPS Update:* For CY 2020, we are increasing the payment rates under the OPPS by an Outpatient Department (OPD) fee schedule increase factor of 2.6 percent. This increase factor is based on the final hospital inpatient market basket percentage increase of 3.0 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS), minus the multifactor productivity (MFP) adjustment required by the Affordable Care Act of 0.4 percentage point. 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) 2020 will be approximately $79.0 billion, an increase of approximately $6.3 billion compared to estimated CY 2019 OPPS payments.

We are continuing to implement the statutory 2.0 percentage point reduction in payments for hospitals failing to meet the hospital outpatient quality reporting requirements, by applying a reporting factor of 0.981 to the OPPS payments and copayments for all applicable services.

• *2-Midnight Rule (Short Inpatient Hospital Stays):* For CY 2020, we are establishing a 2-year exemption from Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC–QIOs) referrals to Recovery Audit Contractors (RACs) and RAC reviews for ''patient status'' (that is, site-of-service) for procedures that are removed from the inpatient only (IPO) list under the OPPS beginning on January 1, 2020.

• *Comprehensive APCs:* For CY 2020, we are creating two new comprehensive APCs (C–APCs). These new C–APCs include the following: C–APC 5182 (Level 2 Vascular Procedures) and C–APC 5461 (Level 1 Neurostimulator and Related Procedures). This increases the total number of C–APCs to 67.

• *Changes to the Inpatient Only (IPO) List:* For CY 2020, we are removing Total Hip Arthroplasty, six spinal procedure codes, and five anesthesia codes from the inpatient only list.

• *Method to Control Unnecessary Increases in the Volume of Clinic Visit Services Furnished in Excepted Off-Campus Provider-Based Departments (PBDs):* For CY 2020, we are completing the phase-in of the reduction in payment for the clinic visit services described by HCPCS code G0463 furnished in expected off-campus provider based departments as a method to control unnecessary increases in the volume of this service. We acknowledge that the district court vacated the volume control policy for CY 2019 and we are working to ensure affected 2019 claims for clinic visits are paid consistent with the court's order. We do not believe it is appropriate at this time to make a change to the second year of the two-year phase-in of the clinic visit policy. The government has appeal rights, and is still evaluating the rulings and considering, at the time of this writing, whether to appeal from the final judgment.

• *Device Pass-Through Payment Applications:* For CY 2020, we evaluated seven applications for device pass-through payments and based on public comments received, we are approving four of these applications for device pass-through payment status. Additionally, we are approving an additional application that was not discussed in the CY 2020 OPPS/ASC proposed rule, but has received a Breakthrough Devices designation from the Food and Drug Administration (FDA) and qualifies for the alternative pathway to the OPPS device pass-through substantial clinical improvement criterion.

• *Changes to Substantial Clinical Improvement Criterion:* For CY 2020, we are finalizing an alternative pathway to the substantial clinical improvement criterion for devices approved under the FDA Breakthrough Devices Program to qualify for device pass-through status beginning with determinations effective on or after January 1, 2020.

• *Cancer Hospital Payment Adjustment:* For CY 2020, 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, we are providing that a target PCR of 0.89 will be used to determine the CY 2020 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.

• *Rural Adjustment:* For 2020 and subsequent years, we are continuing the 7.1 percent adjustment to OPPS payments for certain rural SCHs, including essential access community hospitals (EACHs). We intend to continue the 7.1 percent adjustment for future years in the absence of data to suggest a different percentage adjustment should apply.

• 340B-*Acquired Drugs:* We are continuing to pay ASP–22.5 percent for 340B-acquired drugs including when furnished in nonexcepted off-campus PBDs paid under the PFS. In light of ongoing litigation, we also summarized comments received on a potential remedy for 2018 and 2019. CMS announced in the **Federal Register** (84 FR 51590) its intent to conduct a 340B hospital survey to collect drug acquisition cost data for CY 2018 and 2019. 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 in the event of an adverse decision on appeal. In the event 340B hospital survey data are not used to devise a remedy, we intend to consider the suggestions commenters submitted in response to the comment solicitation in the proposed rule to propose a remedy in the CY 2021 OPPS/ASC proposed rule.

• *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 2020, we are increasing payment rates under the ASC payment system by 2.6 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 3.0 percent minus a proposed multifactor productivity adjustment required by the Affordable Care Act of 0.4 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 2020 will be approximately $4.96 billion, an increase of approximately $230 million compared to estimated CY 2019 Medicare payments.

• *Changes to the List of ASC Covered Surgical Procedures:* For CY 2020, we are adding several procedures to the ASC list of covered surgical procedures. Additions to the list include a total knee arthroplasty procedure, a mosaicplasty procedure, as well as six coronary intervention procedures, as well as 12 surgical procedures with new CPT codes for CY 2020.

• *Changes to the Level of Supervision of Outpatient Therapeutic Services in Hospitals and Critical Access Hospitals:* For CY 2020, we are changing the

minimum required level of supervision from direct supervision to general supervision for all hospital outpatient therapeutic services provided by all hospitals and CAHs. This ensures a standard minimum level of supervision for each hospital outpatient service furnished incident to a physician's service.

- *Hospital Outpatient Quality Reporting (OQR) Program:* For the Hospital OQR Program, we are removing OP–33: External Beam Radiotherapy for Bone Metastases for the CY 2022 payment determination and subsequent years with modification.
- *Ambulatory Surgical Center Quality Reporting (ASCQR) Program:* For the ASCQR Program, we are adopting one new measure, ASC–19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers, beginning with the CY 2024 payment determination and for subsequent years.
- *Prior Authorization Process and Requirements for Certain Hospital Outpatient Department (OPD) Services:* We are finalizing a prior authorization process using the authority at section 1833(t)(2)(F) of the Act as a method for controlling unnecessary increases in the volume of the following five categories of services: (1) Blepharoplasty, (2) botulinum toxin injections, (3) panniculectomy, (4) rhinoplasty, and (5) vein ablation.
- *Organ Procurement Organizations (OPOs) Conditions for Coverage (CfCs) Revision of the Definition of ''Expected Donation Rate.''* We are revising the definition of ''expected donation rate'' that is included in the second outcome measure to match the Scientific Registry of Transplant Recipients (SRTR) definition. In conjunction with this change, we are also temporarily suspending the requirement that OPOs meet two of three outcome measures for the 2022 recertification cycle only.
- *Request for Information Regarding Potential Changes to the Organ Procurement Organization and Transplant Center Regulations:* We solicited public comments regarding what revisions may be appropriate for the current OPO CfCs and the current transplant center CoPs. In addition, we solicited public comments on two potential outcome measures for OPOs.

3. Summary of Costs and Benefits

In sections XXVI. and XXVII. of this 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 70 in section XXV.B of this final rule with comment period displays the distributional impact of all the OPPS changes on various groups of hospitals and CMHCs for CY 2020 compared to all estimated OPPS payments in CY 2019. We estimate that the policies in this final rule with comment period will result in a 1.3 percent overall increase in OPPS payments to providers. We estimate that total OPPS payments for CY 2020, including beneficiary cost-sharing, to the approximately 3,732 facilities paid under the OPPS (including general acute care hospitals, children's hospitals, cancer hospitals, and CMHCs) will increase by approximately $1.21 billion compared to CY 2019 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 a 3.7 percent increase in CY 2020 payments to CMHCs relative to their CY 2019 payments.

b. Impacts of the Updated Wage Indexes

We estimate that our update of the wage indexes based on the FY 2020 IPPS proposed rule wage indexes will result in no estimated payment change for urban hospitals under the OPPS and an estimated increase of 0.7 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 2020 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 required reduction to the cancer hospital payment adjustment required by section 16002 of the 21st Century Cures Act for CY 2020, the target payment-to-cost ratio (PCR) for CY 2020 is 0.89, compared to 0.88 for CY 2019, and therefore has a slight impact on budget neutrality adjustments.

d. Impacts of the OPD Fee Schedule Increase Factor

For the CY 2020 OPPS/ASC, we are establishing an OPD fee schedule increase factor of 2.6 percent and applying that increase factor to the conversion factor for CY 2020. As a result of the OPD fee schedule increase factor and other budget neutrality adjustments, we estimate that urban hospitals will experience an increase of approximately 2.7 percent and that rural hospitals will experience an increase of 2.8 percent. Classifying hospitals by teaching status, we estimate nonteaching hospitals will experience an increase of 2.8 percent, minor teaching hospitals will experience an increase of 2.9 percent, and major teaching hospitals will experience an increase of 2.4 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 2.8 percent in payments. We estimate that hospitals with proprietary ownership will experience an increase of 3.2 percent in payments.

e. Impacts of the ASC Payment Update

For impact purposes, the surgical procedures on the ASC list of covered procedures 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 2020 payment rates, compared to estimated CY 2019 payment rates, generally ranges between an increase of 1 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 increase payments by $230 million under the ASC payment system in CY 2020.

f. Impact of the Changes to the Hospital OQR Program

Across 3,300 hospitals participating in the Hospital OQR Program, we estimate that our requirements will result in the following changes to costs and burdens related to information collection for the Hospital OQR Program compared to previously adopted requirements: There is a net reduction of one measure reported by hospitals, which results in a minimal net reduction in burden of $21,379.

g. Impacts of the Revision of the Definition of ''Expected Donation Rate'' for Organ Procurement Organizations

We are finalizing our revision to the definition of ''expected donation rate'' used in the second outcome measure of the OPO CfCs at 42 CFR 486.318(a) and (b) to eliminate the potential for confusion in the OPO community due to different definitions of the same term; however, due to comments received on the CY 2020 OPPS/ASC proposed rule we are finalizing a policy that would not require all OPOs to meet the standards of the second outcome measure for the 2022 recertification cycle only. As a result, OPOs will only have to meet one of the remaining outcome measures, which may provide temporary relief for a small number of OPOs that, absent this waiver, might have faced de-certification and the appeal process due to only meeting one outcome measure.

For subsequent recertification cycles, all 58 OPOs will once again be required to meet two out of three outcome measures detailed in the OPO CfCs. The revised definition of ''expected donation rate'' used in the second outcome measure will not affect data collection or reporting by the OPTN and SRTR, nor their statistical evaluation of OPO performance; therefore, it will not result in any quantifiable financial impact.

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 this final rule with comment period. 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 include:

- 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, relative payment weights, and the wage and other adjustments that take into account changes in medical practices, changes in technologies, and 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 external advisory panel of experts to annually review 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;
- 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 19, 2018, for a 2-year period (84 FR 26117).

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 19, 2019. Prior to each meeting, we publish a notice in the **Federal Register** to announce the meeting and, when necessary, to solicit nominations for Panel membership, to announce new members, and to announce 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). Further information on the 2019 summer meeting can be found in the meeting notice titled ''Medicare Program: Announcement of the Advisory Panel on Hospital Outpatient Payment (the Panel) Meeting on August 19 through 20, 2019'' (84 FR 26117).

In addition, the Panel has established an operational structure that, in part, currently includes the use of three subcommittees to facilitate its required review process. The three current subcommittees include the following:

- APC Groups and Status Indicator Assignments Subcommittee, which advises 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 subcommittees was established by a majority vote from the full Panel during a scheduled Panel meeting, and the Panel recommended at the August 19, 2019, 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*.

Comment: One commenter supported CMS' extension of the HOP Panel meeting presentation submission deadline when there is a truncated submittal timeframe due to delayed publication of the OPPS/ASC proposed rule. However, to avoid the need to modify the submission deadline in the future, the commenter suggested that CMS revise the submission deadline in the **Federal Register** notice from a firm date to a fluid 21 days from the proposed rule display date to avoid this deadline issue in the future.

Response: We appreciate the commenter's request to modify the HOP Panel meeting submission deadline format. However, frequency, timing, and presentation deadlines are outside the scope of the proposed rule and are generally announced through either a separate **Federal Register** notice or subregulatory channel such as the CMS website, or both.

F. Public Comments Received in Response to the CY 2020 OPPS/ASC Proposed Rule

We received over 3400 timely pieces of correspondence on the CY 2020 OPPS/ASC proposed rule that appeared in the **Federal Register** on August 9, 2019 (84 FR 39398). We note that we received some public comments that were outside the scope of the CY 2020 OPPS/ASC proposed rule. Out-of-scope-public comments are not addressed in this CY 2020 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 2019 OPPS/ASC Final Rule With Comment Period

We received over 540 timely pieces of correspondence on the CY 2019 OPPS/ASC final rule with comment period that appeared in the **Federal Register** on November 30, 2018 (83 FR 61567), some of which contained comments on 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 new or replacement Level II HCPCS codes are set forth in the CY 2020 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.

In the CY 2020 OPPS/ASC proposed rule (84 FR 39406), for CY 2020, we proposed to recalibrate the APC relative payment weights for services furnished on or after January 1, 2020, and before January 1, 2021 (CY 2020), using the same basic methodology that we described in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58827 through 58828), using updated CY 2018 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 APC relative payment weights for CY 2020, we began with approximately 164 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, 2018, and before January 1, 2019, before applying our exclusionary criteria and other methodological adjustments. After the application of those data processing changes, we used approximately 88 million final action claims to develop the proposed CY 2020 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 2020 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 proposed rule (which is available via the internet on the CMS website) included the proposed list of bypass codes for CY 2020. The proposed list of bypass codes contained codes that were reported on claims for services in CY 2018 and, therefore, included codes that were in effect in CY 2018 and used for billing, but were deleted for CY 2019. We retained these deleted bypass codes on the proposed CY 2020 bypass list because these codes existed in CY 2018 and were covered OPD services in that period, and CY 2018 claims data were used to calculate CY 2020 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 2020 were identified by asterisks (*) in the fourth column of Addendum N.

Table 1 contains the list of codes that we proposed to remove from the CY 2020 bypass list.

TABLE 1.—HCPCS CODES TO BE REMOVED FROM THE CY 2020 BYPASS LIST

HCPCS	HCPCS Short Descriptor
G0436	Tobacco-use counsel 3-10 min
71010	Chest x-ray 1 view frontal
71015	Chest x-ray stereo frontal
71020	Chest x-ray 2vw frontal&latl
93965	Extremity study

b. Calculation and Use of Cost-to-Charge Ratios (CCRs)

For CY 2020, in the CY 2020 OPPS/ASC proposed rule (84 FR 39407), 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 2020 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 2018 claims data by comparing these claims data to the most recently available hospital cost reports, which, in most cases, are from CY 2017. For the proposed CY 2020 OPPS payment rates, we used the set of claims processed during CY 2018. 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. 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*.

To ensure the completeness of the revenue code-to-cost center crosswalk, we reviewed changes to the list of revenue codes for CY 2018 (the year of claims data we used to calculate the proposed CY 2020 OPPS payment rates) and found that the National Uniform Billing Committee (NUBC) did not add any new revenue codes to the NUBC 2018 Data Specifications Manual.

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 CMS 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 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 (78 FR 74847). 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 a 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 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 2 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 3 provides statistical values based on the CT and MRI standard cost center CCRs using the different cost allocation methods.

TABLE 2.—PERCENTAGE CHANGE IN ESTIMATED COST FOR CT AND MRI APCs WHEN EXCLUDING CLAIMS FROM PROVIDER USING "SQUARE FEET" AS THE COST ALLOCATION METHOD

APC	APC Descriptor	Percentage Change
5521	Level 1 Imaging without Contrast	-2.5%
5522	Level 2 Imaging without Contrast	5.8%
5523	Level 3 Imaging without Contrast	4.0%
5524	Level 4 Imaging without Contrast	4.9%
5571	Level 1 Imaging with Contrast	6.6%
5572	Level 2 Imaging with Contrast	7.9%
5573	Level 3 Imaging with Contrast	1.8%
8005	CT and CTA without Contrast Composite	14.1%
8006	CT and CTA with Contrast Composite	10.9%
8007	MRI and MRA without Contrast Composite	6.5%
8008	MRI and MRA with Contrast Composite	6.5%

TABLE 3.—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	0.0356	0.0496	0.0772	0.1026
Square Feet Only	0.0288	0.0445	0.0674	0.0930
Direct Assign	0.0506	0.0585	0.0978	0.1186
Dollar Value	0.0424	0.0560	0.0875	0.1146
Direct Assign and Dollar Value	0.0425	0.0562	0.0879	0.1147

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 18.8 percent to 2,207 providers and the number of valid CT CCRs has increased by 16.0 percent to 2,291 providers. However, as shown in Table 2, nearly all imaging APCs would see an increase in payment rates for CY 2020 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 2.

We noted in the CY 2020 OPPS/ASC proposed rule 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 have extended the transition an additional 2 years to offer provider flexibility in applying cost allocation methodologies for CT and MRI cost centers other than ''square feet.'' We noted that we believed we had provided sufficient time for providers to adopt an alternative cost allocation methodology for CT and MRI cost centers if they intended to do so. However, 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, we proposed that for the CY 2020 OPPS we would use 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 2. We noted that we did not believe another extension was warranted and expected to determine the imaging APC relative payment weights for CY 2020 using cost data from all providers, regardless of the cost allocation method employed.

Comment: One commenter noted that approximately half of all hospitals paid under the OPPS had CT and/or MRI cost centers that were reporting CCRs using the preferred methods (''dollar value'' or ''direct assignment''). This commenter further suggested that hospitals not using these preferred methods are either unable or unwilling to make the change to using these preferred methods. This commenter stated that some CT and

MRI procedures show a significant number of CCRs that are close to zero, and that the commenter believed that these hospitals are likely unable to accurately reallocate these costs across hospital departments to new CT and MRI departmental cost centers. This commenter acknowledged that the number of valid CT and MRI CCRs has increased over time, but noted that incorrect cost allocation has negative effects on payment rates for almost all imaging APCs.

Several commenters recommended that CMS continue to exclude ''square feet'' cost allocation data and continue to educate hospitals on the importance of reporting direct CT and MRI services. 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 this will solve the inaccurate reporting of costs for CT and MR services. They further suggested that we should advise hospitals through regulation and cost reporting instructions to no longer report costs separately for CT and MRI cost centers and make sure they review their diagnostic radiology cost center inclusive of CT and MR equipment, space, labor and over factors. This same commenter noted that the benefits of using a single diagnostic radiology cost center include consistency across hospitals, properly accounting for high-cost medical equipment, simplifying and standardizing cost reporting within the diagnostic radiology cost center, eliminating partial allocation of costs to CT and MRI cost centers, and reducing burden. One commenter requested that we work with various hospital organizations to help educate the hospital community on how to report these costs on the CT and MRI CCRs in hopes to transition to this policy over time.

Other commenters requested that we extend the transition to using all claims for one additional year. These same commenters requested that if extending the transition 1 additional year is not possible, that we phase in the payment impacts of this transition over 2 years. One commenter requested that CMS extend the transition for 2 additional years and stated that we should study the effects of this policy even further to better understand its payment impacts. One commenter noted that we should continue the transition policy of removing provider claims using the ''square feet'' cost allocation method to calculate cost-to-charge ratios (CCRs) associated with CT and MRI procedures into 2020 and require providers to report costs via the direct assignment or dollar value methodologies moving forward. Another commenter 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 (MPFS). The commenter noted the resulting reductions in hospital payments would also affect the physician office practice setting. They believed that the OPPS technical payments would fall below the payment rates in the MPFS causing further cuts as mandated by the Deficit Reduction Act of 2005 (DRA), which mandates CMS pay the lesser of MPFS or OPPS rate.

One commenter suggested that, because CMS has various APC groupings for MRI and CT, the individual MRI and CT cost centers are no longer needed. This commenter suggested that, at the time separate cost centers for these services were established, the classification of imaging procedures into APCs was very specific, but that CMS is now ''intermingling'' the MRI and CT costs with other imaging services.

Response: We appreciate the comments regarding the use of CT and MRI cost center CCRs. As we stated in prior rulemaking, we recognize the concerns with regard to the application of the CT and MRI standard cost center CCRs and their use in the OPPS ratesetting. We understand that there is greater sensitivity to the cost allocation method being used on the cost report forms for these relatively new standard imaging cost centers under the OPPS due to the limited size of the OPPS payment bundles and because the OPPS applies the CCRs at the departmental level for cost estimation purposes. However, it is important to note that since we initially established the transition policy in the OPPS in CY 2014, we have continued to develop the OPPS as a prospective payment system. This includes greater packaging and the development of comprehensive APCs. As we have packaged a greater number of items and services with imaging payment under the OPPS, we believe imaging payments are somewhat less sensitive to the cost allocation method being used than they previously were. We also note that we still find value in obtaining more specific cost data and that the CT and MRI-specific cost centers provide useful cost and charge data for ratesetting purposes.

However, to address concerns in the comments about the amount of the decrease in imaging payment in CY 2020 due to ending of the transition period, we are finalizing a 2-year phased-in approach, as suggested by some commenters, that will apply 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. For CY 2020, we will calculate the imaging payment rates using both the transition methodology (excluding providers that use a ''square feet'' cost allocation method) and the standard methodology (including all providers, regardless of cost allocation method) and will assign the imaging APCs a payment rate that includes data representing 50 percent of the transition methodology payment rate and includes data representing 50 percent of the standard methodology payment rate. Beginning in CY 2021, we will set the imaging APC payment rates at 100 percent of the payment rate using the standard payment methodology (including all providers, regardless of cost allocation method). Table 4 below illustrates the estimated impact on geometric mean costs for CT and MRI APCs under our blended approach of utilizing 50 percent of the transitional payment methodology and 50 percent of the standard payment methodology for CY 2020.

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TABLE 4.— ESTIMATED COST IMPACT FOR CT AND MRI APCs UNDER OUR 50/50 BLENDED GEOMETRIC MEAN COST, COMPARED TO STANDARD GEOMETRIC MEAN COST FOR CY 2020

APC	APC Descriptor	Providers using "Square Foot" Included - Geometric Mean Cost	Providers using "Square Foot" Excluded - Geometric Mean Cost	Blended Geometric Mean Cost	% Impact of Blend Relative to Geometric Mean Cost Including "Square Foot" Providers
5521	Level 1 Imaging without Contrast	$79.08	$77.07	$78.08	-1.3%
5522	Level 2 Imaging without Contrast	$106.56	$112.75	$109.66	2.9%
5523	Level 3 Imaging without Contrast	$223.58	$232.46	$228.02	2.0%
5524	Level 4 Imaging without Contrast	$459.90	$482.50	$471.20	2.5%
5571	Level 1 Imaging with Contrast	$172.59	$183.98	$178.29	3.3%
5572	Level 2 Imaging with Contrast	$359.49	$387.74	$373.62	3.9%
5573	Level 3 Imaging with Contrast	$660.06	$672.21	$666.14	0.9%
8005	CT and CTA without Contrast Composite	$221.27	$252.37	$236.82	7.0%
8006	CT and CTA with Contrast Composite	$427.99	$474.48	$451.24	5.4%
8007	MRI and MRA without Contrast Composite	$514.85	$548.08	$531.47	3.2%
8008	MRI and MRA with Contrast Composite	$820.27	$873.30	$846.79	3.2%

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As noted earlier, the Deficit Reduction Act (DRA) of 2005 requires Medicare to limit Medicare payment for certain imaging services covered by the physician fee schedule to not exceed what Medicare pays for these services under the OPPS. As required by law, for certain imaging series paid for under the MPFS, 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 Physician Fee Schedule (PFS) where the technical component payment for many imaging services is capped at the OPPS payment amount. We will continue to monitor OPPS imaging payments in the future and consider the potential impacts of payment changes on the PFS and the ASC payment system.

2. 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 2020. 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, below 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 2018 claims that were used to calculate the final payment rates for this CY 2020 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 2020, in the CY 2020 OPPS/ASC proposed rule (84 FR 39409), we proposed to continue to use geometric mean costs to calculate the proposed relative weights on which the CY 2020 OPPS payment rates are based.

We used the methodology described in sections II.A.2.a. through II.A.2.c. of this 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 2020 shown in Addenda A and B to this final rule with comment period (which are available via the internet on the CMS website). We refer readers to section II.A.4. of this 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 claims data containing lines with the modifier ''PN'' were available, which indicate 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 2020 OPPS, we will continue to remove these claim lines with modifier ''PN'' from the ratesetting process.

Comment: Several commenters noted a potential issue with missing lines with the PN modifier. Specifically, these commenters believed that the CY 2020 proposed rule data, based on CY 2018 claims, excluded approximately 400,000 lines with Healthcare Common Procedure Coding System (HCPCS) codes and the PN modifier. They noted that this would mean that there was over an 80 percent decline from the CY 2017 claims data, which had approximately 2.8 million lines with HCPCS and the PN modifier. These commenters reviewed the 2018 Outpatient Standard Analytic File (SAF) and noted that they found approximately 3.5 million lines with HCPCS codes and the PN modifier. These commenters asserted that the ratesetting data included substantially less PN modifiers than in the SAF file for the same time period. These same commenters assert that if the PN lines were not included in the ratesetting process then the OPPS payment weights are accurate. They noted that, conversely, if the PN lines were included in the payment weights then payments would be inaccurate. These commenters wanted CMS to explain what occurred in the proposed rule data files to ensure that the APC payment weights correctly reflect the exclusion of PN modifier claims in the final rule.

Response: We thank the commenters for their input. First, we would like to note that claim lines with the PN modifier are excluded from the ratesetting process. Please note that the difference between the 2019 OPPS Final Rule and the 2020 OPPS Proposed rule is the following: We processed the claim lines with the PN modifier differently between the two rules, which resulted in the decrease in the number of PN lines in the OPPS limited data set as noted above. Specifically, the programs used for the CY 2020 proposed rule were modified to not factor in those lines as being OPPS lines, which resulted in more lines, and potentially, more total claims being categorized as non-OPPS claims. Previously, even though those lines were excluded from OPPS for ratesetting purposes, they were still considered OPPS in categorizing the claims for the limited data set. This change in processing logic had no effect on ratesetting and *all of the lines with modifier ''PN'' are excluded from the OPPS ratesetting process for both CY 2019 and CY 2020.* We are including these lines as non-OPPS claims in the CY 2020 OPPS final rule limited data set, but as discussed, are continuing to exclude them for ratesetting purposes.

For details of the claims accounting process used in this final rule with comment period, we refer readers to the claims accounting narrative under supporting documentation for this CY 2020 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*.

2. Final Data Development and Calculation of Costs Used for Ratesetting

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.

In the CY 2020 OPPS/ASC proposed rule (84 FR 39409), 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, in order 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 in order to simulate blood-specific CCRs for those hospitals. We proposed to calculate the costs upon which the proposed CY 2020 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 stated in the proposed rule that we continue to believe that this methodology in CY 2020 would 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, as discussed in section II.A.2.b.(1). of the CY 2019 OPPS/ASC final rule with comment period (82 FR 58837 through 58843), 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. In the CY 2020 OPPS/ASC proposed rule (84 FR 39410), 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 would be reflected in the overall costs of the C–APCs (and, as a result, in the payment rates of the C–APCs), we proposed to not 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 also referred readers to Addendum B to the CY 2020 OPPS/ASC proposed rule (which is available via the internet on the CMS website) for the proposed CY 2020 payment rates for blood and blood products (which are 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).

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) Pathogen-Reduced Platelets Payment Rate

In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70322 through 70323), we reiterated that we calculate 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. Because HCPCS code P9072 (Platelets, pheresis, pathogen reduced or rapid bacterial tested, each unit), the predecessor code to HCPCS code P9073 (Platelets, pheresis, pathogen-reduced, each unit), was new for CY 2016, there were no claims data available on the charges and costs for this blood product upon which to apply our blood-specific CCR methodology. Therefore, we established an interim payment rate for HCPCS code P9072 based on a crosswalk to existing blood product HCPCS code P9037 (Platelets, pheresis, leukocytes reduced, irradiated, each unit), which we believed provided the best proxy for the costs of the new blood product. In addition, we stated that once we had claims data for HCPCS code P9072, we would calculate its payment rate using the claims data that should be available for the code beginning in CY 2018, which is our practice for other blood product HCPCS codes for which claims data have been available for 2 years.

We stated in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59233) that, although our standard practice for new codes involves using claims data to set payment rates once claims data become available, we were concerned that there may have been confusion among the provider community about the services that HCPCS code P9072 described. That is, as early as 2016, there were discussions about changing the descriptor for HCPCS code P9072 to include the phrase ''or rapid bacterial tested'', which is a less costly technology than pathogen reduction. In addition, effective January 2017, the code descriptor for HCPCS code P9072 was changed to describe rapid bacterial testing of platelets and, effective July 1, 2017, the descriptor for the temporary successor code (HCPCS code Q9988) for HCPCS code P9072 was changed again back to the original descriptor for HCPCS code P9072 that was in place for 2016.

Based on the ongoing discussions involving changes to the original HCPCS code P9072 established in CY 2016, we believed that claims from CY 2016 for pathogen reduced platelets may have potentially reflected certain claims for rapid bacterial testing of platelets. Therefore, we decided to continue to crosswalk the payment amount for services described by HCPCS code P9073 (the successor code to HCPCS code P9072 established January 1, 2018) to the payment amount for services described by HCPCS code P9037 for CY 2018 (82 FR 59232), to determine the payment rate for services described by HCPCS code P9072. In the CY 2019 OPPS/ASC proposed rule (83 FR 37058), for CY 2019, we discussed that we had reviewed the CY 2017 claims data for the two predecessor codes to HCPCS code P9073 (HCPCS codes P9072 and Q9988), along with the claims data for the CY 2017 temporary code for pathogen test for platelets (HCPCS code Q9987), which describes rapid bacterial testing of platelets. We found that there were over 2,200 claims billed with either HCPCS code P9072 or Q9988 in the CY 2017 claims data available for CY 2019 rulemaking. Accordingly, we believed that there were a sufficient number of claims to calculate a payment rate for HCPCS code P9073 for CY 2019 without using a crosswalk.

We also performed checks to estimate the share of claims that may have been billed for rapid bacterial testing of platelets as compared to the share of claims that may have been billed for pathogen-reduced, pheresis platelets (based on when HCPCS code P9072 was an active procedure code from January 1, 2017 to June 30, 2017). First, we found that the geometric mean cost for pathogen-reduced, pheresis platelets, as reported by HCPCS code Q9988 when billed separately from rapid bacterial testing of platelets, was $453.87, and

that over 1,200 claims were billed for services described by HCPCS code Q9988. Next, we found that the geometric mean cost for rapid bacterial testing of platelets, as reported by HCPCS code Q9987 on claims, was $33.44, and there were 59 claims reported for services described by HCPCS code Q9987, of which 3 were separately paid.

These findings implied that almost all of the claims billed for services reported with HCPCS code P9072 were for pathogen-reduced, pheresis platelets. In addition, the geometric mean cost for services described by HCPCS code P9072, which may have contained rapid bacterial testing of platelets claims, was $468.11, which was higher than the geometric mean cost for services described by HCPCS code Q9988 of $453.87, which should not have contained claims for rapid bacterial testing of platelets. Because the geometric mean for services described by HCPCS code Q9987 was only $33.44, it would be expected that if a significant share of claims billed for services described by HCPCS code P9072 were for the rapid bacterial testing of platelets, the geometric mean cost for services described by HCPCS code P9072 would be lower than the geometric mean cost for services described by HCPCS code Q9988. Instead, we found that the geometric mean cost for services described by HCPCS code Q9988 was higher than the geometric mean cost for services described by HCPCS code P9072.

However, we received many comments from providers and other stakeholders including blood product industry stakeholder groups and the company who developed the pathogen-reduced platelets technology requesting that we not implement our proposal for CY 2019, and instead that we should once again establish the payment rate for HCPCS code P9073 by performing a crosswalk from the payment amount for services described by HCPCS code P9073 to the payment amount for services described by HCPCS code P9037. The commenters were concerned that the payment rate for HCPCS code P9073 calculated by using claims data for that service was too low. Several commenters believed the claim costs for pathogen-reduced platelets were lower than actual costs because of coding errors by providers, providers who did not use pathogen-reduced platelets when billing the service, and confusion over whether to use the hospital CCR or the blood center CCR to report charges for pathogen-reduced platelets. We considered the comments we received and decided not to finalize our proposal for CY 2019 to calculate the payment rate for services described by HCPCS code P9073 using claims payment history. Instead, for CY 2019, we established the payment rate for services described by HCPCS code P9073 by crosswalking the payment rate for the services described by HCPCS code P9073 from the payment rate for services described by HCPCS code P9037 (83 FR 58834).

For CY 2020 and subsequent years, we proposed to calculate the payment rate for services described by HCPCS code P9073 by using claims payment history, which is the standard methodology used under the OPPS to calculate payment rates for HCPCS codes with at least 2 years of claims history. Claims for HCPCS code P9073 and its predecessor codes have been billed under the OPPS for over 3 years and we believe providers have had sufficient time to become familiar with the services covered by the procedure code and the appropriate charges and CCRs used to report the service. Also, it has been more than a year and half since the issue in which payment for pathogen-reduced platelets and payment for rapid bacterial testing were combined under the same code was resolved. In our analysis of claims data from CY 2018, we found that approximately 4,700 claims have been billed for services described by HCPCS code P9073 and the estimated payment rate for services described by HCPCS code P9073 based on the claims data was approximately $585. The claims-based payment rate for services described by HCPCS code P9073 was approximately $60 less than the estimated crosswalked payment rate using HCPCS code P9037 of approximately $645. The claims data show that services described by HCPCS code P9073 have been reported regularly by providers during CY 2018 and the payment rate is close to the payment rate of the crosswalked payment rate for services described by HCPCS code P9037. Therefore, we believe that the payment rate for services described by HCPCS code P9073 can be determined using claims data without a crosswalk from the payment rate for services described by HCPCS code P9037.

We refer readers to Addendum B of the proposed rule for the proposed payment rate for services described by HCPCS code P9073 reportable under the OPPS. Addendum B is available via the internet on the CMS website.

Comment: We received comments that opposed the proposal to end the crosswalk between P9073 (Platelets, pheresis, pathogen-reduced, each unit) and P9037 (Platelets, pheresis, leukocytes reduced, irradiated, each unit) and calculate the payment rate for services described by HCPCS code P9073 using claims payment history. The commenters stated that the 2018 claims data used to establish the CY 2020 payment rate for pathogen-reduced platelets continue to include erroneous claims and is therefore inaccurate. The commenters further state, as an example of the inaccuracies of the 2018 claims data, that approximately 30 percent of the 2018 claims data for P9073 contain costs that are at least $100 lower than the costs of P9037, which is a less expensive technology. The commenters requested that we continue the crosswalk between these two codes for both CYs 2020 and 2021 to allow hospitals time to continue to correct errors in their chargemasters and to prevent underpayment to hospitals for pathogen-reduced platelets. The commenters also claim that hospitals may be reluctant to adopt a relatively new technology, such as pathogen-reduced platelets, if the payment is too low.

Response: We continue to believe that, beginning in CY 2020, it is appropriate to calculate the payment rate for services described by HCPCS code P9073 using the standard methodology (which involves using data from CY 2018 claims for the code). We have previously acknowledged (83 FR 58834) that there was confusion among the provider community surrounding the reporting and billing for P9073 and have made exceptions to our standard methodology for calculating payment rates for this service. At this time, we believe providers have had sufficient time to become familiar with the services covered by the procedure code and we believe the issue in which payment for pathogen-reduced platelets and payment for rapid bacterial testing was combined under the same code has been resolved. Additionally, in response to concerns that hospitals may be reluctant to adopt the pathogen-reduced platelet technology based on a payment rate that is too low, in our analysis of claims data from CY 2018, we found that approximately 5,300 claims have been billed for services described by HCPCS code P9073, which is significantly higher that the approximately 2,200 claims billed in 2017 for services described by the predecessor codes for HCPCS code P9073, HCPCS codes Q9988 and P9072. Also, the estimated CY 2020 payment rate for services described by HCPCS code P9073 based on the CY 2018 claims data is approximately $600

which is comparable to the CY 2020 estimated crosswalked payment rate using HCPCS code P9037 of approximately $620. These data suggest that a crosswalk is no longer necessary. Further, we have now used a cross-walk for P9073 and its predecessor codes for 4 years, which is longer than the typical 2-year period for which we normally cross-walk new HCPCS codes. We agreed with past commenters that an extended period of cross-walking payment for P9073 was necessary to address the coding confusion in 2016 that may have led to the claims data reflecting costs for services not described by HCPCS code P9073. However, the above-referenced coding issues were resolved in January 2018, so we have no reason to believe that the data may reflect the costs for services other than those described by P9073.

Accordingly, for CY 2020 and subsequent years, we are finalizing the policy to calculate the payment rate for services described by HCPCS code P9073 by using claims payment history and to end the crosswalk between HCPCS codes P9037 and P9073.

(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.

In the CY 2020 OPPS/ASC proposed rule, for CY 2020, we proposed to use the costs derived from CY 2018 claims data to set the proposed CY 2020 payment rates for brachytherapy sources because CY 2018 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 2020 OPPS. 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 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 2020 payment rates for brachytherapy sources were included in Addendum B to the proposed rule (which is available via the internet on the CMS website) and were 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. For CY 2020, we proposed to continue to assign status indicator ''U'' to HCPCS code C2645 (Brachytherapy planar source, palladium-103, per square millimeter). Our CY 2018 claims data available for the proposed CY 2020 rule, included two claims with over 9,000 units of HCPCS code C2645. Therefore, we stated our belief that the CY 2018 claims data were adequate to establish an APC payment rate for HCPCS code C2645 and to discontinue our use of external data for this brachytherapy source. Specifically, we proposed to set the proposed CY 2020 payment rate at the geometric mean cost of HCPCS code C2645 based on CY 2018 claims data, which is $1.02 per mm^2.

Comment: One commenter stated that the reduction in the payment rate for HCPCS code C2645 (Brachytherapy planar source, palladium-103, per square millimeter) for CY 2020 will preclude outpatient use for an FDA-cleared, predominantly outpatient indication, for C2645. Additionally, the commenter argued that the two claims used to establish the payment rate for C2645 are not a sufficient volume for ratesetting and that the claims are most likely erroneous in that the brachytherapy source was used for procedures on the inpatient-only list.

Response: Claims that include brachytherapy sources along with procedures on the inpatient-only list are sufficient and appropriate to use for our ratesetting process as brachytherapy sources are line-item paid. However, given the limited number of claims for HCPCS C2645 for both CY 2020 and previous calendar years and the new FDA-approved outpatient indication for HCPCS code C2645, we are persuaded that the proposed CY 2020 payment rate, which is significantly lower than that of the rate in effect in prior years, may not adequately represent the costs associated with C2645. 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 maintain the CY 2019 rate for this brachytherapy source, despite the lower geometric mean costs of $1.03 per mm² available in the claims data used for this final rule with comment period. We believe this situation is unique, given the very limited number of claims for this brachytherapy source for both CY 2020 ratesetting purposes and previous calendar years.

After consideration of the public comment we received, we are not finalizing the proposed rate for C2645 and are instead assigning the brachytherapy source described by HCPCS code C2645 a payment rate of $4.69 mm² for CY 2020 through use of our equitable adjustment authority.

Comment: Some commenters recommended that we reevaluate our approach to ratesetting HCPCS C2642 (Brachytherapy source, stranded, cesium-131, per source) and stated that our proposed CY 2020 payment rate of $67.29 per source for HCPCS code C2642 would be too low to ensure fair and adequate reimbursement. Additionally, one provider who billed C2642 stated there was a clerical error and that it may have inadvertently underreported the actual costs for C2642 incurred by the provider.

Response: Based on the most current available data for the CY 2020 OPPS/ASC final rule with comment period, the geometric mean for HCPCS code C2642 based on 85 claims from CY 2018 is $75.06 per source. We note that the CY 2019 payment rate for HCPCS Code C2642 was $79.94 per source. We believe that the variation in costs for HCPCS code C2642 does not appear unusual or erroneous and that the CY 2020 geometric mean for HCPCS code C2642 based on CY 2018 claims data is consistent with historical payment rates for this brachytherapy source.

Comment: One commenter stated that the geometric mean cost and payment for brachytherapy sources has fluctuated significantly since 2013. The commenter argued that such fluctuations may put financial pressure on providers and create access barriers for beneficiaries to receive brachytherapy. The commenter requested we review and consider removing outliers to ensure payment stability for low-volume brachytherapy sources in future rulemaking.

Response: We thank the commenter for their recommendation and will take it under consideration in future rulemaking. As discussed in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68259 through 68271), geometric mean costs better encompass the variation in costs that occur when providing a service because, in addition to the individual cost values that are reflected by medians, geometric means reflect the magnitude of the cost measurements, and thus are more sensitive to changes in the data. OPPS relative payment weights based on geometric mean costs would better capture the range of costs associated with providing services. Further, geometric means capture cost changes 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 outliers when determining brachytherapy geometric mean costs and payment rates.

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 directed 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 2020

(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).

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 this final rule with comment period

(which is available via the internet on the CMS website).

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 this final 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 2020, in the CY 2020 OPPS/ASC proposed rule (84 FR 39414), 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 2020, along with all of the other proposed complexity adjustments, in Addendum J to the CY 2020 OPPS/ASC proposed rule (which is available via the internet on the CMS website).

Addendum J to the proposed rule included 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 proposed rule also contained summary cost statistics for each of the paired code combinations that describe a complex code combination that would qualify for a complexity adjustment and were 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 were 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 were 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 proposed rule allowed 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: Several commenters requested that CMS alter the established C–APC complexity adjustment eligibility criteria to allow additional code combinations to qualify for complexity adjustments. Some commenters reiterated their request to allow clusters of procedures, consisting of a ''J1'' code-pair and multiple other associated add-on codes used in combination with that ''J1'' code-pair to qualify for complexity adjustments. Other commenters requested that CMS allow procedures assigned status indicator ''S'' or ''T'' to be eligible for complexity adjustments, to allow a C–APC to receive payment at the C–APC rate two levels higher within the clinical family when there is a violation of the two-times rule in the receiving C–APC and also to account for patient characteristics such as comorbidities and sociodemographic factors in the complexity adjustment policy. One commenter recommended that HCPCS code 0546T—Radiofrequency spectroscopy, real time, intraoperative margin assessment, at the time of partial mastectomy, with report—be assigned to APC 5091—Level 1 Breast/Lymphatic Surgery and Related Procedures and designated for complexity adjustment to APC 5092—Level 2 Breast/Lymphatic Surgery and Related Procedures for CY 2020.

We also received a comment requesting that CMS modify its complexity adjustment criteria and apply the complexity adjustment to all blue light cystoscopy with Cysview procedures in the HOPD, including eliminating the claim frequency requirement to determine eligibility for the complexity adjustment and expanding the eligibility for a complexity adjustment to other APCs besides C–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.

We also do not believe that it is necessary to provide payment for claims including qualifying code combinations at two APC levels higher than the originating APC. As stated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58842), we believe that payment at the next higher paying C–APC is adequate for code combinations that exhibit materially greater resource requirements than the primary service and that, in many cases, paying the rate assigned to two levels higher may lead to a significant overpayment. As mentioned previously, we do not create new APCs with a comprehensive geometric mean cost that is higher than the highest geometric mean cost C–APC in a clinical family just to accommodate potential complexity adjustments. 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). Therefore, a policy to pay for claims with qualifying code combinations at two C–APC levels higher than the originating APC is not always feasible.

Lastly, as stated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58843), we do not believe that it is necessary to adjust the complexity adjustment criteria to allow claims that include more than two ''J1'' procedures, procedures that are not assigned to C–APCs, or procedures performed at certain hospitals with patients with more comorbidities, to qualify for a complexity adjustment. As mentioned earlier, we believe the current criteria are adequate to determine if a combination of procedures represents a complex, costly subset of the primary service.

With regard to the requests for further complexity adjustments for blue light cystoscopy procedures using the drug Cysview, as discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59243–59246), we acknowledged that there are additional equipment, supplies, operating room time, and other resources required to perform blue light cystoscopy in addition to white light cystoscopy. We also acknowledged stakeholder concerns that the payment for blue light cystoscopy procedures involving Cysview® may be creating a barrier to beneficiaries receiving access to reasonable and necessary care for which there may not be a clinically comparable alternative. Based on these issues, 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 2020, there are three code combinations of six total involving C9738 and procedure codes used to describe white light cystoscopy that will qualify for a complexity adjustment. At this time, we do not believe that further modifications to the C–APC policy are necessary.

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 2020, as proposed, without modification.

(2) Additional C–APCs for CY 2020

For CY 2020 and subsequent years, in the CY 2020 OPPS/ASC proposed rule (84 FR 39414), 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, in the proposed rule (84 FR 39414), we proposed to add two C–APCs under the existing C–APC payment policy in CY 2020: Proposed C–APC 5182 (Level 2

Vascular Procedures); and proposed C–APC 5461 (Level 1 Neurostimulator and Related Procedures). These APCs were selected to be included in this proposal because, similar to other C–APCs, these APCs include primary, comprehensive services, such as major surgical procedures, that are typically reported with other ancillary and adjunctive services. Also, similar to other APCs that have been converted to C–APCs, there are higher APC levels within the clinical family or related clinical family of these APCs that have previously been assigned to a C–APC. Table 4 of the proposed rule listed the proposed C–APCs for CY 2020. All C–APCs were displayed in Addendum J to the proposed rule (which is available via the internet on the CMS website). Addendum J to the proposed rule also contained all of the data related to the C–APC payment policy methodology, including the list of proposed complexity adjustments and other information.

We also are considering developing an episode-of-care for skin substitutes and are interested in comments regarding a future C–APC for procedures using skin substitute products furnished in the hospital outpatient department setting. We note that this comment solicitation is discussed in section V.B.7. of the proposed rule and this final rule with comment period.

Comment: Several commenters supported the creation of the two new proposed C–APCs, encouraging CMS to continue to evaluate outpatient charge and cost data for additions to the list of C–APCs during future rulemaking periods. One commenter requested that CMS closely monitor payments for the proposed C–APC 5461 (Level 1 Neurostimulator and Related Products) relative to costs of the procedure to ensure accurate compensation and availability in the ASC setting.

Response: We appreciate the commenters' support and note that we annually review the most recent data available to determine costs associated with furnishing a service and update payment rates accordingly.

Comment: We received comments requesting that CMS create a C–APC for autologous hematopoietic stem cell transplant similar to the C–APC established for allogeneic hematopoietic stem cell transplant. The commenters stated CMS' APC rate-setting process of using single and pseudo-single procedure claims results in an inadequately low APC payment rate for autologous stem cell transplant and believed that the creation of a C–APC for autologous hematopoietic stem cell transplant would improve payment rates by allowing a greater number of claims to be used in the rate setting process. The Advisory Panel on Hospital Outpatient Payment (HOP Panel) also recommended that CMS consider creating a comprehensive APC for autologous stem cell transplantation and that CMS provide a rationale if it decides not to create such an APC.

Response: We thank the commenter for this comment. In order to determine whether it would be appropriate to create a C–APC for autologous hematopoietic stem cell transplant, we modeled this change with APC 5242—Level 2 Blood Product Exchange and Related Services, which includes CPT code 38241 Hematopoietic progenitor cell (hpc); autologous transplantation as well as APC 5243—Level 3 Blood Product Exchange and Related Services, in keeping with our practice of converting APCs to C–APCs that have higher APC levels within the clinical family that are assigned to a C–APC.

After analyzing the results, we found that creating a C–APC for APC 5242 would increase the number of single claims available for ratesetting for this APC by approximately 8 percent, however creating new C–APCs in the Stem Cell Transplant clinical family would decrease the geometric mean cost of C–APC 5244—Level 4 Blood Product Exchange and Related Services by approximately 75 percent due to complexity adjustments of code combinations within the clinical family, specifically complexity adjustments from C–APC 5243 to C–APC 5244. Therefore, at this time we do not believe it is appropriate to create a C–APC for autologous hematopoietic stem cell transplant.

Comment: Two manufacturers of drugs used in ocular procedures requested that CMS discontinue the C–APC payment policy for existing C–APCs that include procedures involving their drugs and instead provide separate payment for the drugs. The manufacturer commenters believed that the C–APC packaging policy, which packages payment for certain drugs that are adjunctive to the primary service, results in underpayment for the drugs and violates the 2 times rule.

Response: We continue to believe that the procedures assigned to the proposed C–APCs, including the procedures involving the drugs used in ocular procedures mentioned by the commenters, are appropriately paid through a C–APC and the costs of drugs (as well as other items or services furnished with the procedures) are reflected in hospital billing, and therefore the rates that are established for the ocular procedures. As stated in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79584), procedures assigned to C–APCs are primary services (mostly major surgical procedures) that are typically the focus of the hospital outpatient stay. In addition, with regard to the packaging of the drugs based on the C–APC policy, as stated in previous rules (78 FR 74868 through 74869 and 74909 and 79 FR 66800), items included in the packaged payment provided with the primary ''J1'' service include all drugs, biologicals, and radiopharmaceuticals payable under the OPPS, regardless of cost, except those drugs with pass-through payment status. In accordance with section 1833(t)(2) of the Act and § 419.31 of the regulations, we annually review the items and services within an APC group to determine if there are any APC violations of the 2 times rule and whether there are any revisions to APC assignments that may be necessary or any exceptions that should be made.

Comment: Several commenters, including device manufacturer associations, expressed concern that the C–APC payment rates may not adequately reflect the costs associated with services and requested that CMS not establish any additional C–APCs. These comments questioned the broader C–APC payment methodology, ratesetting accuracy, the impact of C–APCs on broader agency objectives, and recommended methodological changes to better capture costs of providing comprehensive services before further expansion. Some commenters were concerned that hospital 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.

Response: We appreciate the comments. We continue to believe that the proposed new C–APCs for CY 2020 are appropriate to be added to the existing C–APC payment policy. 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 looked at data from 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 involved claims data 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.

Comment: One commenter requested that CMS discontinue the C–APC payment policy for single session stereotactic radiosurgery (SRS) procedures, stating concerns that the C–APC methodology does not account for the complexity of delivering radiation therapy and fails to capture appropriately coded claims. The commenters also 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 2020 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 2020 (82 FR 59242 and 59243).

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.

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: We received requests for clarifications related to C–APC 8011 Comprehensive Observation Services (status indicator ''J2''). One commenter requested that CMS clarify the distinction between status indicators for ''V'' and ''J2''. Another commenter questioned the rationale for the established criteria for payment through C–APC 8011, specifically the requirement that the claim does not contain a procedure described by a HCPCS code to which we have assigned status indicator ''T'' that is reported with a date of service on the same day or 1 day earlier than the date of service associated with services described by HCPCS code G0378.

Response: The comprehensive observation services C–APC (C–APC 8011) was established in CY 2016 (80 FR 70333 through 70336) to provide payment for extended assessment and management encounters. C–APC 8011 is paid and status indicator ''J2'' is assigned when a specific combination of services is performed. This combination of services was described in previous rulemaking (80 FR 70333 through 70336) in detail and is repeated for clarity below. 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'' results in a single prospective payment for the comprehensive observation services based on the costs of all reported services on the claim. We make payment for all other items and services reported on the hospital outpatient claim as being adjunctive to the specific combination of observation services. The assignment of status indicator ''V'' describes a clinic or emergency department visit. It does not describe services paid through a comprehensive APC and it will not trigger payment through C–APC 8011.

With regard to the comment questioning the rationale for the requirement that the claim does not contain a procedure described by a HCPCS code to which we have assigned status indicator ''T'' that is reported with a date of service on the same day or 1 day earlier than the date of service associated with services described by HCPCS code G0378 in order to be paid through C–APC 8011, this criterion was incorrectly quoted as the final policy in the CY 2020 OPPS/ASC proposed rule (84 FR 39412). This language has been updated in this final rule with comment period. This criterion was proposed in the CY 2016 OPPS/ASC proposed rule, however a modification of this criterion was finalized. We refer readers to the discussion of the establishment of C–APC 8011 in the CY 2016 OPPS/ASC Final Rule with comment period (80 FR 70335–70336). In this rule, we stated in response to commenters' concerns regarding packaging payment for potentially high-cost surgical procedures into the payment for an observation C–APC, we finalized a policy that claims reporting procedures assigned status indicator ''T'' should not qualify for payment through C–APC 8011, regardless of whether the procedure assigned status indicator ''T'' was furnished before or after observation services (described by HCPCS code G0378) were provided. We state the final criteria for assignment for payment through C–APC 8011 in the CY 2016 OPPS/ASC final rule with comment period, including that the

claims must not contain a procedure described by a HCPCS code to which we have assigned status indicator ''T'' (80 FR 70335).

After consideration of the public comments we received, we are finalizing the proposed C–APCs for CY 2020. Table 4 below lists the final C–APCs for CY 2020. 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 2020.

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TABLE 5.—CY 2020 C-APCs

C-APC	CY 2020 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	

C-APC	CY 2020 APC Group Title	Clinical Family	New C-APC
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	
5377	Level 7 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	
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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(3) 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.

For example, for CY 2017, there were seven claims generated for HCPCS code 0100T (Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intraocular retinal electrode array, with vitrectomy), which involves the use of the Argus® II Retinal Prosthesis System. However, several of these claims were not available for ratesetting because HCPCS code 0100T was reported with a ''J1'' procedure and, therefore, payment was packaged into the associated C–APC payment. If these services had been separately paid under the OPPS, there would be at least two additional single claims available for ratesetting. As mentioned previously, the purpose of the new technology APC policy is to ensure that there are sufficient claims data for new services, which is particularly important for services with a low volume such as procedures described by HCPCS code 0100T. Another concern is the costs reported for the claims when payment is not packaged for a new technology procedure may not be representative of all of the services included on a claim that is generated, which may also affect our ability to assign the new service to the most appropriate clinical APC.

To address this issue and help 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 proposed excluded 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. For CY 2020, we proposed to continue to exclude payment for any procedure that is assigned to a New Technology APC from being packaged when included on a claim with a ''J1'' service assigned to a C–APC.

Some stakeholders have raised questions about whether the policy established in the CY 2019 OPPS/ASC final rule with comment period would also apply to comprehensive observation services assigned status indicator ''J2.'' We recognize that the policy described and adopted in the CY 2019 rulemaking may have been ambiguous with respect to this issue. While our intention in the CY 2019 rulemaking was only to exclude payment for services assigned to New Technology APCs from being bundled into the payment for a comprehensive ''J1'' service, we believe that there may also be some instances in which it would be clinically appropriate to provide a new technology service when providing comprehensive observation services. We would not generally expect

that to be the case, because procedures assigned to New Technology APCs typically are new or low-volume surgical procedures, or are specialized tests to diagnosis a specific condition. In addition, it is highly unlikely a general observation procedure would be assigned to a New Technology APC because there are clinical APCs already established under the OPPS to classify general observation procedures. As we stated in the CY 2016 OPPS/ASC final rule with comment period, observation services may not be used for post-operative recovery and, as such, observation services furnished with services assigned to status indicator ''T'' will always be packaged (80 FR 70334). Therefore, we proposed that payment for services assigned to a New Technology APC when included on a claim for a service assigned status indicator ''J2'' assigned to a C–APC will be packaged into the payment for the comprehensive service. Nonetheless, we sought public comments on whether it would be clinically appropriate to exclude payment for any New Technology APC procedures from being packaged into the payment for a comprehensive ''J2'' service starting in CY 2020.

Comment: Several commenters, including device manufacturers, device manufacturer associations and physicians were opposed to our proposal to package payment for procedures assigned to a New Technology APC into the payment for comprehensive observation services assigned status indicator ''J2''. The commenters stated that there were instances where beneficiaries receiving observation services may require the types of procedures that are assigned to new technology APCs. Several commenters specifically mentioned the HeartFlow Analysis, and stated that it could be performed appropriately for a patient receiving observation services. The commenters also stated that providing separate payment for this new technology procedure will allow CMS to collect sufficient claims data to enable assignment of the procedure to an appropriate clinical APC.

Response: We appreciate the stakeholders' comments regarding this proposal and agree that, although rare, there are situations in which it is clinically appropriate to provide a new technology service when providing comprehensive observation services. As discussed in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58847), the purpose of the new technology APC policy is to ensure that there are sufficient claims data for new services to assign these procedures to an appropriate clinical APC and therefore, we excluded procedures assigned to New Technology APCs from packaging under the C–APC policy. In the CY 2019 final rule, we specifically stated that the exclusion policy included circumstances when New Technology procedures were billed with comprehensive services assigned to status indicator ''J1'', however we believe this rationale is also applicable to comprehensive observation services that are assigned status indicator ''J2''. Therefore, we are modifying our policy for excluding procedures assigned to New Technology APCs from the C–APC policy. For CY 2020, we are finalizing our policy to continue to exclude payment for any procedure that is assigned to a New Technology APC from being packaged when included on a claim with a ''J1'' service assigned to a C–APC. For CY 2020, we are also finalizing a policy to exclude payment for any procedures that are assigned to a New Technology APC from being packaged into the payment for comprehensive observation services assigned to status indicator ''J2'' when they are included on a claim with ''J2'' procedures.

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

In the CY 2020 OPPS/ASC proposed rule (84 FR 39398), 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.

In the CY 2020 OPPS/ASC proposed rule (84 FR 39398), for CY 2020, 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 2020. 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 2020. In addition, we are finalizing our proposal to set the payment rate for composite APC 8010 for CY 2020 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, in order 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).

In the CY 2020 OPPS/ASC proposed rule (84 FR 39398), 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 stated that 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 2020 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 2018 claims available for the CY 2020 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), were identified by asterisks in Addendum N to the CY 2020 OPPS/ASC proposed rule (which is available via the internet on the CMS website) and were discussed in more detail in section II.A.1.b. of the CY 2020 OPPS/ASC proposed rule.

For the CY 2020 OPPS/ASC proposed rule, we were able to identify approximately 700,000 ''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 2020 geometric mean costs for the multiple imaging composite APCs. Table 5 of the CY 2020 OPPS/ASC proposed rule listed 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 2020.

We did not receive any public comments on these proposals. 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 6 below 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 2020.

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TABLE 6.—OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCs

Family 1 – Ultrasound	
CY 2020 APC 8004 (Ultrasound Composite)	**CY 2020 Approximate APC Geometric Mean Cost = $301.09**
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 2020 APC 8005 (CT and CTA without Contrast Composite)*	**CY 2020 Approximate APC Geometric Mean Cost = $221.27**
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
74261	Ct colonography, w/o dye
74176	Ct angio abd & pelvis

CY 2020 APC 8006 (CT and CTA with Contrast Composite)	CY 2020 Approximate APC Geometric Mean Cost = $427.99
70487	Ct maxillofacial w/dye
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
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
74262	Ct colonography, w/dye
75635	Ct angio abdominal arteries
74177	Ct angio abd & pelv w/contrast
74178	Ct angio abd & pelv 1+ regns

* 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 2020 APC 8007 (MRI and MRA without Contrast Composite)*	**CY 2020 Approximate APC Geometric Mean Cost = $514.85**
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
CY 2020 APC 8008 (MRI and MRA with Contrast Composite)	**CY 2020 Approximate APC Geometric Mean Cost = $820.27**
70549	Mr angiograph neck w/o & w/dye
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
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), and the CY 2019 OPPS/ASC final rule with comment period (83 FR 58854). 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 2020, 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 the CY 2020 OPPS/ASC proposed rule (84 FR 39423 through 39424), beginning in CY 2020, we proposed to conditionally package the costs of selected newly identified ancillary services into payment with 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 and finalized changes to the packaging policies beginning in CY 2020.

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 packaging of Cysview 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, 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, to pay separately for Cysview® when it is used with blue light cystoscopy in the ASC setting, 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 payment for this drug is 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 nor do we have any evidence to show that separate payment for all diagnostic imaging drugs (radiopharmaceuticals, contrast agents) is required. 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 include:

- 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 would be 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 Treatments

(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. In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59255), we summarized these public comments. The public comments ranged from requests to unpackage most items and services that are either conditionally or unconditionally packaged under the OPPS, including drugs and devices, to specific requests for separate payment for a specific drug or device.

In terms of Exparel® in particular, we received several requests to pay separately for the drug Exparel® rather than packaging payment for it as a surgical supply. We had previously stated that we considered Exparel® to be a drug that functions as a surgical supply because it is indicated for the alleviation of postoperative pain (79 FR 66874 and 66875). We had also stated before that we considered 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. (We note that Exparel® is a liposome injection of bupivacaine, an amide local anesthetic, indicated for single-dose infiltration into the surgical site to produce postsurgical analgesia. In 2011, Exparel® was approved by FDA for single-dose infiltration into the surgical site to provide postsurgical analgesia.[1] [2] Exparel® had pass-through payment status from CYs 2012 through 2014 and was separately paid under both the OPPS and the ASC payment system during this 3-year period. Beginning in CY 2015, Exparel® was packaged as a surgical supply under both the OPPS and the ASC payment system.)

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 52485, we reiterated our position with regard to payment for Exparel®, 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 CMS would continue to explore and evaluate packaging policies under the OPPS and consider these policies in future rulemaking.

In addition to stakeholder feedback regarding OPPS packaging policies in response to the CY 2019 OPPS/ASC proposed rule, the President's Commission on Combating Drug Addiction and the Opioid Crisis (the Commission) had recommended that CMS examine payment policies for certain drugs that function as a supply, specifically non-opioid pain management treatments (83 FR 37068). The Commission was established in 2017 to study ways to combat and treat drug abuse, addiction, and the opioid crisis. The Commission's report [3] included a recommendation for CMS to ''. . . review and modify ratesetting policies that discourage the use of non-opioid treatments for pain, such as certain bundled payments that make alternative treatment options cost prohibitive for hospitals and doctors, particularly those options for treating immediate postsurgical pain . . . .'' [4] With respect to the packaging policy, the Commission's report states that ''. . . the current CMS payment policy for 'supplies' related to surgical procedures creates unintended incentives to prescribe opioid medications to patients for postsurgical pain instead of administering non-opioid pain medications. Under current policies, CMS provides one all-inclusive bundled payment to hospitals for all 'surgical supplies,' which includes hospital administered drug products intended to manage patients' postsurgical pain. This policy results in the hospitals receiving the same fixed fee from Medicare whether the surgeon administers a non-opioid medication or not.'' [5] HHS also presented an Opioid Strategy in April 2017 [6] that aims in part to support cutting-edge research and advance the practice of pain management. On October 26, 2017, the President declared the opioid crisis a national public health emergency under Federal law [7] and this declaration was most recently renewed on April 19, 2019.[8]

For the CY 2019 rulemaking, we reviewed available literature with respect to Exparel®, including a briefing document [9] submitted for FDA Advisory Committee Meeting held February 14–15, 2018, by the manufacturer of Exparel® that notes that ''. . . Bupivacaine, the active pharmaceutical ingredient in Exparel®, is a local anesthetic that has been used for infiltration/field block and peripheral nerve block for decades'' and that ''since its approval, Exparel® has been used extensively, with an estimated 3.5 million patient exposures in the US.'' [10] On April 6, 2018, FDA approved Exparel®'s new indication for use as an interscalene brachial plexus nerve block to produce postsurgical regional analgesia.[11] Therefore, we also stated in the CY 2019 OPPS/ASC proposed rule that, based on our review of currently available OPPS Medicare claims data and public information from the manufacturer of the drug, we did not believe that the OPPS packaging policy had discouraged the use of Exparel® for either of the drug's indications when furnished in the hospital outpatient department setting.

In the CY 2019 OPPS/ASC proposed rule, in response to stakeholder comments on the CY 2018 OPPS/ASC final rule with comment period (82 FR 52485) and in light of the recommendations regarding payment policies for certain drugs, we evaluated the impact of our packaging policy for drugs that function as a supply when used in a surgical procedure on the utilization of these drugs in both the hospital outpatient department and the ASC setting. Our packaging policy is that the costs associated with packaged drugs that function as a supply are included in the ratesetting methodology for the surgical procedures with which they are billed, and the payment rate for the associated procedure reflects the costs of the packaged drugs and other packaged items and services to the extent they are billed with the procedure. In our evaluation, we used currently available data to analyze the utilization patterns associated with

[1] 2011 product label available at: *https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/022496s000lbl.pdf.*

[2] 2011 FDA approval letter available at: *https://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/022496Orig1s000Approv.pdf.*

[3] President's Commission on Combating Drug Addiction and the Opioid Crisis, Report (2017). Available at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf.*

[4] Ibid, at page 57, Recommendation 19.

[5] Ibid.

[6] Available at: *https://www.hhs.gov/about/leadership/secretary/speeches/2017-speeches/secretary-price-announces-hhs-strategy-for-fighting-opioid-crisis/index.html.*

[7] Available at: *https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html.*

[8] Available at: *https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx.*

[9] Food and Drug Administration, Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee Briefing Document (2018). Available at: *https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM596314.pdf.*

[10] Ibid, page 9.

[11] 2018 updated product label available at: *https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/022496s009lbledt.pdf.*

specific drugs that function as a supply over a 5-year time period to determine whether this packaging policy reduced the use of these drugs. If the packaging policy discouraged the use of drugs that function as a supply or impeded access to these products, we would expect to see a significant decline in utilization of these drugs over time, although we note that a decline in utilization could also reflect other factors, such as the availability of alternative products, or a combination thereof.

The results of the evaluation of our packaging policies under the OPPS and the ASC payment system showed decreased utilization for certain drugs that function as a supply in the ASC setting, in comparison to the hospital outpatient department setting. In light of these results, as well as the Commission's recommendation to examine payment policies for non-opioid pain management drugs that function as a supply, we stated that we believe it was appropriate to pay separately for evidence-based non-opioid pain management drugs that function as a supply in a surgical procedure in the ASC setting to address the decreased utilization of these drugs and to encourage use of these types of drugs rather than prescription opioids. Therefore, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58855 through 58860), we finalized the proposed 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 stated that we would continue to analyze the issue of access to non-opioid alternatives in the hospital outpatient department setting and in the ASC setting as we implemented section 6082 of the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act (Pub. L. 115–271) enacted on October 24, 2018 (83 FR 58860 through 58861).

(2) Evaluation and CY 2020 Proposal for 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. Pursuant to these requirements, in our evaluation of whether there are payment incentives for using opioids instead of non-opioid alternatives, for the CY 2020 OPPS/ASC proposed rule, 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. We focused on covered OPD services for this review, including services assigned to C–APCs, surgical APCs, and other pain management services. We believed that if the packaging policy discouraged the use of these non-opioid alternatives or impeded access to these products, we would expect to see a decline in the utilization over time, although we note that a decline in utilization could also reflect other factors, such as the availability of alternative products or a combination thereof.

We evaluated continuous peripheral nerve blocks and neuromodulation alternatives to determine if the current packaging policy represented a barrier to access. For each product, we examined the most recently available Medicare claims data. All of the alternatives examined showed consistent or increasing utilization in recent years, with no products showing decreases in utilization.

We also evaluated drugs that function as surgical supplies over a 6-year time period (CYs 2013 through 2018). During our evaluation, we did not observe significant declines in the total number of units used in the hospital outpatient department for a majority of the drugs included in our analysis. In fact, under the OPPS, we observed the opposite effect for several drugs that function as surgical supplies, including Exparel® (HCPCS code C9290). This trend indicates appropriate packaged payments that adequately reflect the cost of the drug and are not prohibiting beneficiary access.

From CYs 2013 through 2018, we found that there was an overall increase in the OPPS Medicare utilization of Exparel® of approximately 491 percent (from 2.3 million units to 13.6 million units) during this 6-year time period. The total number of claims reporting the use of Exparel® increased by 463 percent (from 10,609 claims to 59,724 claims) over this 6-year time period. This increase in utilization continued, even after the expiration of the 3-year period of pass-through payment status for this drug in 2014, resulting in a 109-percent overall increase in the total number of units used between CYs 2015 and 2018, from 6.5 million units to 13.6 million units. The number of claims reporting the use of Exparel® increased by 112 percent during this time period, from 28,166 claims to 59,724 claims.

The results of our review and evaluation of our claims data do not provide evidence to indicate that the OPPS packaging policy has had the unintended consequence of discouraging the use of non-opioid treatments for postsurgical pain management in the hospital outpatient department. Therefore, based on this data evaluation, we stated in the proposed rule that we do not believe that changes are necessary under the OPPS for the packaged drug policy for drugs that function as a surgical supply, nerve blocks, surgical injections, and neuromodulation products when used in a surgical procedure in the OPPS setting at this time.

For Exparel®, we reviewed claims data for development of the CY 2020 OPPS/ASC proposed rule and, based on these data and available literature, we concluded that there is no clear evidence that the OPPS packaging policy discourages the use of Exparel® for either of the drug's indications in the hospital outpatient department setting because the use of Exparel® continues to increase in this setting. Accordingly, we stated in the proposed rule that we continue to believe it is appropriate to package payment for the use of

Exparel®, as we do for other postsurgical pain management drugs, when it is furnished in a hospital outpatient department. In addition, our updated review of claims data for the proposed rule showed a continued decline in the utilization of Exparel® in the ASC setting, which we believed supports our proposal to continue paying separately for Exparel® in the ASC setting.

Therefore, for CY 2020, 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. However, we invited public comments on this proposal and asked the public to provide peer-reviewed evidence, if any, to describe existing evidence-based non-opioid pain management therapies used in the outpatient and ASC setting. We also invited the public to provide detailed claims-based evidence to document how specific unfavorable utilization trends are due to the financial incentives of the payment systems rather than other factors.

Multiple stakeholders, largely manufacturers of devices and drugs, requested separate payments for various non-opioid pain management treatments, such as continuous nerve blocks (including a disposable elastomeric pump that delivers non-opioid local anesthetic to a surgical site or nerve), cooled thermal radiofrequency ablation, and local anesthetics designed to reduce postoperative pain for cataract surgery and other procedures. These stakeholders suggested various mechanisms through which separate payment or a higher-paying APC assignment for the primary service could be made. The stakeholders offered surveys, reports, studies, and anecdotal evidence of varying degrees to support why the devices, drugs, or services offer an alternative to or a reduction of the need for opioid prescriptions. The majority of these stakeholder offerings lacked adequate sample size, contained possible conflicts of interest such as studies conducted by employees of device manufacturers, have not been fully published in peer-reviewed literature, or have only provided anecdotal evidence as to how the drug or device could serve as an alternative to, or reduce the need for, opioid prescriptions.

After reviewing the 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 are necessary for CY 2020. Additionally, MedPAC's March 2019 Report to Congress supports our conclusion; specifically, Chapter 16 of MedPAC's report, titled Mandated Report: Opioids and Alternatives in Hospital Settings—Payments, Incentives, and Medicare Data, concludes that there is no clear indication that Medicare's OPPS provides systematic payment incentives that promote the use of opioid analgesics over non-opioid analgesics.[12] However, we invited public comments on whether there were other non-opioid pain management alternatives for which our payment policy should be revised to allow separate payment. We requested public comments that provided 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. We noted that evidence that current payment policy provides a payment incentive for using opioids instead of non-opioid alternatives should align with available Medicare claims data.

We provide a summary of the comments received and our responses to those comments below.

Comment: Multiple commenters, including hospital associations, medical specialty societies, and drug manufacturers, requested that we pay separately for Exparel and other drugs that function as surgical supply 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. The manufacturer of Exparel, Pacira Pharmaceuticals, presented a 5-year OPPS claims data analysis of hospital trends in Exparel use and a 200 hospital survey on purchasing decisions for non-opioid alternatives, concluding that Medicare's packaging policy has led to hospitals reducing or stopping Exparel use.

Response: As we stated in the CY 2019 OPPS/ASC final rule (83 FR 58856), 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 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 (including Exparel) solely because of the OPPS packaged payment policy. We observed increasing Exparel utilization in the HOPD setting with the total units increasing from 9.0 million in 2017 to 13.6 million in 2018, despite the bundled 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 and other non-opioid pain management drugs presents a widespread barrier to their use.

In addition, higher 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 higher utilization in the OPPS setting should mitigate the need for separate payment. 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. As stated earlier in this section, the OPPS packages payments for multiple interrelated items and services into a single payment to create incentives for hospitals to furnish

[12] Available at: *http://www.medpac.gov/-documents-/reports.*

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 OPD and ASC settings for potential future rulemaking.

We also stated in the CY 2020 OPPS/ASC proposed rule that, although we found increases in utilization for Exparel when it is paid under the OPPS, we did notice a continued decline in Exparel utilization in the ASC setting. While several variables may contribute to this difference in utilization and claims reporting between the hospital outpatient department and the ASC setting, one potential explanation is that, in comparison to hospital outpatient departments, ASCs tend to provide specialized care and a more limited range of services. Also, ASCs are paid, in aggregate, approximately 55 percent of the OPPS rate. Therefore, fluctuations in payment rates for specific services may impact these providers more acutely than hospital outpatient departments, and as a result, ASCs may be less likely to choose to furnish non-opioid postsurgical pain management treatments, which are typically more expensive than opioids. Another possible contributing factor is that ASCs do not typically report packaged items and services and, accordingly, our analysis may be undercounting the number of Exparel units utilized in the ASC setting.

Therefore, 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. This policy and related comments are addressed in section XIII.D.3. of this final rule with comment period.

As we stated previously in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59250), our packaging policies are designed to support our strategic goal of using larger payment bundles in the OPPS to maximize hospitals' incentives to provide clinically appropriate care in the most efficient manner. The packaging policies established under the OPPS also typically apply when services are provided in the ASC setting, and the policies have the same strategic goals in both settings. While unpackaging and paying separately for drugs that function as surgical supplies is a departure from our overall packaging policy for drugs, we believe that the proposed change will continue to incentivize the use of non-opioid pain management drugs and is responsive to the Commission's recommendation to examine payment policies for non-opioid pain management drugs that function as a supply, with the overall goal of combating the current opioid addiction crisis. As previously noted, a discussion of the CY 2020 proposal for payment of non-opioid pain management drugs in the ASC setting was presented in further detail in section XIII.D.3 of the CY 2020 OPPS/ASC proposed rule, and we refer readers to section XIII.D.3 of this CY 2020 OPPS/ASC final rule with comment period for further discussion of the final policy for CY 2020. As stated above, we also requested public comments in the CY 2020 OPPS/ASC proposed rule that provide peer-reviewed evidence, 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. We also stated that evidence that current payment policy provides a payment incentive for using opioids instead of non-opioid alternatives should align with available Medicare claims data.

Comment: Several commenters supported the assignment of status indicator ''K'' (Nonpass-Through Drugs and Nonimplantable Biologicals, Including Therapeutic Radiopharmaceuticals) and continuing to pay separately for the drug Prialt (HCPCS J2278, injection, ziconitide), a non-narcotic pain reliever administered via intrathecal injection. Commenters provided data indicating that Prialt potentially could lower opioid use, including opioids such as morphine. In addition to continued separate payment, several commenters recommended CMS reduce or eliminate the coinsurance for the drug in order to increase beneficiary access. Commenters stated that due to the drug's significant cost, the 20 percent coinsurance would put the drug out of reach for beneficiaries. Additionally, commenters stated that there is not enough financial incentive for providers to use Prialt in their patients compared to lower cost opioids. Commenters claim that Prialt is only paid at invoice cost, which they believe discourages provider use.

Response: We thank commenters for their feedback and for their support of the continued assignment of status indicator ''K'' to HCPCS J2278. Prialt is paid at its average sales price plus 6 percent according to the ASP methodology under the OPPS. We note that under section 1833(t)(8) of the Act, the payment is subject to applicable deductible and coinsurance, and we are unaware of statutory authority to alter beneficiary coinsurance for payments made under the OPPS. We note that because the dollar value of beneficiary coinsurance is directly proportionate to the payment rate (which is ASP + 6 percent for HCPCS code J2278), a lower sales price for the drug (which would lead to a lower Medicare payment rate under current policy) would be necessary for beneficiaries to have a lower coinsurance amount.

Comment: Many commenters requested that the drug Omidria (HCPCS code C9447, injection, phenylephrine ketorolac) be excluded from the packaging policy 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 the available data and multiple peer-reviewed articles on Omidria meet the section 6082 criteria for packaging exclusion. Commenters asserted that the use of Omidria decreases patients' need for fentanyl during surgeries and another commenter stated that Omidria reduces opioid use after cataract surgeries. In addition, commenters asserted that the OPPS and ASC payment system do not address the cost of packaged products used by small patient populations. Therefore, the OPPS and ASC payment structures for packaged supplies creates an access barrier and patients are forced to use inferior products that have increased complication risk and require the continued use of opioids to manage pain. One commenter referenced the results of a study that showed that Omidria reduces the need for opioids during cataract surgery by nearly 80 percent while decreasing pain scores by more than 50 percent.

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 per OPPS policy. Subsequently, Omidria's pass-through status was reinstated in October 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 2018 (Pub. L. 115–141). While our analysis supports the commenter's assertion that there was a decrease in the utilization of Omidria in 2018 following its pass-through expiration, we note that there could be many reasons that utilization declines after the pass-through period ends that are unrelated to the lack of separate payment, including the availability of other alternatives on the market (many of which had been used for several years before Omidria came on the market and are sold for a lower price), or physician preference among others.

Further, our clinical advisors' review of the clinical evidence submitted concluded that the study the commenter submitted was not sufficiently compelling or authoritative to overcome contrary evidence. Moreover, the results of a CMS study 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 results also did not suggest any decrease in opioid utilization post-surgery for procedures involving Omidria. At this time, we do not have compelling evidence to exclude Omidria from packaging after its current pass-through expires on September 30, 2020. We will continue to analyze the evidence and monitor utilization of this drug.

Comment: One commenter requested that MKO Melt, a non-FDA-approved, compounded drug comprised of midazolam/ketamine/ondansetron be excluded from the packaging policy under section 1833(t)(22)(A)(iii) of the Act. The commenter contended that MKO Melt are drugs functioning as a surgical supply in the ASC setting. The commenter provided a reference to a study titled, ''Anesthesia for opioid addict: Challenges for perioperative physician'' by Goyal et al., on the need for pain management in the opioid-dependent patient. The commenter also referenced a review article, ''Perioperative Management of Acute Pain in the Opioid-dependent Patient,'' by Mitra et al., on the special needs of opioid-dependent patients in surgeries and the potential opioid relapse in those patients who are recovering from opioid use disorder. Additionally, the commenter referenced a clinical trial registered in *clinicaltrials.gov* (NCT03653520) that supports sublingual MKO Melt for use during cataract surgeries to replace opioids. The study looked at 611 patients that were divided into three arms: (1) MKO melt arm, (2) diazepam/tramadol/ondansetron arm, (3) diazepam only arm. The study concluded that the MKO melt arm had the lowest incidence for supplemental injectable anesthesia to control pain.

Response: We thank the commenter for the comment. Based on the information provided, we are not able to validate that MKO Melt reduces the use of opioids. We note that ketamine, one of the components of MKO melt, exhibits some addictive properties. Moreover, we did not identify any compelling evidence that MKO Melt is effective for patients with a prior opioid addiction nor did we receive any data demonstrating that the current OPPS packaging policy incentivized providers to use opioids over MKO Melt. In accordance with our review under section 1833(t)(22)(A)(i) of the Act, as well as the lack of HCPCS code for the drug, and FDA approval, we were not able to establish any compelling evidence that MKO should be excluded from packaged payment.

Comment: Several commenters, including individual physicians, medical associations, and device manufacturers, supported separate payment for continuous peripheral nerve blocks as the commenters believed they significantly reduce opioid use. One commenter suggested that CMS provide separate payment for HCPCS code A4306 (Disposable drug delivery system, flow rate of less than 50 ml per hour) in the hospital outpatient department setting and the ASC setting because packaging represents a cost barrier for providers. The commenter contended that continuous nerve block procedures have been shown in high quality clinical studies to reduce the use of opioids, attaching studies for review. The commenter stated that separate payment for A4306 will remove the financial disincentive for HOPDs and ASCs to use these items, and would encourage continuous nerve blocks as a non-opioid alternative for post-surgical pain management.

Response: We appreciate the commenters' suggestion. We examined the data for A4306 and noted an overall trend of increasing utilization from CY 2014 through CY 2017. There was a slight decrease in utilization in CY 2018. However, we note that this slight decline may be an outlier, given the four year trend of consistently increasing utilization. Additionally, the geometric mean cost for HCPCS code A4306 was approximately $30 each year during that 4-year period. We acknowledge that use of these items may help in the reduction of opioid use. However, we note that packaged payment of such an item does not prevent the use of these items, as we found with the overall increased utilization of this product. We do not believe that the current utilization trends for HCPCS code A4306 suggest that the packaged payment is preventing use and remind readers that payment for packaged items is included in the payment for the primary service. We share the commenter's concern about the need to reduce opioid use and will take the commenter's suggestion regarding the need for separate payment for HCPCS code A4306 into consideration for future rulemaking.

Comment: Multiple commenters identified other non-opioid pain management alternatives that they believe decrease the dose, duration, and/or number of opioid prescriptions beneficiaries receive during and following an outpatient visit or procedure (especially for beneficiaries at high-risk for opioid addiction) and that may warrant separate payment for CY 2020. Commenters representing various stakeholders requested separate payments for various non-opioid pain management treatments, such as continuous nerve blocks, neuromodulation radiofrequency ablation, implants for lumbar stenosis, enhanced recovery after surgery, IV acetaminophen, IV ibuprofen, Polar ice devices for postoperative pain relief, THC oil, acupuncture, and dry needling procedures.

For neuromodulation, several commenters noted that spinal cord stimulators (SCS) may lead to a reduction in the use of opioids for chronic pain patients. One manufacturer commented that SCS provides the opportunity to potentially stabilize or decrease opioid usage and that neuromodulation retains its efficacy over multiple years. Regarding barriers to access, the commenter noted that Medicare beneficiaries often do not have access to SCS until after they have exhausted other treatments, which often includes opioids. The commenter presented evidence from observational studies that use of SCS earlier in a patient's treatment could help reduce opioid use while controlling pain, suggesting CMS look for ways to incorporate SCS earlier in the treatment continuum.

Another commenter asserted that the standard endpoints, such as a greater than 50 percent reduction in pain, that are used to determine if a neuromodulation-based non-opioid pain

alternative therapy is effective are well-established and validated in all types of clinical trials and that CMS should establish a general, national coverage determination for neuromodulation-based non-opioid pain therapy based on these endpoints, rather than taking the time to create and process specific national coverage determinations or local coverage determinations. The commenter suggested that this would be a much faster and streamlined process for enhancing Medicare beneficiary access to neuromodulation-based pain management therapies.

One of the manufacturers of a high-frequency SCS device stated that additional payment was warranted for non-opioid pain management treatments because they provide an alternative treatment option to opioids for patients with chronic, leg, or back pain. The commenter provided supporting studies that claimed that patients treated with their high-frequency SCS device reported a statistically significant average decrease in opioid use compared to the control group. This commenter also submitted data that showed a decline in the mean daily dosage of opioid medication taken and that fewer patients were relying on opioids at all to manage their pain when they used the manufacturer's device.

Other commenters wrote regarding their personal experiences with radiofrequency ablation for sacral iliac joints and knees. One commenter referenced several studies, one of which found a decrease in analgesic medications associated with radiofrequency ablation; however, it did not provide evidence regarding a decrease in opioid usage.

One national hospital association commenter recommended that while ''certainly not a solution to the opioid epidemic, unpackaging appropriate non-opioid therapies, like Exparel, is a low-cost tactic that could change long-standing practice patterns without major negative consequences.'' This same commenter suggested that Medicare consider separate payment for IV acetaminophen, IV ibuprofen, and Polar ice devices for postoperative pain relief after knee procedures. The commenter also noted that therapeutic massage, topically applied THC oil, acupuncture, and dry needling procedures are very effective therapies for relief of both postoperative pain and long-term and chronic pain. Several other commenters expressed support for separate payment for IV acetaminophen.

Response: We appreciate the detailed responses from commenters on this topic. At this time, we have not found compelling evidence for other non-opioid pain management alternatives described above to warrant separate payment under the OPPS or ASC payment systems for CY 2020. We plan to take these comments and suggestions into consideration for future rulemaking. We agree that providing incentives to avoid and/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 prescriptions, we encourage providers to use them when medically necessary. We note that some of the items and services mentioned by commenters are not covered by Medicare, and we do not intend to establish payment for noncovered items and services at this time. 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 reviewing the non-opioid pain management alternatives suggested by the commenters as well as the studies and other data provided to support the request for separate payment, we have not determined that separate payment is warranted at this time for any of the non-opioid pain management alternatives discussed above.

Comment: Several commenters addressed payment barriers that may inhibit access to non-opioid pain management treatments discussed throughout this section. Several commenters disagreed with CMS's assessment that current payment policies do not represent barriers to access for certain non-opioid pain management alternatives. Commenters encouraged CMS to provide timely insurance coverage for evidence-informed interventional procedures early in the course of treatment when clinically appropriate. Several other commenters encouraged CMS to more broadly evaluate all of its packaging policies to help ensure patient access to appropriate therapies and to evaluate how packaging affects the utilization of a medicine.

Response: We appreciate the various, insightful comments we received from stakeholders regarding barriers that may inhibit access to non-opioid alternatives for pain treatment and management in order to more effectively address the opioid epidemic. We will take these comments into consideration for future rulemaking. Many of these comments have been previously addressed throughout this section. CMS recognizes that medical exposure to opioids entails inherent risks, which may include delayed recovery, diversion, misuse, accidental overdose, development or re-emergence of addiction, and neonatal abstinence syndrome. However, there are challenges in developing a methodology to identify disincentives to use opioid alternatives. In the context of the opioid crisis, and given the central role the federal government plays in addressing it, these issues are of particular concern to CMS. Because of this, CMS intends to work with an interagency task force to review available data and to develop criteria for revisions to payment for opioid alternatives that are effective for pain relief or in reducing opioid use.

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 2020. Under this policy, the only FDA-approved drug that meets this criteria is Exparel.

We will continue to analyze the issue of access to non-opioid alternatives in the OPPS and the ASC settings for 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 XII.D.3 of this final rule with comment period.

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 2019 OPPS/ASC final rule with comment period (83 FR 58860 through 58861), we applied this policy and calculated the relative payment weights for each APC for CY 2019 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 2020, as we did for CY 2019, we proposed to continue to apply the policy established in CY 2013 and calculate relative payment weights for each APC for CY 2020 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 2020, as we did for CY 2019, 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 2020, as we did for CY 2019, 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 did not receive any public comments on our proposal to continue to use the geometric mean cost of APC 5012 to standardize relative payment weights for CY 2020. Therefore, we are finalizing our proposal and assigning APC 5012 the relative payment weight of 1.00, and using the relative payment weight for APC 5012 to derive the unscaled relative payment weight for each APC for CY 2020.

We note that in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59004 through 59015), 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, and we are continuing the policy with the second year of the two-year transition in CY 2020. 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 will result from the change in payments for these clinic visits will not be 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 refer readers to section X.C. of this CY 2020 OPPS/ASC final rule with comment period for further discussion of this final policy.

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 2020 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 2019 scaled relative payment weights to the estimated aggregate weight using the proposed CY 2020 unscaled relative payment weights.

For CY 2019, we multiplied the CY 2019 scaled APC relative payment weight applicable to a service paid under the OPPS by the volume of that service from CY 2018 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 2020, we proposed to apply the same process using the estimated CY 2020 unscaled relative payment weights rather than scaled relative payment weights. We proposed to calculate the weight scalar by dividing the CY 2019 estimated aggregate weight by the unscaled CY 2020 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 2020 OPPS final 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 2020 to the estimated total relative payment weights in CY 2019 using CY 2018 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 2020 unscaled relative payment weights for purposes of budget neutrality. We proposed to adjust the estimated CY 2020 unscaled relative payment weights by multiplying them by a proposed weight scalar of 1.4401 to ensure that the proposed CY 2020 relative payment weights are scaled to be budget neutral. The proposed CY 2020 relative payment weights listed in Addenda A and B to the proposed rule (which are available via the internet on the CMS website) were scaled and incorporated the recalibration adjustments discussed in sections II.A.1. and II.A.2. of the 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 this final rule with comment period) is included in the budget neutrality calculations for the CY 2020 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 2020. Using updated final rule claims data, we are updating the

estimated CY 2020 unscaled relative payment weights by multiplying them by a weight scalar of 1.4349 to ensure that the final CY 2020 relative payment weights are scaled to be budget neutral. The final CY 2020 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 2020 IPPS/LTCH PPS proposed rule (84 FR 19401), consistent with current law, based on IHS Global, Inc.'s fourth quarter 2018 forecast of the FY 2020 market basket increase, the proposed FY 2020 IPPS market basket update was 3.2 percent. However, sections 1833(t)(3)(F) and 1833(t)(3)(G)(v) of the Act, as added by section 3401(i) of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148) and as amended by section 10319(g) of that law and further amended by section 1105(e) of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), provide adjustments to the OPD fee schedule increase factor for CY 2020.

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). According to the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19402), the proposed MFP adjustment for FY 2020 was 0.5 percentage point.

For CY 2020, we proposed that the MFP adjustment for the CY 2020 OPPS is 0.5 percentage point (84 FR 39428). We proposed that if more recent data become subsequently available after the publication of the proposed rule (for example, a more recent estimate of the market basket increase and the MFP adjustment), we would use such updated data, if appropriate, to determine the CY 2020 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 this CY 2020 OPPS/ASC final rule with comment period.

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 2020 an OPD fee schedule increase factor of 2.7 percent for the CY 2020 OPPS (which was 3.2 percent, the final estimate of the hospital inpatient market basket percentage increase, less the final 0.5 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 this final rule with comment period.

In the CY 2020 OPPS/ASC proposed rule, we proposed to amend 42 CFR 419.32(b)(1)(iv)(B) by adding a new paragraph (11) to reflect the requirement in section 1833(t)(3)(F)(i) of the Act that, for CY 2020, we reduce the OPD fee schedule increase factor by the MFP adjustment as determined by CMS.

To set the OPPS conversion factor for CY 2020, we proposed to increase the CY 2019 conversion factor of $79.490 by 2.7 percent. In accordance with section 1833(t)(9)(B) of the Act, we proposed further to adjust the conversion factor for CY 2020 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 0.9993 for wage index changes. This adjustment was comprised of a 1.0005 proposed budget neutrality adjustment, using our standard calculation, of comparing proposed total estimated payments from our simulation model using the proposed FY 2020 IPPS wage indexes to those payments using the FY 2019 IPPS wage indexes, as adopted on a calendar year basis for the OPPS as well as a 0.9988 proposed budget neutrality adjustment for the proposed CY 2020 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 2020 IPPS wage index policy (84 FR 19398). We stated in the proposed rule that we believed it was appropriate to ensure that this proposed wage index transition policy (that is, the proposed CY 2020 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 2020 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 2020 OPPS wage index (which, as we discussed in section II.C of the proposed rule, would use the FY 2020 IPPS post-reclassified wage index and any adjustments, including without limitation any adjustments finalized under the IPPS to address wage index disparities).

We did not receive any public comments on our proposed methodology for calculating the wage index budget neutrality adjustments discussed earlier in this section. Therefore, for the reasons discussed above and in the CY 2020 OPPS/ASC proposed rule (84 FR 39428 through 39429), we are finalizing our methodology for calculating the wage index budget neutrality adjustments as proposed, without modification. For CY 2020, we are finalizing an overall budget neutrality factor of 0.9981 for wage index changes. This adjustment is comprised of a 0.9990 budget neutrality adjustment, using our standard

calculation of comparing total estimated payments from our simulation model using the final FY 2020 IPPS wage indexes to those payments using the FY 2019 IPPS wage indexes, as adopted on a calendar year basis for the OPPS as well as a 0.9991 budget neutrality adjustment for the CY 2020 5 percent cap on wage index decreases to ensure that this transition wage index is implemented in a budget neutral manner. We note that the final wage index budget neutrality adjustment figures set forth above differ from the figures set forth in the proposed rule due to updated data for the final rule.

For the CY 2020 OPPS, we are maintaining the current rural adjustment policy, as discussed in section II.E. of the proposed rule. Therefore, the proposed budget neutrality factor for the rural adjustment is 1.0000.

For the CY 2020 OPPS/ASC proposed rule, 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 proposed rule and this final rule with comment period. We proposed to calculate a CY 2020 budget neutrality adjustment factor for the cancer hospital payment adjustment by comparing estimated total CY 2020 payments under section 1833(t) of the Act, including the proposed CY 2020 cancer hospital payment adjustment, to estimated CY 2020 total payments using the CY 2019 final cancer hospital payment adjustment, as required under section 1833(t)(18)(B) of the Act. The proposed CY 2020 estimated payments applying the proposed CY 2020 cancer hospital payment adjustment were the same as estimated payments applying the CY 2019 final cancer hospital payment adjustment. Therefore, we proposed to apply a budget neutrality adjustment factor of 0.9998 to the conversion factor for the cancer hospital payment adjustment. In accordance with section 16002(b) of the 21st Century Cures Act, we stated in the proposed rule that we are applying 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 2020 OPPS/ASC proposed rule, we estimated that proposed pass-through spending for drugs, biologicals, and devices for CY 2020 would equal approximately $268.8 million, which represented 0.34 percent of total projected CY 2020 OPPS spending. Therefore, the proposed conversion factor would be adjusted by the difference between the 0.14 percent estimate of pass-through spending for CY 2019 and the 0.34 percent estimate of proposed pass-through spending for CY 2020, resulting in a proposed decrease for CY 2020 of 0.20 percent. Proposed estimated payments for outliers would remain at 1.0 percent of total OPPS payments for CY 2020. We estimated for the proposed rule that outlier payments would be 1.03 percent of total OPPS payments in CY 2019; the 1.00 percent for proposed outlier payments in CY 2020 would constitute a 0.03 percent increase in payment in CY 2020 relative to CY 2019.

For the CY 2020 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 0.7 percent (that is, the proposed OPD fee schedule increase factor of 2.7 percent further reduced by 2.0 percentage points). This would result in a proposed reduced conversion factor for CY 2020 of $79.770 for hospitals that fail to meet the Hospital OQR Program requirements (a difference of −1.628 in the conversion factor relative to hospitals that met the requirements).

In summary, for CY 2020, 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 to satisfy the statutory requirements of sections 1833(t)(3)(F) and (t)(3)(G)(v) of the Act. We proposed to use a reduced conversion factor of $79.770 in the calculation of payments for hospitals that fail to meet the Hospital OQR Program requirements (a difference of −1.628 in the conversion factor relative to hospitals that met the requirements).

For CY 2020, we proposed to use a conversion factor of $81.398 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 2.7 percent for CY 2020, the required proposed wage index budget neutrality adjustment of approximately 0.9993, the proposed cancer hospital payment adjustment of 0.9998, and the proposed adjustment of −0.20 percentage point of projected OPPS spending for the difference in pass-through spending that resulted in a proposed conversion factor for CY 2020 of $81.398. We referred readers to section XXVI.B. of the proposed rule for a discussion of the estimated effect on the conversion factor of a policy to pay for 340B-acquired drugs at ASP + 3 percent, which is a policy on which we solicited comments for potential future rulemaking in the event of an adverse decision on appeal in the ongoing litigation involving our payment policy for 340B-acquired drugs.

Comment: One commenter, a state hospital association, asserts its member hospitals receive payments from CMS that are substantially lower than the costs their members incur to provide services. The commenter believes underpayments occur because the CMS hospital market basket estimate of inflation of 2.7 percent substantially underestimates overall health care inflation which the commenter claims to be between 5.5 percent and 7 percent. The commenter also states that hospital payments from CMS are reduced because of payment sequestration and the policy to reduce payment rates for clinic visits at off-campus hospital outpatient departments to 40 percent of the standard OPPS payment rate. The commenter suggests that CMS should help hospitals in all states regain this lost revenue by implementing a much larger annual increase in the market basket amount. The commenter advocates a 4.7 percent market basket adjustment in CY 2020, and even larger percentage increases in following years.

Response: The percentage change in the hospital market basket reflects the average change in the price of goods and services purchased by hospitals in order to provide medical care. A general measure of health care inflation (such as the Consumer Price Index for Medical Care Services) would not be appropriate as it is not specific to hospital medical services and is not reflective of the input price changes experienced by hospitals but rather the inflation experienced by the consumer for their medical expenses. In addition, the OPPS conversion factor is not designed to redress payment reductions made in a non-budget neutral manner. The policies cited by the commenter are intended to reduce Medicare expenditures. If the conversion factor was to be increased to offset these payment reductions, it would defeat the intent of these policy initiatives.

Comment: A commenter expressed their support for the proposed market basket increase of 2.7 percent.

Response: We appreciate the support of the commenter.

After reviewing the public comments we received, we are finalizing these proposals without modification. For CY 2020, 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 0.88 for CY 2019, is 0.89 for CY 2020. As a result, we are applying a budget neutrality adjustment factor of 0.9999 to the conversion factor for the cancer hospital payment adjustment.

As a result of these finalized policies, the OPD fee schedule increase factor for the CY 2020 OPPS is 2.6 percent (which reflects the 3.0 percent final estimate of the hospital inpatient market basket percentage increase, less the final 0.4 percentage point MFP adjustment). For CY 2020, we are using a conversion factor of $80.784 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 2.6 percent for CY 2020, the required wage index budget neutrality adjustment of approximately 0.9981, and the adjustment of 0.88 percentage point of projected OPPS spending for the difference in pass-through spending that results in a conversion factor for CY 2020 of $80.784.

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 this final rule with comment period.

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). In the CY 2020 OPPS/ASC proposed rule (84 FR 39429), we proposed to continue this policy for the CY 2020 OPPS. We refer readers to section II.H. of this final rule with comment period 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. Therefore, for the reasons discussed above and in the CY 2020 OPPS/ASC proposed rule (84 FR 39429), we are finalizing our proposal, without modification, to continue this policy as discussed above for the CY 2020 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 standardize 60 percent of estimated claims costs for geographic area wage variation using the same FY 2020 pre-reclassified wage index that that is used 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 the CY 2020 OPPS, we proposed to implement this provision in the same manner as we have since CY 2011. 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. In the CY 2020 OPPS/ASC proposed rule (84 FR 39430), we referred readers to the FY 2011 through FY 2019 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; and for FY 2019, 83 FR 41380. We did not receive any public comments on this proposal. Accordingly, for the reasons discussed above and in the CY 2020 OPPS/ASC proposed rule (84 FR 39430), 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 2020 OPPS/ASC proposed rule (84 FR 39430) that the FY 2020 IPPS wage indexes continue to reflect a number of adjustments implemented over the past few years, including, but not limited to, reclassification of hospitals to different geographic areas, the rural floor provisions, an adjustment for occupational mix, and an adjustment to the wage index based on commuting patterns of employees (the out-migration adjustment). Also, we noted that, as discussed in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19393 through 19399), we proposed a number of policies under the IPPS to address wage index disparities between high and low wage index value hospitals. In particular, in the FY 2020 IPPS/LTCH

PPS proposed rule, we proposed to (1) calculate the rural floor without including the wage data of urban hospitals that have reclassified as rural under section 1886(d)(8)(E) of the Act (as implemented in § 412.103) (84 FR 19396 through 19398); (2) remove the wage data of urban hospitals that have reclassified as rural under § 412.103 from the calculation of ''the wage index for rural areas in the State'' for purposes of applying section 1886(d)(8)(C)(iii) of the Act (84 FR 19398); (3) increase the wage index values for hospitals with a wage index below the 25th percentile wage index value across all hospitals by half the difference between the otherwise applicable final wage index value for a year for that hospital and the 25th percentile wage index value for that year, and to offset the estimated increase in payments to hospitals with wage index values below the 25th percentile by decreasing the wage index values for hospitals with wage index values above the 75th percentile wage index value across all hospitals (84 FR 19394 through 19396); and (4) apply a 5-percent cap for FY 2020 on any decrease in a hospital's final wage index from the hospital's final wage index in FY 2019, as a proposed transition wage index to help mitigate any significant negative impacts on hospitals (84 FR 19398). In addition, in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19398), we proposed to apply a budget neutrality adjustment to the standardized amount so that our proposed transition wage index for hospitals that may be negatively impacted (described in item (4) above) would be implemented in a budget neutral manner. Furthermore, in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19398 through 19399), we noted that our proposed adjustment relating to the rural floor calculation also would be budget neutral. We referred readers to the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19373 through 19399) for a detailed discussion of all proposed changes to the FY 2020 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 2019 IPPS/LTCH PPS final rule (83 FR 41362), 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 provide detailed information on the update to the statistical areas since July 15, 2015, and are 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. We continue to believe that it is important for the OPPS to use the latest labor market area delineations available as soon as is reasonably possible in order to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions. For a complete discussion of the adoption of the updates set forth in OMB Bulletin No. 17–01, we refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 58864 through 58865).

As we stated in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42301), for the FY 2020 IPPS wage indexes, we are using the OMB delineations that were adopted, beginning with FY 2015 (based on the revised delineations issued in OMB Bulletin No. 13–01) to calculate the area wage indexes, with updates as reflected in OMB Bulletin Nos. 15–01 and 17–01. Similarly, in the CY 2020 OPPS/ASC proposed rule (84 FR 39431), for the proposed CY 2020 OPPS wage indexes, we proposed to continue to use the OMB delineations that were adopted under the OPPS, beginning with CY 2015 (based on the revised delineations issued in OMB Bulletin No. 13–01) to calculate the area wage indexes, with updates as reflected in OMB Bulletin Nos. 15–01 and 17–01. We did not receive any public comments on our proposal. Accordingly, for the reasons discussed above and in the CY 2020 OPPS/ASC proposed rule (84 FR 39430 through 39431), we are finalizing our proposal to continue to use the OMB delineations that were adopted beginning with CY 2015 to calculate area wage indexes under the OPPS, with updates as reflected in the OMB Bulletin Nos. 15–01, and 17–01.

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 2020, under the OPPS, we are continuing to use only the FIPS county codes for purposes of crosswalking counties to CBSAs.

In the CY 2020 OPPS/ASC proposed rule (84 FR 39431), we proposed to use the FY 2020 hospital 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 standardized amount for CY 2020. Therefore, we stated in the proposed rule that any adjustments for the FY 2020 IPPS post-reclassified wage index, including, but not limited to, any policies finalized under the IPPS to address wage index disparities between low and high wage index value hospitals, would be reflected in the final CY 2020 OPPS wage index beginning on January 1, 2020. (We referred readers to the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19373 through 19399) and the proposed FY 2020 hospital wage index files posted on the CMS website.) With regard to budget neutrality for the CY 2020 OPPS wage index, we referred readers to section II.B. of the CY 2020 OPPS/ASC proposed rule. We stated that we continue to 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. Summarized below are the comments we received regarding our proposal to use the final FY 2020 hospital IPPS post-reclassified wage index for urban and rural areas as the wage index for the OPPS, including any adjustments for the final FY 2020 IPPS post-reclassified wage index as discussed above, along with our responses.

Comment: Several commenters supported CMS adopting the finalized post-reclassified wage index from the FY 2020 IPPS/LTCH PPS final rule for use under the OPPS. Many of these commenters noted that the gap in payment between rural and urban hospitals has contributed to disparities in care and noted that increasing the wage index for hospitals with wage index values below the 25th percentile wage index value will help to lessen the gap. Some of these commenters noted that this change will help rural areas have access to quality, affordable health care. One commenter supported the proposal to increase the wage index for hospitals with wage index values below the 25th percentile, but wanted CMS to consider this solution temporary until the wage index is more equitable between hospitals.

Response: We appreciate the commenters' support. In response to the comment that CMS should consider the increase in the wage index for hospitals with wage index values below the 25th percentile wage index value (that it, low wage index hospitals) temporary until the wage index is more equitable between hospitals, as we stated in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42326 through 42327), the increase in the IPPS wage index for low wage index hospitals is not intended to be permanent. As we stated in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42326 through 42327), we expect that this policy will be in place for at least 4 years in order to allow employee compensation increases implemented by low wage index hospitals sufficient time to be reflected in the wage index calculation. We stated in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42327) that, once there has been sufficient time for that increased employee compensation to be reflected in the wage data, there should not be a continuing need for this policy.

Comment: Several commenters supported the proposal to increase the wage index for low wage index hospitals but wanted it implemented in a non-budget neutral manner. They believe this would mitigate disparities for median wage index hospitals. Several commenters opposed the proposal to recalculate the wage index to help the lowest wage hospitals. These commenters believed that applying a budget neutrality adjustment for all hospitals to offset the increase in payments for low wage index hospitals would result in a significant loss of resources for patient care in other hospitals. While these commenters understood and appreciated the goal of the proposed changes to increase the wage index for low wage hospitals, they did not believe that these policies would help rural hospitals. They believed that certain communities would benefit from increasing the wage index for low wage hospitals but believed this policy does not adequately recognize differences in geographic labor markets. They further claimed that the offsetting reductions to the wage index in some areas will hinder hospitals' ability to attract and recruit quality health care practitioners.

Some commenters noted that OPPS payments to hospitals in their respective states would decrease by millions in CY 2020 due to the budget neutral implementation of the increase in the wage index for low wage hospitals. These commenters noted that any reduction in Medicare payments would force hospitals to reduce staff and/or salary and benefits. One commenter noted that, for many years, the disparities among geographic areas have continued to grow and have resulted in challenges recruiting staff. Some commenters recommended CMS convene a meeting to understand all of the challenges and issues in order to develop a comprehensive reform of the wage index. One commenter recommended that, if CMS is going to redistribute the area wage index, CMS offset the increased wage index for very low wage areas with a budget neutrality adjustment to the wage index applied evenly to all hospitals. However, this commenter preferred that CMS not use budget neutrality for the area wage index. They did not believe that the budget neutrality adjustment policy follows statutory requirements for adjusting the area wage index that require CMS to address real differences in labor costs. Several commenters believed CMS went beyond its authority in reallocating funding from hospitals in high wage areas, to provide funding to low wage area hospitals, without any relationship to actual wage-related data for the impacted areas. Another commenter strongly opposed decreasing payments to some or all hospitals to offset an increase in the area wage index for low wage index hospitals and did not believe the rationale in the FY 2020 IPPS final rule supported this change. One commenter opposed CMS making a budget neutrality adjustment across all hospitals as well as the transition wage index adjustment to ensure that no hospital's wage index decreases by more than 5 percent. This commenter believed that these adjustments negatively impact hospitals in the bottom quartile of wage index that would have seen a larger increase in payment without these additional adjustments.

Response: As we stated in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42331), the intent of the wage index increase for hospitals with wage indexes below the 25th percentile wage index value across all hospitals (that is, low wage index hospitals) is to increase the accuracy of the wage index as a technical adjustment, and not to use the wage index as a policy tool to address non-wage issues related to rural hospitals, or the laudable goals of the overall financial health of hospitals in low wage areas or broader wage index reform. As we stated in the FY 2020 IPPS/LTCH PPS final rule, we believe the wage index increase we finalized for

low wage index hospitals increases the accuracy of the wage index as a relative measure because it allows low wage index hospitals to increase their employee compensation in ways that we would expect if there were no lag in reflecting compensation adjustments in the wage index. Thus, we stated in the FY 2020 IPPS/LTCH PPS final rule that we believe the IPPS wage index adjustment for low wage index hospitals will appropriately reflect the relative hospital wage level in those areas compared to the national average wage level. We further stated in the FY 2020 IPPS/LTCH PPS final rule that because this policy is based on the actual wages that we expect low wage index hospitals to pay, it falls within the scope of the authority of section 1886(d)(3)(E) of the Act.

However, we note that, in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42331 through 42332), we did not finalize our budget neutrality proposal to decrease the wage index for hospitals with wage index values above the 75th percentile wage index value to offset the estimated increase in payments to low wage index hospitals. Instead, in the FY 2020 IPPS/LTCH PPS final rule, consistent with our current methodology for implementing wage index budget neutrality under the IPPS, we finalized a budget neutrality adjustment to the IPPS national standardized amount for all hospitals so that the increase in the IPPS wage index for low wage index hospitals is implemented in a budget neutral manner. As explained in the FY 2020 IPPS/LTCH PPS final rule (84 FR42331), under section 1886(d)(3)(E) of the Act, the IPPS wage index adjustment is required to be implemented in a budget neutral manner. We further noted in the FY 2020 IPPS/LTCH PPS final rule that, even if the wage index were not required to be budget neutral, we would consider it inappropriate to use the wage index to increase or decrease overall spending. Similarly, under section 1886(t)(2)(D) and (9)(B) of the Act, the OPPS wage index adjustment is required to be implemented in a budget neutral manner. Accordingly, consistent with the policy finalized in the FY 2020 IPPS/LTCH PPS final rule, in this CY 2020 OPPS/ASC final rule with comment period, we are finalizing a budget neutrality adjustment to the conversion factor for all hospitals paid under the OPPS so that the increase in the OPPS wage index for low wage index hospitals is implemented in a budget neutral manner. We refer readers to section II.B. of this final rule with comment period for a discussion of budget neutrality. In addition, we refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42328 through 42332) for further discussion of the final FY 2020 IPPS wage index policies (including the transition wage index adjustment) and detailed responses to similar comments.

In the CY 2020 OPPS/ASC proposed rule (84 FR 39431), we proposed to use the FY 2020 IPPS post-reclassified wage index for urban and rural areas as the wage index under the OPPS to determine the wage adjustments for both the OPPS payment rate and the copayment standardized amount. Because we continue to believe that using the IPPS post-reclassified wage index as the source of the wage index adjustment factor under the OPPS is reasonable and logical given the inseparable, subordinate status of the HOPD within the hospital overall, as proposed, we are finalizing the use of the FY 2020 hospital IPPS post-reclassified wage index for urban and rural areas as the wage index under the OPPS to determine the wage adjustments for both the OPPS payment rate and the copayment standardized amount for CY 2020. Accordingly, any adjustments for the final FY 2020 IPPS post-reclassified wage index, including, but not limited to, any policies finalized in the FY 2020 IPPS/LTCH PPS final rule to address wage index disparities between low and high wage index value hospitals, will be reflected in the final CY 2020 OPPS wage index beginning on January 1, 2020.

Comment: Several commenters noted support for the revised rural floor policy finalized in the FY 2020 IPPS/LTCH final rule. Many of these commenters supported the proposal to exclude the wage data of urban hospitals that reclassify as rural in calculating the rural floor. These commenters suggested that including the wage data of these hospitals in the rural floor calculation has inflated wage index values in certain states and that excluding the wage data of these hospitals will have positive effects on OPPS payment for rural hospitals.

Response: We thank commenters for their support.

Comment: A few commenters opposed the change to exclude the wage data of urban hospitals that have been reclassified as rural in calculating the IPPS rural floor. One of these commenters believed that CMS lacks the legal authority to remove from the rural floor calculation the wage data of hospitals that have been reclassified from urban to rural as implemented in the FY 2020 IPPS/LTCH final rule. This commenter believed CMS misread the applicable law in Section 1886(d)(8)(E) of the Act. One of the commenter's believed that removing the urban to rural reclassifications from the calculation of the rural floor penalizes hospitals that are allowed to reclassify under HHS authority.

One commenter believed that CMS should put more structure around the rural floor policy and should not apply the rural floor in primarily urban states with only one or two rural facilities. The commenter believed that this would reduce the potential for gaming the system in determining an equitable wage adjustment.

Response: We addressed similar comments in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42334 through 42336). As provided in the FY 2020 IPPS/LTCH final rule (84 FR 42334), in the absence of broader wage index reform from Congress, we believe it is appropriate to revise the rural floor calculation as part of an effort to reduce wage index disparities. Regarding CMS's statutory authority to exclude the wage data of urban hospitals reclassified as rural from the IPPS rural floor calculation, as we stated in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42334), we believe our calculation methodology is permissible under section 1886(d)(8)(E) of the Act (as implemented in § 412.103) and the rural floor statute (section 4410 of Pub. L. 105–33). Further, as we discussed in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42336), we do not believe this policy penalizes or adversely impacts urban hospitals that have reclassified as rural. We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42332 through 42336) for further discussion of this policy and detailed responses to similar comments. We note that impact files and supporting data files available on the FY 2020 IPPS Final Rule Home Page provide the data necessary to understand the impact of the finalized policies under the IPPS. Furthermore, we appreciate the comment that CMS should not apply the rural floor in primarily urban states with only one or two rural facilities; however, because we consider this comment to be outside the scope of the CY 2020 OPPS wage index proposals, we are not addressing it in this final rule with comment period.

As we discussed above, we continue to believe that using the IPPS post-reclassified wage index as the source of the wage index adjustment factor under the OPPS is reasonable and logical given the inseparable, subordinate status of the HOPD within the hospital overall. Thus, as proposed, we are using the FY 2020 hospital IPPS post-reclassified

wage index for urban and rural areas as the wage index under the OPPS to determine the wage adjustments for both the OPPS payment rate and the copayment standardized amount for CY 2020. Accordingly, as we proposed, any adjustments for the final FY 2020 IPPS post-reclassified wage index, including, but not limited to, the revised rural floor calculation methodology and other IPPS wage index policies finalized in the FY 2020 IPPS/LTCH PPS final rule to address wage index disparities, will be reflected in the final CY 2020 OPPS wage index beginning on January 1, 2020.

After considering the public comments received, for the reasons discussed earlier in this section and in the CY 2020 OPPS/ASC proposed rule, we are finalizing without modification our proposal to use the final FY 2020 IPPS post-reclassified wage index for urban and rural areas as the wage index under the OPPS to determine the wage adjustments for both the OPPS payment rate and the copayment standardized amount for CY 2020. Accordingly, as we proposed, any adjustments for the final FY 2020 IPPS post-reclassified wage index (as set forth in the FY 2020 IPPS/LTCH PPS final rule, 84 FR 42300 through 42339), including, but not limited to, any policies finalized in the FY 2020 IPPS/LTCH PPS final rule to address wage index disparities between low and high wage index value hospitals (as set forth at 84 FR 42300 through 42339), will be reflected in the final CY 2020 OPPS wage index beginning on January 1, 2020. As discussed above, we note that in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42325 through 42332), we did not finalize our budget neutrality proposal to decrease the wage index for hospitals with wage index values above the 75th percentile wage index value to offset the estimated increase in payments to hospitals with wage index values below the 25th percentile wage index value, and thus this budget neutrality policy will not be applied under the OPPS. Instead, in the FY 2020 IPPS/LTCH PPS final rule, consistent with our current methodology for implementing IPPS wage index budget neutrality, we finalized a budget neutrality adjustment to the IPPS national standardized amount for all hospitals so that the increase in the IPPS wage index for low wage index hospitals is implemented in a budget neutral manner. Consistent with this IPPS policy, in this CY 2020 OPPS/ASC final rule with comment period, we are finalizing a budget neutrality adjustment to the conversion factor for all hospitals paid under the OPPS so that the increase in the OPPS wage index for low wage index hospitals is implemented in a budget neutral manner. We refer readers to section II.B. of this final rule with comment period for a discussion of budget neutrality.

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 were paid under the IPPS, based on its geographic location and any applicable wage index adjustments. In the CY 2020 OPPS/ASC proposed rule (84 FR 39431), we proposed to continue this policy for CY 2020, and included a brief summary of the major proposed FY 2020 IPPS wage index policies and adjustments that we proposed to apply to these hospitals under the OPPS for CY 2020, which we have summarized below. We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42300 through 42339) for a detailed discussion of the final changes to the FY 2020 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 2020, we proposed to continue our policy of allowing 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 MMA). In addition, for non-IPPS hospitals paid under the OPPS, we proposed to apply any policies that are finalized under the IPPS relating to wage index disparities. We also proposed that the wage index that would apply to non-IPPS hospitals for CY 2020 would include the rural floor adjustment. We did not receive any public comments on these proposals. Accordingly, for the reasons discussed above and in the CY 2020 OPPS/ASC proposed rule (84 FR 39431), we are finalizing these proposals without modifications.

For CMHCs, for CY 2020, 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 to apply any policies that are finalized under the IPPS relating to wage index disparities. In addition, we proposed that the wage index that would apply to CMHCs for CY 2020 would include the rural floor adjustment. Also, we proposed that the wage index that would apply to CMHCs would not include the out-migration 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 2020 OPPS/ASC proposed rule (84 FR 39431), we are finalizing these proposals without modifications.

Table 4 associated with the FY 2020 IPPS/LTCH PPS final rule (available via the internet on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) identifies counties eligible for the out-migration adjustment. Table 2 associated with the FY 2020 IPPS/LTCH PPS final rule (available for download via the website above) identifies IPPS hospitals that will receive the out-migration adjustment for FY 2020. We are including the out-migration adjustment information from Table 2 associated with the FY 2020 IPPS/LTCH PPS final rule as Addendum L to this final rule with comment period with the addition of non-IPPS hospitals that will receive the section 505 out-migration adjustment under this CY 2020 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: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. At this link, readers will find a link to the final FY 2020 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, CMS uses 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), CMS uses the statewide average default CCRs to determine the payments

mentioned earlier if it is unable 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. CMS also uses 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 referred readers to the CY 2020 OPPS proposed rule Claims Accounting Narrative that is posted on the CMS website. In the CY 2020 OPPS/ASC proposed rule (84 FR 39432), we proposed to update the default ratios for CY 2020 using the most recent cost report data. We indicated that we would update these ratios in this final rule with comment period if more recent cost report data are available.

We did not receive any public comments on our proposal to use statewide average default CCRs if we cannot calculate a CCR for a hospital and to use these CCRs to adjust charges on claims to costs for setting the final CY 2020 OPPS payment weights. Therefore, we finalizing our proposal without modification.

As we stated in the CY 2020 OPPS/ASC proposed rule (84 FR 39432), 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. 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 the CMS 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.

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 2020

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 2019. 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.

In the CY 2020 OPPS/ASC proposed rule (84 FR 58870 through 58871), for the CY 2020 OPPS, 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: Several commenters supported the proposal to continue the 7.1 percent payment adjustment.

Response: We appreciate the commenters' support.

Comment: One commenter requested that CMS make the 7.1 percent rural adjustment permanent. The commenter appreciated the policy that CMS adopted in CY 2019 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 commenter 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 commenter for their input. We believe that our currrent 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 before any changes to the rural adjustment percentage would be implemented.

Comment: Some commenters requested that CMS expand the payment adjustment for rural SCHs and EACHs to additional types of hospitals. One 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. Another 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. One commenter requested that payment rates for OPPS services for all rural hospitals be increased to reduce financial vulnerability for rural hospitals related to the high share of Medicare and Medicaid beneficiaries they serve.

Response: We thank the commenters for their comments. However, 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, our follow-up analyses performed in recent years have not shown differences in costs for all services for any of the additional types of providers mentioned by the commenters. Accordingly, we do not believe we currently have a basis to expand the payment adjustment to any providers other than rural SCHs and EACHs.

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 2020

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), 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).

2. Policy for CY 2020

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.

In the CY 2020 OPPS/ASC proposed rule (84 FR 39433), for CY 2020, 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 2020. To calculate the proposed CY 2020 target PCR, we are using the same extract of cost report data from HCRIS, as discussed in section II.A. of the CY 2020 OPPS/ASC proposed rule and this final rule with comment period, used to estimate costs for the CY 2020 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 2018 claims data that we used to model the impact of the proposed CY 2020 APC relative payment weights (3,770 hospitals) because it is appropriate to use the same set of hospitals that are being used to calibrate the modeled CY 2020 OPPS. The cost report data for the hospitals in this dataset were from cost report periods with fiscal year ends ranging from 2016 to 2018. 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 23 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 3,539 hospitals with cost report data.

Using this smaller dataset of cost report data, we estimated 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, 2019 to update the adjustment. This updated yields a target PCR of 0.90. We limited the dataset to hospitals with CY 2018 claims data that we used to model the impact of the CY 2020 APC relative payment weights (3,763) because it is appropriate to use the same set of hospitals that we are using to calibrate the modeled CY 2020 OPPS. The cost report data for the hospitals in the dataset were from cost report periods with fiscal years ends ranging from 2010 to 2018. We then removed the cost report data of the 46 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 21 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 3,523 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 7 shows the estimated percentage increase in OPPS payments to each cancer hospital for CY 2020, due to the cancer hospital payment adjustment policy. The actual amount of the CY 2020 cancer hospital payment adjustment for each cancer hospital will be determined at cost report settlement and will depend on each hospital's CY 2020 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 7.—ESTIMATED CY 2020 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 2020 due to Payment Adjustment
050146	City of Hope Comprehensive Cancer Center	36.7%
050660	USC Norris Cancer Hospital	23.0%
100079	Sylvester Comprehensive Cancer Center	7.1%
100271	H. Lee Moffitt Cancer Center & Research Institute	23.3%
220162	Dana-Farber Cancer Institute	36.1%
330154	Memorial Sloan-Kettering Cancer Center	48.0%
330354	Roswell Park Cancer Institute	20.7%
360242	James Cancer Hospital & Solove Research Institute	21.1%
390196	Fox Chase Cancer Center	9.5%
450076	M.D. Anderson Cancer Center	42.1%
500138	Seattle Cancer Care Alliance	50.2%

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 2019, 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 $4,825 (the fixed-dollar amount threshold) (83 FR 58874 through 58875). 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 2018 OPPS payments, using CY 2018 claims available for the CY 2020 OPPS/ASC proposed rule (84 FR 39434 through 39435) was approximately 1.0 percent of the total aggregated OPPS payments. Therefore, for CY 2018, 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 2020 OPPS final rule with comment period, we estimate that we paid approximately 1.00 percent of the total aggregated OPPS payments in outliers for CY 2018.

For the CY 2020 OPPS/ASC proposed rule, using CY 2018 claims data and CY 2019 payment rates, we estimated that the aggregate outlier payments for CY 2019 would be approximately 1.03 percent of the total CY 2019 OPPS payments. We provided estimated CY 2020 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 2020

In the CY 2020 OPPS/ASC proposed rule (84 FR 39434 through 39435), for CY 2020, 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 2020 OPPS/ASC proposed rule (84 FR 39435), 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 2020 OPPS/ASC proposed rule and this final rule with comment period.

To ensure that the estimated CY 2020 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 $4,950.

We calculated the proposed fixed-dollar threshold of $4,950 using the standard methodology most recently used for CY 2019 (83 FR 58874 through 58875). For purposes of estimating outlier payments for the proposed rule, we used the hospital-specific overall ancillary CCRs available in the April 2019 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 2020 hospital outlier payments for the proposed rule, we inflated the charges on the CY 2018 claims using the same inflation factor of 1.11189 that we used to estimate the IPPS fixed-dollar outlier threshold for the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19596). We used an inflation factor of 1.05446 to estimate CY 2019 charges from the CY 2018 charges reported on CY 2018 claims. The methodology for determining this charge inflation factor is discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41717 through 41718). 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 2020 IPPS outlier calculation to the CCRs used to simulate the proposed CY 2020 OPPS outlier payments to determine the fixed-dollar threshold. Specifically, for CY 2020, we proposed to apply an adjustment factor of 0.97517 to the CCRs that were in the April 2019 OPSF to trend them forward from CY 2019 to CY 2020. The methodology for calculating the proposed adjustment is discussed in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19597).

To model hospital outlier payments for the proposed rule, we applied the overall CCRs from the April 2019 OPSF after adjustment (using the proposed CCR inflation adjustment factor of 0.97517 to approximate CY 2020 CCRs) to charges on CY 2018 claims that were adjusted (using the proposed charge inflation factor of 1.11189 to approximate CY 2020 charges). We simulated aggregated CY 2020 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 2020 OPPS payments. We estimated that a proposed fixed-dollar threshold of $4,950, 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 referred readers to section XIV. of this 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 2020.

3. Final Outlier Calculation

Consistent with historical practice, we used updated data for this final rule with comment period for outlier calculations. For CY 2020, we are applying the overall CCRs from the October 2019 OPSF file after adjustment (using the CCR inflation adjustment factor of 0.97615 to approximate CY 2020 CCRs) to charges on CY 2018 claims that were adjusted using a charge inflation factor of 1.11100 to approximate CY 2020 charges. These are the same CCR adjustment and charge inflation factors that were used to set the IPPS fixed-dollar threshold for the FY 2020 IPPS/LTCH PPS final rule (84 FR 42629). We simulated aggregated CY 2020 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 2020 OPPS payments. We estimated that a

fixed-dollar threshold of $5,075 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 2020 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 proposed 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 proposed CY 2020 scaled weight for the APC by the CY 2020 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.

In the CY 2020 OPPS/ASC proposed rule (84 FR 39435), we demonstrated 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 proposed 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.

We did not receive any public comments on these steps under the methodology that we included in the CY 2020 CY OPPS/ASC proposed rule to determine the APC payments for CY 2020. Therefore, we are using the steps in the methodology specified below, as we proposed, to demonstrate the calculation of the final CY 2020 OPPS payments using the same parameters.

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 0.980 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 2020 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, under the CY 2020 OPPS policy for continuing to use the OMB labor market area delineations based on the 2010 Decennial Census data for the wage indexes used under the IPPS, a hold harmless policy for the wage index may apply, 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 2020 under the IPPS, reclassifications through the Medicare Geographic Classification Review Board (MGCRB), section 1886(d)(8)(B) ''Lugar'' hospitals, reclassifications under section 1886(d)(8)(E) of the Act, as defined in § 412.103 of the regulations, and hospitals designated as urban under section 601(g) of Public Law 98–21. For further discussion of the changes to the FY 2020 IPPS wage indexes, as applied to the CY 2020 OPPS, we refer readers to section II.C. of this final rule with comment period. We are continuing to apply a wage index floor of 1.00 to frontier States, in accordance with section 10324 of the Affordable Care Act of 2010.

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 proposed FY 2020 IPPS, which are listed in Table 2 associated with the FY 2020 IPPS/LTCH PPS proposed 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 2020 IPPS Proposed Rule Home Page'' and select ''FY 2020 Proposed 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 above. 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 CY 2020 full national unadjusted payment rate for APC 5071 is $609.94. The reduced national unadjusted payment rate for APC 5071 for a hospital that fails to meet the Hospital OQR Program requirements is $598.35. This reduced rate is calculated by multiplying the reporting ratio of 0.981 by the full unadjusted payment rate for APC 5071.

The FY 2020 wage index for a provider located in CBSA 35614 in New York, which includes the proposed adoption of IPPS 2020 wage index policies, is 1.2866. The labor-related portion of the full national unadjusted payment is approximately $470.84 (.60 * $609.94 * 1.2866). The labor-related portion of the reduced national unadjusted payment is approximately $461.90 (.60 * $598.35 * 1.2866). The nonlabor-related portion of the full national unadjusted payment is approximately $243.98 (.40 * $609.94). The nonlabor-related portion of the reduced national unadjusted payment is approximately $239.34 (.40 * $598.35). The sum of the labor-related and nonlabor-related portions of the full national adjusted payment is approximately $714.82 ($470.84 + $243.98). The sum of the portions of the reduced national adjusted payment is approximately $701.24 ($461.90 + $239.34).

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

In the CY 2020 OPPS/ASC proposed rule (84 FR 39437), 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, 2020 are included in Addenda A and B to the proposed rule (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 2020 OPPS/ASC proposed rule and this final rule with comment period, for CY 2020, 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, $121.99 is approximately 20 percent of the full national unadjusted payment rate of $609.94. For APCs with only a minimum unadjusted copayment in Addenda A and B to this final rule with comment period (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 0.980.

The proposed unadjusted copayments for services payable under the OPPS that will be effective January 1, 2020, 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 national unadjusted payment rates and copayment rates shown in Addenda A

and B to this final rule with comment period reflect the CY 2020 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

Payment for OPPS procedures, services, and items are generally based on medical billing codes, specifically, HCPCS codes, that are reported on 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 CPT (Current Procedural Terminology), a numeric and alphanumeric coding system maintained by the American Medical Association (AMA), and consist of Category I, II, and III CPT codes. Level II, 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. 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 American Medical Association (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. 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 our proposals 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 status indicators. Certain payment status indicators provide separate payment while other payment status indicators do not. In section XI. (CY 2020 OPPS Payment Status and Comment Indicators) of this final rule with comment period, we discuss the various status indicators used under the OPPS. We also provide a complete list of the status indicators and their definitions in Addendum D1 to this CY 2020 OPPS/ASC final rule with comment period.

1. HCPCS Codes That Were Effective April 1, 2019 for Which We Solicited Public Comments in the CY 2020 OPPS/ASC Proposed Rule

For the April 2019 update, there were no new CPT codes. However, eight new Level II HCPCS codes were established and made effective on April 1, 2019. These codes and their long descriptors were displayed in Table 7 of the proposed rule and are now listed in Table 8 of this final rule with comment period. Through the April 2019 OPPS quarterly update CR (Transmittal 4255, Change Request 11216, dated March 15, 2019), we recognized several new Level II HCPCS codes for separate payment under the OPPS. In the CY 2020 OPPS/ASC proposed rule (84 FR 39531–39532), we solicited public comments on the proposed APC and status indicator assignments for these Level II HCPCS codes, which were listed in Table 7 of the proposed rule.

We did not receive any public comments on the proposed OPPS APC and status indicator assignments for the new Level II HCPCS codes implemented in April 2019. Therefore, we are finalizing the proposed APC and status indicator assignments for these codes, as indicated in Table 8 below. We note that several of the HCPCS C-codes have been replaced with HCPCS J-codes, effective January 1, 2020. Their replacement codes are listed in Table 8. The final payment rates for these codes 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.

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TABLE 8.—NEW HCPCS CODES EFFECTIVE APRIL 1, 2019

CY 2019 HCPCS Code	CY 2020 HCPCS Code	CY 2020 Long Descriptor	Final CY 2020 SI	Final CY 2020 APC
C9040	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
C9041	C9041	Injection, coagulation factor Xa (recombinant), inactivated (andexxa), 10 mg	G	9198
C9042*	J9036	Injection, bendamustine hydrochloride, (Belrapzo/bendamustine), 1 mg	G	9313
C9043	J0642	Injection, khapzory, 0.5 mg	G	9334
C9044	J9119	Injection, cemiplimab-rwlc, 1 mg	G	9304
C9045	J9313	Injection, moxetumomab pasudotox-tdfk, 0.01 mg	G	9305
C9046	C9046	Cocaine hydrochloride nasal solution for topical administration, 1 mg	G	9307
C9141**	J7208	Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl, (jivi), 1 i.u.	G	9299

*HCPCS code C9042, which was effective April 1, 2019, was deleted June 30, 2019 and replaced with HCPCS code J9036 (Injection, bendamustine hydrochloride, (Belrapzo/bendamustine), 1 mg) effective July 1, 2019.

**HCPCS code C9141, which was effective April 1, 2019, was deleted June 30, 2019 and replaced with HCPCS code J7208 (Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl, (jivi), 1 i.u.), 1 mg) effective July 1, 2019.

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2. HCPCS Codes That Were Effective July 1, 2019 for Which We Solicited Public Comments in the CY 2020 OPPS/ASC Proposed Rule

For the July 2019 update, 58 new codes were established and made effective July 1, 2019. The codes and long descriptors were listed in Table 8 of the proposed rule. Through the July 2019 OPPS quarterly update CR (Transmittal 4313, Change Request 11318, dated May 24, 2019), we recognized several new codes for separate payment and assigned them to appropriate interim OPPS status indicators and APCs. In the CY 2020 OPPS/ASC proposed rule, we solicited public comments on the proposed APC and status indicator assignments for the codes implemented on July 1, 2019, all of which were listed in Table 8 of the proposed rule.

We received some public comments related to CPT codes 0546T, 0548T, 0549T, 0554T, 0555T, 0556T, 0557T, and 0558T, which we address in section III.D. (OPPS APC-Specific Policies) of this final rule with comment period. With the exception of the eight codes, we did not receive any public comments on the proposed OPPS APC and status indicator assignments for the other new CPT and Level II HCPCS codes implemented in July 2019. Therefore, we are finalizing the proposed APC and status indicator assignments for the July 2019 codes, including the eight codes on which we received public comments, as indicated in Table 9 below. We note that several of the HCPCS C-codes have been replaced with HCPCS J-codes, effective January 1, 2020. Their replacement codes are listed in Table 9. The final payment rates for the codes can be found in Addendum B to this final rule with comment period. In addition, the status indicator meanings 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.

BILLING CODE 4120–01–P

TABLE 9.—NEW HCPCS CODES EFFECTIVE JULY 1, 2019

CY 2019 HCPCS Code	CY 2020 HCPCS Code	CY 2020 Long Descriptor	Final CY 2020 SI	Final CY 2020 APC
C9047	C9047	Injection, caplacizumab-yhdp, 1 mg	G	9199
C9048	J1096	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg	G	9308
C9049	J9269	Injection, tagraxofusp-erzs, 10 micrograms	G	9309
C9050	J9210	Injection, emapalumab-lzsg, 1 mg	G	9310
C9051	J0121	Injection, omadacycline, 1 mg	G	9311
C9052	J1303	Injection, ravulizumab-cwvz, 10 mg	G	9312
C9756	C9756	Intraoperative near-infrared fluorescence lymphatic mapping of lymph node(s) (sentinel or tumor draining) with administration of indocyanine green (ICG) (List separately in addition to code for primary procedure)	N	N/A
J1444	J1444	Injection, ferric pyrophosphate citrate powder, 0.1 mg of iron	N	N/A
J7208	J7208	Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl, (jivi), 1 i.u.	G	9299
J7677	J7677	Revefenacin inhalation solution, fda-approved final product, non-compounded, administered through DME, 1 microgram	M	N/A
J9030	J9030	BCG live intravesical instillation, 1 mg	K	9322
J9036	J9036	Injection, bendamustine hydrochloride, (Belrapzo/bendamustine), 1 mg	G	9313
J9356	J9356	Injection, trastuzumab, 10 mg and Hyaluronidase-oysk	K	9314
Q5112	Q5112	Injection, trastuzumab-dttb, biosimilar, (Ontruzant), 10 mg	E2	N/A
Q5113	Q5113	Injection, trastuzumab-pkrb, biosimilar, (Herzuma), 10 mg	E2	N/A
Q5114	Q5114	Injection, Trastuzumab-dkst, biosimilar, (Ogivri), 10 mg	E2	N/A

CY 2019 HCPCS Code	CY 2020 HCPCS Code	CY 2020 Long Descriptor	Final CY 2020 SI	Final CY 2020 APC
Q5115	Q5115	Injection, rituximab-abbs, biosimilar, (Truxima), 10 mg	E2	N/A
0543T	0543T	Transapical mitral valve repair, including transthoracic echocardiography, when performed, with placement of artificial chordae tendineae	C	N/A
0544T	0544T	Transcatheter mitral valve annulus reconstruction, with implantation of adjustable annulus reconstruction device, percutaneous approach including transseptal puncture	C	N/A
0545T	0545T	Transcatheter tricuspid valve annulus reconstruction with implantation of adjustable annulus reconstruction device, percutaneous approach	C	N/A
0546T	0546T	Radiofrequency spectroscopy, real time, intraoperative margin assessment, at the time of partial mastectomy, with report	N	N/A
0547T	0547T	Bone-material quality testing by microindentation(s) of the tibia(s), with results reported as a score	E1	N/A
0548T*	0548T*	Transperineal periurethral balloon continence device; bilateral placement, including cystoscopy and fluoroscopy	J1	5376
0549T	0549T	Transperineal periurethral balloon continence device; unilateral placement, including cystoscopy and fluoroscopy	J1	5375
0550T	0550T	Transperineal periurethral balloon continence device; removal, each balloon	J1	5374
0551T	0551T	Transperineal periurethral balloon continence device; adjustment of balloon(s) fluid volume	T	5371
0552T	0552T	Low-level laser therapy, dynamic photonic and dynamic thermokinetic energies, provided by a physician or other qualified health care professional	M	N/A
0553T	0553T	Percutaneous transcatheter placement of iliac arteriovenous anastomosis implant, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention	E1	N/A

CY 2019 HCPCS Code	CY 2020 HCPCS Code	CY 2020 Long Descriptor	Final CY 2020 SI	Final CY 2020 APC
0554T	0554T	Bone strength and fracture risk using finite element analysis of functional data, and bone-mineral density, utilizing data from a computed tomography scan; retrieval and transmission of the scan data, assessment of bone strength and fracture risk and bone mineral density, interpretation and report	M	N/A
0555T	0555T	Bone strength and fracture risk using finite element analysis of functional data, and bone-mineral density, utilizing data from a computed tomography scan; retrieval and transmission of the scan data	S	5731
0556T	0556T	Bone strength and fracture risk using finite element analysis of functional data, and bone-mineral density, utilizing data from a computed tomography scan; assessment of bone strength and fracture risk and bone mineral density	S	5523
0557T	0557T	Bone strength and fracture risk using finite element analysis of functional data, and bone-mineral density, utilizing data from a computed tomography scan; interpretation and report	M	N/A
0558T	0558T	Computed tomography scan taken for the purpose of biomechanical computed tomography analysis	S	5521
0559T	0559T	Anatomic model 3D-printed from image data set(s); first individually prepared and processed component of an anatomic structure	Q1	5733
0560T	0560T	Anatomic model 3D-printed from image data set(s); each additional individually prepared and processed component of an anatomic structure (List separately in addition to code for primary procedure)	N	N/A
0561T	0561T	Anatomic guide 3D-printed and designed from image data set(s); first anatomic guide	Q1	5733
0562T	0562T	Anatomic guide 3D-printed and designed from image data set(s); each additional anatomic guide (List separately in addition to code for primary procedure)	N	N/A

CY 2019 HCPCS Code	CY 2020 HCPCS Code	CY 2020 Long Descriptor	Final CY 2020 SI	Final CY 2020 APC
0084U	0084U	Red blood cell antigen typing, DNA, genotyping of 10 blood groups with phenotype prediction of 37 red blood cell antigens	A	N/A
0085U	0085U	Cytolethal distending toxin B (CdtB) and vinculin IgG antibodies by immunoassay (ie, ELISA)	D	N/A
0086U	0086U	Infectious disease (bacterial and fungal), organism identification, blood culture, using rRNA FISH, 6 or more organism targets, reported as positive or negative with phenotypic minimum inhibitory concentration (MIC)-based antimicrobial susceptibility	A	N/A
0087U	0087U	Cardiology (heart transplant), mRNA gene expression profiling by microarray of 1283 genes, transplant biopsy tissue, allograft rejection and injury algorithm reported as a probability score	A	N/A
0088U	0088U	Transplantation medicine (kidney allograft rejection), microarray gene expression profiling of 1494 genes, utilizing transplant biopsy tissue, algorithm reported as a probability score for rejection	A	N/A
0089U	0089U	Oncology (melanoma), gene expression profiling by RTqPCR, PRAME and LINC00518, superficial collection using adhesive patch(es)	Q4	N/A
0090U	0090U	Oncology (cutaneous melanoma), mRNA gene expression profiling by RT-PCR of 23 genes (14 content and 9 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a categorical result (ie, benign, indeterminate, malignant)	A	N/A
0091U	0091U	Oncology (colorectal) screening, cell enumeration of circulating tumor cells, utilizing whole blood, algorithm, for the presence of adenoma or cancer, reported as a positive or negative result	E1	N/A

CY 2019 HCPCS Code	CY 2020 HCPCS Code	CY 2020 Long Descriptor	Final CY 2020 SI	Final CY 2020 APC
0092U	0092U	Oncology (lung), three protein biomarkers, immunoassay using magnetic nanosensor technology, plasma, algorithm reported as risk score for likelihood of malignancy	Q4	N/A
0093U	0093U	Prescription drug monitoring, evaluation of 65 common drugs by LC-MS/MS, urine, each drug reported detected or not detected	Q4	N/A
0094U	0094U	Genome (eg, unexplained constitutional or heritable disorder or syndrome), rapid sequence analysis	A	N/A
0095U	0095U	Inflammation (eosinophilic esophagitis), ELISA analysis of eotaxin-3 (CCL26 [C-C motif chemokine ligand 26]) and major basic protein (PRG2 [proteoglycan 2, pro eosinophil major basic protein]), specimen obtained by swallowed nylon string, algorithm reported as predictive probability index for active eosinophilic esophagitis	Q4	N/A
0096U	0096U	Human papillomavirus (HPV), high-risk types (ie, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68), male urine	Q4	N/A

CY 2019 HCPCS Code	CY 2020 HCPCS Code	CY 2020 Long Descriptor	Final CY 2020 SI	Final CY 2020 APC
0097U	0097U	Gastrointestinal pathogen, multiplex reverse transcription and multiplex amplified probe technique, multiple types or subtypes, 22 targets (Campylobacter [C. jejuni/C. coli/C. upsaliensis], Clostridium difficile [C. difficile] toxin A/B, Plesiomonas shigelloides, Salmonella, Vibrio [V. parahaemolyticus/V. vulnificus/V. cholerae], including specific identification of Vibrio cholerae, Yersinia enterocolitica, Enteroaggregative Escherichia coli [EAEC], Enteropathogenic Escherichia coli [EPEC], Enterotoxigenic Escherichia coli [ETEC] lt/st, Shiga-like toxin-producing Escherichia coli [STEC] stx1/stx2 [including specific identification of the E. coli O157 serogroup within STEC], Shigella/Enteroinvasive Escherichia coli [EIEC], Cryptosporidium, Cyclospora cayetanensis, Entamoeba histolytica, Giardia lamblia [also known as G. intestinalis and G. duodenalis], adenovirus F 40/41, astrovirus, norovirus GI/GII, rotavirus A, sapovirus [Genogroups I, II, IV, and V])	Q4	N/A
0098U	0098U	Respiratory pathogen, multiplex reverse transcription and multiplex amplified probe technique, multiple types or subtypes, 14 targets (adenovirus, coronavirus, human metapneumovirus, influenza A, influenza A subtype H1, influenza A subtype H3, influenza A subtype H1-2009, influenza B, parainfluenza virus, human rhinovirus/enterovirus, respiratory syncytial virus, Bordetella pertussis, Chlamydophila pneumoniae, Mycoplasma pneumoniae)	Q4	N/A

CY 2019 HCPCS Code	CY 2020 HCPCS Code	CY 2020 Long Descriptor	Final CY 2020 SI	Final CY 2020 APC
0099U	0099U	Respiratory pathogen, multiplex reverse transcription and multiplex amplified probe technique, multiple types or subtypes, 20 targets (adenovirus, coronavirus 229E, coronavirus HKU1, coronavirus, coronavirus OC43, human metapneumovirus, influenza A, influenza A subtype, influenza A subtype H3, influenza A subtype H1-2009, influenza, parainfluenza virus, parainfluenza virus 2, parainfluenza virus 3, parainfluenza virus 4, human rhinovirus/enterovirus, respiratory syncytial virus, Bordetella pertussis, Chlamydophila pneumonia, Mycoplasma pneumoniae)	Q4	N/A
0100U	0100U	Respiratory pathogen, multiplex reverse transcription and multiplex amplified probe technique, multiple types or subtypes, 21 targets (adenovirus, coronavirus 229E, coronavirus HKU1, coronavirus NL63, coronavirus OC43, human metapneumovirus, human rhinovirus/enterovirus, influenza A, including subtypes H1, H1-2009, and H3, influenza B, parainfluenza virus 1, parainfluenza virus 2, parainfluenza virus 3, parainfluenza virus 4, respiratory syncytial virus, Bordetella parapertussis [IS1001], Bordetella pertussis [ptxP], Chlamydia pneumoniae, Mycoplasma pneumoniae)	Q4	N/A
0101U	0101U	Hereditary colon cancer disorders (eg, Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis), genomic sequence analysis panel utilizing a combination of NGS, Sanger, MLPA, and array CGH, with MRNA analytics to resolve variants of unknown significance when indicated (15 genes [sequencing and deletion/duplication], EPCAM and GREM1 [deletion/duplication only])	A	N/A

CY 2019 HCPCS Code	CY 2020 HCPCS Code	CY 2020 Long Descriptor	Final CY 2020 SI	Final CY 2020 APC
0102U	0102U	Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), genomic sequence analysis panel utilizing a combination of NGS, Sanger, MLPA, and array CGH, with MRNA analytics to resolve variants of unknown significance when indicated (17 genes [sequencing and deletion/duplication])	A	N/A
0103U	0103U	Hereditary ovarian cancer (eg, hereditary ovarian cancer, hereditary endometrial cancer), genomic sequence analysis panel utilizing a combination of NGS, Sanger, MLPA, and array CGH, with MRNA analytics to resolve variants of unknown significance when indicated (24 genes [sequencing and deletion/duplication], EPCAM [deletion/duplication only])	A	N/A
0104U	0104U	Hereditary pan cancer (eg, hereditary breast and ovarian cancer, hereditary endometrial cancer, hereditary colorectal cancer), genomic sequence analysis panel utilizing a combination of NGS, Sanger, MLPA, and array CGH, with MRNA analytics to resolve variants of unknown significance when indicated (32 genes [sequencing and deletion/duplication], EPCAM and GREM1 [deletion/duplication only])	D	N/A

*The predecessor code for CPT code 0548T was HCPCS code C9746 (Transperineal implantation of permanent adjustable balloon continence device, with cystourethroscopy, when performed and/or fluoroscopy, when performed), which was effective July 1, 2017 and deleted on June 30, 2019.

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3. October 2019 HCPCS Codes for Which We Are Soliciting Public Comments in This CY 2020 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 9 of the proposed rule and reprinted as Table 10 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 2020, 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 status indicator 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 2020 OPPS/ASC proposed rule (84 FR 39449), we proposed to continue this process for CY 2020. Specifically, for CY 2020, we proposed to include in Addendum B to the CY 2020 OPPS/ASC final rule with comment period the new HCPCS codes effective October 1, 2019, that would be incorporated in the October 2019 OPPS quarterly update CR. Also, as stated above, the October 1, 2019 codes are flagged with comment indicator ''NI'' in Addendum B to this CY 2020 OPPS/

ASC final rule with comment period to indicate that we have assigned the codes an interim OPPS payment status for CY 2020. We are inviting public comments on the interim status indicator 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 code Q4184 (Cellesta or Cellesta Duo, per square centimeter), which was assigned to comment indicator ''NI'' in Addendum B of the CY 2019 OPPS/ASC final rule. The comment and our response can be found in section V.B.7 (Skin Substitutes) of this CY 2020 OPPS/ASC final rule with comment period.

4. January 2020 HCPCS Codes

a. New Level II HCPCS Codes for Which We Are Soliciting Public Comments in This CY 2020 OPPS/ASC Final Rule With Comment Period

As shown in Table 10 below, and as stated in the CY 2020 OPPS/ASC proposed rule (84 FR 39449), 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 status indicators 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 2020, we proposed to include in Addendum B to the CY 2020 OPPS/ASC final rule with comment period the new Level II HCPCS codes effective January 1, 2020, that would be incorporated in the January 2020 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 2020, the Level II HCPCS codes effective January 1, 2020 codes are flagged with comment indicator ''NI'' in Addendum B to this CY 2020 OPPS/ASC final rule with comment period to indicate that we have assigned the codes an interim OPPS payment status for CY 2020. We are inviting public comments on the interim status indicator 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 2020 OPPS/ASC Proposed Rule

For CY 2020, we received the CY 2020 CPT code updates that would be effective January 1, 2020, from AMA in time for inclusion in the CY 2020 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 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 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 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 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 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.

As stated above, for the CY 2020 OPPS update, we received the CY 2020 CPT codes from AMA in time for inclusion in the CY 2020 OPPS/ASC proposed rule. The new, revised, and deleted CY 2020 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 status indicator 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 2020 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 status indicator assignments. The 5-digit placeholder codes were included in Addendum O, specifically under the column labeled ''CY 2020 OPPS/ASC Proposed Rule 5-Digit AMA Placeholder Code,'' to the proposed rule. We noted that the final CPT code numbers will be included in this CY 2020 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 to comment indicator ''NP''.

In summary, in the CY 2020 OPPS/ASC proposed rule, we solicited public comments on the proposed CY 2020 status indicator and APC assignments for the new and revised Category I and III CPT codes that will be effective January 1, 2020. 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 status indicator and APC assignments for these codes (with their final CPT code numbers) in the CY 2020 OPPS/ASC final rule with comment period. The proposed status indicator 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 2020 OPPS/ASC proposed

rule. We have responded to those public comments in sections III.D. (OPPS APC-Specific Policies), IV.B. (Device-Intensive Procedures) and XII. (Updates to the ASC Payment System) of this CY 2020OPPS/ASC final rule with comment period.

The final status indicators, APC assignments, and payment rates for the new CPT codes that are effective January 1, 2020 can be found in Addendum B to this final rule with comment period. In addition, the status indicator meanings can be found in Addendum D1 (OPPS Payment Status Indicators for CY 2020) to this final rule with comment period. Both Addendum B and D1 are available via the internet on the CMS website.

Finally, Table 10 below, which is a reprint of Table 9 from the CY 2020 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.

TABLE 10.—COMMENT TIMEFRAME FOR NEW AND REVISED HCPCS CODES

OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 2019	HCPCS (CPT and Level II codes)	April 1, 2019	CY 2020 OPPS/ASC proposed rule	CY 2020 OPPS/ASC final rule with comment period
July 2019	HCPCS (CPT and Level II codes)	July 1, 2019	CY 2020 OPPS/ASC proposed rule	CY 2020 OPPS/ASC final rule with comment period
October 2019	HCPCS (CPT and Level II codes)	October 1, 2019	CY 2020 OPPS/ASC final rule with comment period	CY 2021 OPPS/ASC final rule with comment period
January 2020	CPT Codes	January 1, 2020	CY 2020 OPPS/ASC proposed rule	CY 2020 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2020	CY 2020 OPPS/ASC final rule with comment period	CY 2021 OPPS/ASC final rule with comment period

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 2020 OPPS/ASC proposed rule (84 FR 39451–39452), for CY 2020, 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 HOP Panel recommendations for specific services for the CY 2020 OPPS update are discussed in the relevant specific sections throughout this CY 2020 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 2020 OPPS/ASC proposed rule (84 FR 39451 through 39452), for CY 2020, 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 2020 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 2020 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 2020 included in the proposed rule were related to changes in costs of services that were observed in the CY 2018 claims data newly available for CY 2020 ratesetting. Addendum B to the CY 2020 OPPS/ASC proposed rule identified with a comment indicator ''CH'' those procedure codes for which we proposed a change to the APC assignment or status indicator, or both, that were initially assigned in the July 1, 2019 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 2020 in the CY 2020 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 2018 claims data available for the CY 2020 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 2020, 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 2018 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, such as device-dependent CPT/HCPCS codes, 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 10 of the proposed rule listed the 18 APCs that we proposed to make an exception for under the 2 times rule for CY 2020 based on the criteria cited above and claims data submitted between January 1, 2018, and December 31, 2018, and processed on or before December 31, 2018. In the proposed

rule, we stated that for the final rule with comment period, we intend to use claims data for dates of service between January 1, 2018, and December 31, 2018, that were processed on or before June 30, 2019, and updated CCRs, if available.

Based on the updated final rule CY 2018 claims data used for this CY 2020 final rule with comment period, we were able to remedy two APC violation out of the 18 APCs that appeared in Table 10 of the CY 2020 OPPS/ASC proposed rule. Specifically, APC 5672 (Level 2 Pathology) and APC 5733 (Level 3 Minor Procedures) no longer met the criteria for exception to the 2 times rule in this final rule with comment period. In addition, based on our analysis of the final rule claims data, we found a total of 17 APCs with violations of the 2 times rule. Of these 17 total APCs, 16 were identified in the proposed rule and one newly identified APC. Specifically, we found the following 16 APCs from the proposed rule continued to have violations of the 2 times rule for this final rule with comment period:

- APC 5112 (Level 2 Musculoskeletal Procedures);
- APC 5161 (Level 1 ENT Procedures)
- APC 5181 (Level 1 Vascular Procedures)
- APC 5311 (Level 1 Lower GI Procedures)
- APC 5521 (Level 1 Imaging without Contrast);
- APC 5522 (Level 2 Imaging without Contrast);
- APC 5523 (Level 3 Imaging without Contrast);
- APC 5524 (Level 4 Imaging without Contrast);
- APC 5571 (Level 1 Imaging with Contrast)
- APC 5612 (Level 2 Therapeutic Radiation Treatment Preparation);
- APC 5691 (Level 1 Drug Administration);
- APC 5721 (Level 1 Diagnostic Tests and Related Services);
- APC 5731 (Level 1 Minor Procedures);
- APC 5734 (Level 4 Minor Procedures);
- APC 5822 (Level 2 Health and Behavior Services); and
- APC 5823 (Level 3 Health and Behavior Services).

In addition, we found that APC 5593 (Level 3 Nuclear Medicine and Related Services) violated the 2 times rule using the final rule with comment period claims data.

Although we did not receive any comments on Table 10 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 2018 costs from hospital claims and cost report data available for this CY 2020 final rule with comment period, we are finalizing our proposals with some modifications. Specifically, we are finalizing our proposal to except 16 of the 18 proposed APCs from the 2 times rule for CY 2020 and also excepting one additional APC (APC 5593). As noted above, we were able to remedy two of the proposed rule 2 time violations in this final rule with comment period.

In summary, Table 11 below lists the 17 APCs that we are excepting from the 2 times rule for CY 2020 based on the criteria described earlier and a review of updated claims data for dates of service between January 1, 2018 and December 31, 2018, that were processed on or before June 30, 2019, 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: *http://www.cms.gov.*

TABLE 11—APC EXCEPTIONS TO THE 2 TIMES RULE FOR CY 2020

CY 2020 APC	CY 2020 APC Title
5112	Level 2 Musculoskeletal Procedures
5161	Level 1 ENT Procedures
5181	Level 1 Vascular 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
5691	Level 1 Drug Administration
5721	Level 1 Diagnostic Tests and Related Services
5731	Level 1 Minor Procedures
5734	Level 4 Minor Procedures
5822	Level 2 Health and Behavior Services
5823	Level 3 Health and Behavior Services

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 2019, 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 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 (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 2020, we included the proposed payment rates for New Technology APCs 1491 to 1599 and 1901 through 1908 in Addendum A to the CY 2020 OPPS/ASC proposed rule (which is available via the internet on the CMS website). The final payment rates for these New Technology APCs are included in Addendum A to the CY 2020 OPPS/ASC final rule with comment period (which is available via the internet on the CMS website).

2. Establishing Payment Rates for Low-Volume New Technology Procedures

Procedures 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. One of the objectives of establishing New Technology APCs is to generate sufficient claims data for a new procedure so that it can be assigned to an appropriate clinical APC. Some procedures that are assigned to New Technology APCs have very low annual volume, which we consider to be fewer than 100 claims. We consider procedures with fewer than 100 claims annually as low-volume procedures because there is a higher probability that the payment data for a procedure 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 procedure 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 procedure for these low-volume procedures.

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 procedure to a new technology APC allows us to gather claims data to price the procedure 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 procedures 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 procedures with fewer than 100 claims annually as low-volume procedures because there is a higher probability that the payment data for a procedure 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 procedure 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 procedure. 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 2020, 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).

Comment: One commenter expressed support for the continuation of our policy regarding payment rates for low-volume new technology procedures.

Response: We appreciate the commenter's support.

After considering the public comments we received, we are finalizing this proposal without modification.

3. Procedures Assigned to New Technology APC Groups for CY 2020

As we explained 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 2020, in the CY 2020 OPPS/ASC proposed rule (84 FR 39454), 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).

a. Magnetic Resonance-Guided Focused Ultrasound Surgery (MRgFUS) (APCs 1575, 5114, and 5414)

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 2020. 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.

As shown in Table 11 of the CY 2020 OPPS/ASC proposed rule, and as listed in Addendum B to the CY 2020 OPPS/ASC proposed rule, we proposed to continue to assign the procedures described by CPT codes 0071T and 0072T to APC 5414 (Level 4 Gynecologic Procedures) for CY 2020. We also proposed to continue to assign the APC to status indicator ''J1'' (Hospital Part B services paid through a comprehensive APC). In addition, we proposed to continue to assign the services described by HCPCS code C9734 (Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (mr) guidance) to APC 5115 (Level 5 Musculoskeletal Procedures) for CY 2020. We also proposed to continue to assign HCPCS code C9734 to status indicator ''J1''. We refer readers to Addendum B to the proposed rule for the proposed payment rates for CPT codes 0071T and 0072T and HCPCS code C9734 under the OPPS. Addendum B is available via the internet on the CMS website.

For the procedure described by CPT code 0398T, we have identified 37 paid claims from CY 2016 through CY 2018 (1 claim in CY 2016, 11 claims in CY 2017, and 25 claims in CY 2018). We note that the procedure described by CPT code 0398T was first assigned to a New Technology APC in CY 2016. Accordingly, there are 3 years of claims data available for the OPPS ratesetting purposes. The payment amounts for the claims vary widely, with a cost of approximately $29,254 for the sole CY 2016 claim, a geometric mean cost of approximately $4,647 for the 11 claims from CY 2017, and a geometric mean cost of approximately $11,716 for the 25 claims from CY 2018. We are concerned about the large fluctuation in the cost of the procedure described by CPT code 0398T from year to year and the relatively small number of claims available to establish a payment rate for the service. 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, as discussed in section III.C.2. of the proposed rule, we proposed to apply 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 costs using multiple years of claims data to select the appropriate payment rate for purposes of assigning CPT code 0398T to a New Technology APC. We believe using this approach to assign CPT code 0398T to a New Technology APC is more likely to yield a payment rate that will be representative of the cost of the procedure described by CPT code 0398T, despite the fluctuating geometric mean costs for the procedure available in the claims data used for the proposed rule. We continue to believe that the situation for the procedure described by CPT code 0398T is unique, given the limited number of claims for the procedure and the high variability for the cost of the claims, which makes it challenging to determine a reliable payment rate.

Our analysis found that the estimated geometric mean cost of the 37 claims over the 3 year period for which there are claims was approximately $8,829, the estimated arithmetic mean cost of the claims was approximately $10,021, and the median cost of the claims was approximately $11,985. While the results of using different methodologies range from approximately $8,800 to nearly $12,000, two of the estimates fall within the cost bands of New Technology APC 1575 (New

Technology—Level 38 ($10,001-$15,000)), with a proposed payment rate of $12,500.50. Consistent with our low volume policy for procedures assigned to a new technology APC, we presented the result of each statistical methodology in the proposed rule, and we sought public comments on which methodology should be used to establish payment for the procedures described by CPT code 0398T. We noted that we believe that the median cost estimate was the most appropriate representative cost of the procedure described by CPT code 0398T because it was consistent with the payment rates established for the procedure from CY 2017 to CY 2019 and did not involve any trimming of claims. Calculating the payment rate using either the geometric mean cost or the arithmetic mean cost would involve trimming the one paid claim from CY 2016, because the paid amount for the claim of $29,254 is substantially larger than the amount for any other paid claim reported for the procedure described by CPT code 0398T. The median cost estimate for CPT code 0398T also falls within the same New Technology APC cost band that was used to set the payment rate for CY 2019, which is $12,500.50 for this procedure. Therefore, for purposes of determining the proposed CY 2020 payment rate, we proposed to estimate the cost for the procedure described by CPT code 0398T by calculating the median cost of the 37 paid claims for the procedures in CY 2016 through CY 2018, and assigned the procedure described by CPT code 0398T to the New Technology APC that includes the estimated cost. Accordingly, we proposed to maintain the procedure described by CPT code 0398T in APC 1575 (New Technology—Level 38 ($10,001-$15,000)), with a proposed payment rate of $12,500.50 for CY 2020. 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.

TABLE 12.—CY 2020 STATUS INDICATOR (SI), APC ASSIGNMENT, AND PAYMENT RATE FOR THE MAGNETIC RESONANCE IMAGE GUIDED HIGH INTENSITY FOCUSED ULTRASOUND (MRgFUS) PROCEDURES

CPT/ HCPCS Code	Long Descriptor	CY 2019 OPPS SI	CY 2019 OPPS APC	CY 2019 OPPS Payment Rate	Final CY 2020 OPPS SI	Final CY 2020 OPPS APC	Final CY 2020 OPPS Payment Rate
0071T	Focused ultrasound ablation of uterine leiomyomata, including mr guidance; total leiomyomata volume less than 200 cc of tissue.	J1	5414	$2,361.27	J1	5414	Refer to OPPS Addendum B.
0072T	Focused ultrasound ablation of uterine leiomyomata, including mr guidance; total leiomyomata volume greater or equal to 200 cc of tissue.	J1	5414	$2,361.27	J1	5414	Refer to OPPS Addendum B.
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	S	1575	Refer to OPPS Addendum B.

CPT/ HCPCS Code	Long Descriptor	CY 2019 OPPS SI	CY 2019 OPPS APC	CY 2019 OPPS Payment Rate	Final CY 2020 OPPS SI	Final CY 2020 OPPS APC	Final CY 2020 OPPS Payment Rate
C9734	Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (mr) guidance.	J1	5115	$10,713.88	J1	5115	Refer to OPPS Addendum B.

Comment: Multiple commenters, including the developer of MRgFUS, stated that the proposed payment rate for CPT code 0398T was too low because they believed the claims data for CPT code 0398T continue to underestimate the resources used to perform the procedure even when using the low-volume payment policy to establish the payment rate for the procedure. The developer also used the example of the service described by HCPCS code C9734 (Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (mr) guidance), where the payment rate for the service had doubled from $5,222 in CY 2017 to $11,675 in the CY 2020 proposed rule, to argue that a similar increase could occur for CPT code 0398T. Commenters suggested several ideas for what they believed would be a more appropriate rate. Commenters believed the claims cost data reported for CPT code 0398T does not fully reflect the resource costs for the time the procedure takes, the cost of single-use supplies for the procedure, and hours of use of a provider's MRI machine. To reflect these costs, several commenters supported restoring the payment rate from CY 2018 of $17,500.50. Other commenters simply requested a higher rate than what was proposed such as a payment rate of either $22,000 or $25,000.

Response: We appreciate the commenters' concerns, but the claims data we currently have for CPT code 0398T do not support a higher payment rate even when using the low-volume payment policy. Also, while the payment rate for HCPCS code C9734 (Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (mr) guidance) doubled from CY 2017 to CY 2020, the payment rate increase for HCPCS code C9734 is not predictive of the changes in cost that may occur with 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). Rather, the payment rate for each service, including that described by HCPCS code C9734, is generally based on the costs associated with furnishing the service, which, in turn, drives the APC assignment. The geometric mean for C9734, which represents the cost of the individual procedure, increased from $8,655 in CY 2017 to $9,294 in CY 2020, and was reassigned to a higher level APC based clinical and resource similarity to other services.

Under the low-volume payment policy, we utilized 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 CPT code 0398T to a New Technology APC. We identified 43 claims reporting the procedure described by CPT code 0398T for the 3-year period of CY 2016 through CY 2018. We found the geometric mean cost for the procedure described by CPT code 0398T is approximately $8,485, the arithmetic mean cost is approximately $9,672, and the median cost is approximately $11,182. Based on our methodology, we will use the median cost of CPT code 0398T to set the payment rate for the procedure because the median cost is the highest rate of the three statistical methods and may reflect some of the higher resource costs, as described by commenters, for the procedure. The median cost for CPT code 0398T falls within the same New Technology APC 1575 (New Technology—Level 38 ($10,001–$15,000)) with a proposed payment rate of $12,500.50 that was proposed as the APC assignment for CPT code 0398T in the proposed rule.

Comment: Two commenters supported the assignment of CPT code 0398T to New Technology APC 1575 (New Technology—Level 38 ($10,001–$15,000)) with a proposed payment rate of $12,500.50. One of the commenters supported the proposed new technology APC assignment because it is reflective of the median cost of the service and would ensure that what the commenter believed would be a severe underpayment calculated from the geometric mean would not be used to establish the payment rate for CPT code 0398T, which the commenter believed could discourage providers from performing the service.

Response: We appreciate the support of the commenters.

Comment: One commenter, the developer, supported the assignment of HCPCS code C9734 to APC 5115 (Level 5 Musculoskeletal Procedures) for CY 2020.

Response: We appreciate the support of the commenter.

After consideration of the public comments we received, we are finalizing our proposal for the APC assignment of CPT code 0398T. Specifically, we are continuing to assign this code to New Technology APC 1575 (New Technology—Level 38 ($10,001–$15,000)), with a payment rate of $12,500.50, for CY 2020 through use of our low-volume payment policy for new technology procedures. In addition, we are finalizing our proposal, without modification, to assign HCPCS code C9734 to APC 5115. We also are finalizing our proposal to continue to assign CPT codes 0071T and 0072T to APC 5414, without modification. Table 11 above lists the final CY 2018 status

indicator and APC assignments for MRgFUS procedures. We refer readers to Addendum B of this final rule with comment period for the final payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

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 the Food and Drug Administration (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, 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 2020, 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.

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 fall within the same New Technology APC cost band ($145,001–$160,000), where the Argus® II procedure is assigned for CY 2019. Consistent with our policy stated in section III.C.2. of the proposed rule, 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 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 2020. 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.

Comment: Two commenters, including the manufacturer, supported the assignment of 0100T to APC 1908 (New Technology—Level 52 ($145,001–$160,000)), with a proposed payment rate of $152,500.50 for CY 2020.

Response: We appreciate the support of the commenters. Consistent with our policy for low-volume services assigned to a New Technology APC, for this final rule, we calculated 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. We identified 41 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 $146,042, the arithmetic mean cost to be approximately $151,453, and the median cost to be approximately $151,426. All of the resulting estimates from using the three statistical methodologies fall within the same New Technology APC cost band ($145,001–$160,000), that was proposed as the APC assignment for CPT code 0100T in the proposed rule. Therefore, we are finalizing our proposal 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 payment rate of $152,500.50 for CY 2020. 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.

As we discussed in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58898), the claims data from CY 2017 showed another payment issue with regard to the Argus® II procedure. We found that payment for the Argus® II procedure was sometimes bundled into the payment for another procedure. Therefore in CY 2019, we implemented a policy to exclude payment for all procedures assigned to New Technology APCs from being bundled into the payment for procedures assigned to a C–APC. For CY 2020, we proposed to continue this policy as described in section II.A.2.b.(3) of the proposed rule. Our proposal would continue to exclude payment for any procedure that is assigned to a New Technology APC from being packaged when included on a claim with a service assigned to status indicator ''J1''. While we did not propose to exclude payment for a procedure assigned to a New Technology APC from being packaged when included on a claim with a service assigned to status indicator ''J2'', we sought public comments on this issue.

Comment: Several commenters, including device manufacturers, device manufacturer associations and physicians were opposed to our proposal to package payment for procedures assigned to a New Technology APC into the payment for comprehensive observation services assigned status indicator ''J2''. The commenters stated that there were instances where beneficiaries receiving observation services may require the types of procedures that are assigned to New Technology APCs. Several commenters specifically mentioned HeartFlow, and stated that it could be performed appropriately for a patient receiving observation services. The commenters also stated that providing separate payment for this new technology procedure will allow CMS to collect sufficient claims data to enable assignment of the procedure to an appropriate clinical APC.

Response: We appreciate the stakeholders' comments regarding this proposal and agree that, although rare, there are situations in which it is clinically appropriate to provide a new technology service when providing comprehensive observation services. As discussed in the CY 2019 OPPS/ASC

final rule with comment period (83 FR 58847), the purpose of the new technology APC policy is to ensure that there are sufficient claims data for new services in order to assign these procedures to a clinical APC and therefore, we excluded procedures assigned to New Technology APCs from packaging under the C–APC policy. In the CY 2019 final rule, we specifically stated that the exclusion policy included circumstances when New Technology procedures were billed with comprehensive services assigned to status indicator ''J1'', however we believe this rationale is also applicable to comprehensive observations services that are assigned status indicator ''J2''.

Accordingly, for CY 2020 and subsequent years, we are modifying our policy for excluding procedures assigned to New Technology APCs from the C–APC policy. That is, we are finalizing our proposal to exclude payment for any procedure that is assigned to a New Technology APC from being packaged when included on a claim with a ''J1'' service assigned to a C–APC. For CY 2020 and subsequent years, we are also finalizing a policy to exclude payment for any procedures that are assigned to a New Technology APC from being packaged into the payment for comprehensive observation services assigned to status indicator ''J2'' when they are included on a claim with ''J2'' procedures. This policy is also described in section II.A.2.b.(3) of this final rule.

c. 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 (eg, 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. We have not received any claims data for this service. Therefore, we proposed to continue to assign the procedure described by HCPCS code C9751 to New Technology APC 1571 (New Technology—Level 34 ($8,001–$8,500)), with a proposed payment rate of $8,250.50 for CY 2020. Details regarding HCPCS code C9751 were shown in Table 12 of the CY 2020 OPPS/ASC proposed Rule, which is reprinted below in Table 13.

TABLE 13.—CY 2020 PROPOSED OPPS APC AND STATUS INDICATOR FOR HCPCS CODE C9751 ASSIGNED TO NEW TECHNOLOGY APC

CY 2020 HCPCS Code	Long Descriptor	Proposed CY 2020 OPPS SI	Proposed CY 2020 OPPS APC
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	1571

Comment: The developer of the procedure noted that there will be clinical trials for HCPCS code C9751 in CY 2020 and it is anticipated the procedure also will have a limited market release in CY 2020. Therefore, the developer is expecting claims to be reported billed with HCPCS code C9751 for CY 2020.

Response: We appreciate the update on the expected utilization for HCPCS code C9751 for CY 2020.

Comment: One commenter supported our proposal to assign HCPCS code C9751 to New Technology APC 1571 (New Technology—Level 34 ($8,001-$8,500)), with a proposed payment rate of $8,250.50 for CY 2020.

Response: We appreciate the support of the commenter.

After considering the public comments, we are finalizing our proposal to assign HCPCS code C9751 to New Technology APC 1571 (New Technology—Level 34 ($8,001–$8,500)), with a payment rate of $8,250.50 for CY 2020.

d. Pathogen Test for Platelets

As stated in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59281), HCPCS code P9100 is used to report any test used to identify bacterial or other pathogen contamination in blood platelets. Currently, there are two rapid bacterial detection tests cleared by FDA that are described by HCPCS code P9100. According to their instructions for use, rapid bacterial detection tests should be performed on platelets from 72 hours after collection. Currently, certain rapid and culture-based tests can be used to extend the dating for platelets from 5 days to 7 days. Blood banks and transfusion services may test and use 6-day old to 7-day old platelets if the test results are negative for bacterial contamination.

HCPCS code P9100 was assigned in CY 2019 to New Technology APC 1493 (New Technology—Level 1C ($21–$30)), with a payment rate of $25.50. For CY 2020, based on CY 2018 claims data, there are approximately 1,100 claims reported for this service with a geometric mean cost of approximately $32. This geometric mean cost would result in the assignment of the service described by HCPCS code P9100 to a New Technology APC, based on the associated cost band, with a higher payment rate than where the service is currently assigned. Therefore, for CY 2020, we proposed to reassign the service described by HCPCS code P9100 to New Technology APC 1494 (New Technology—Level 1D ($31–$40)), with a proposed payment rate of $35.50.

Comment: One commenter expressed support for the proposal.

Response: We appreciate the support of the commenter.

After considering the public comments, we are finalizing our proposal to assign HCPCS code P9100 to New Technology APC 1494 (New Technology—Level 1D ($31–$40)), with a payment rate of $35.50.

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 procedures in the OPPS, payment for analytics that are performed after the main diagnostic/image procedure are packaged into the payment for the primary procedure. However, in CY 2018, we determined that HeartFlow should receive a separate payment because the procedure 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.

For CY 2020, based on our analysis of the CY 2018 claims data available for the proposed rule, we found that over 840 claims had been submitted for payment for HeartFlow during CY 2018. We stated that the estimated geometric mean cost of HeartFlow was $788.19, or roughly $660 lower that the payment rate for CY 2019 of $1,450.50. Therefore, for CY 2020, 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. We proposed to reassign the service described by CPT code 0503T to New Technology APC 1509 (New Technology—Level 9 ($701–$800)), with a proposed payment rate of $750.50 for CY 2020. We sought public comments on this proposal.

Comment: Multiple commenters requested that we retain the CY 2019 OPPS APC assignment of APC 1516 (New Technology—Level 16 ($1401–$1500)) for HeartFlow with a payment rate of $1,450.50. The commenters were concerned that reducing the payment rate to $750.50 would discourage hospitals from using the service because they stated that the list price of the HeartFlow service is substantially higher than the proposed payment rate. Commenters were concerned that reduced utilization of HeartFlow would cause some beneficiaries to have unnecessary invasive coronary angiograms that are more costly than the HeartFlow procedure.

Multiple commenters, including the developer of HeartFlow, provided additional reasons to maintain the current payment rate for the service of $1,450.50 despite claims data suggesting a lower payment rate for HeartFlow. The commenters believed that 78 single frequency claims used for the proposed rule solely represented a single year and that such a low number of claims would be an insufficient number of claims on which to base a payment rate reduction for the service. Two commenters suggested that CMS should collect another one or two years of claims data before making changes to the current payment rate. One of the commenters believed the reason the estimated cost of HeartFlow derived from claims data is substantially less than the current payment rate may be due to providers submitting claims without marked up gross charges for the services they provide.

Another commenter, the developer, encouraged CMS 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 current payment rate for HeartFlow. The developer suggested that CMS should use its own assessment of the resources required to perform the HeartFlow service to set the payment rate for the service. The developer cited instances in the last four years where CMS used its equitable adjustment authority to mitigate either large fluctuations or declines in annual payment rates. These cases include: (1) A CY 2018 decision to use multiple years of claims data to pay a higher rate for CPT code 0100T (Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intraocular retinal electrode array, with vitrectomy) of $122,500.50 rather than the payment rate generated by the most recent year of claims data of $95,000.50; (2) a CY 2016 decision regarding the payment rate of CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis) where the median cost of $18,365 was used to set the payment rate instead of the geometric mean cost of $13,865 because only 39 single frequency claims were reported for the service, and where we stated that ''the median cost would be a more appropriate measure of the central tendency for purposes of calculating the cost and the payment rate for the procedure;'' (3) a CY 2016 decision to adjust the geometric mean per diem cost for the partial hospital program to ensure a per diem payment for fewer services was less than a per diem payment for a larger number of services; and (4) a CY 2018 decision to establish a payment rate of $17,500.50 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) instead of proposed payment rate of $9,750.50.

The developer believes that the proposed New Technology APC assignment for HeartFlow, which would result in a nearly 50 percent reduction in the payment rate between CY 2019 and CY 2020, is similar to these cases described in their comment. Therefore, the developer asked us to use our equitable adjustment authority to

maintain the CY 2019 payment rate of $1,450.50 for the service rather than adopt the proposed payment rate.

Response: The proposed payment rate for CPT code 0503T was based on claims data from CY 2018, which is the first year the service was payable in the OPPS. For ratesetting for CY 2018 and CY 2019, there were no claims data available showing the cost of the service. Also, there were no services identified as comparable to CPT code 0503T, which meant we could not estimate the cost of CPT code 0503T by using the cost of a similar service. Accordingly, we previously based pricing for the service on pricing information provided by the developer of the procedure.

We recognize that there was a low volume of claims for HeartFlow based on the data available for the proposed rule and, thus, we should have applied the low-volume policy for new technology services in the proposed rule.

However, for the final rule, using the most recently available data, there are now 957 total claims billed with CPT code 0503T and 101 single frequency claims. We appreciate the concerns of the commenters who stated that there were not enough claims billed with HeartFlow to use claims data to revise the rate for HeartFlow. While 101 single claims is above the threshold we established for low-volume services assigned to a new technology APC, we agree with the commenters that a payment reduction of nearly 50 percent is significant for a new technology that still has relatively low volume.

Accordingly, given the low number of single frequency claims for CPT code 0503T, that number of claims for the Heartflow procedure was below the low-volume payment policy threshold for the proposed rule, and that it is only two claims above the threshold using data available for this final rule with comment period, we have 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 is just above our threshold to use the low-volume payment policy, we still have 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 falls 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 helps to account for some of the higher costs of CPT code 0503T identified by the commenters that may not have been reflected by either the median or the geometric mean. We acknowledge the commenters' concern and recognize that it may be theoretically possible that the reported cost of CPT code 0503T is higher than what we calculated from the claims data due to some providers reporting costs lower than actual costs for the service. However, we rely on hospitals to bill all CPT codes accurately in accordance with their code descriptors and CPT and CMS instructions, as applicable, and to report charges on claims and charges and costs on their Medicare hospital cost reports appropriately. In addition, we do not specify the methodologies that hospitals must use to set charges for this or any other service.

After consideration of the public comments we received, we are utilizing our new technology low-volume payment policy to set the payment rate for the HeartFlow service CPT code 0503T based on the arithmetic mean for the procedure. Specifically, we are assigning CPT code 0503T to New Technology APC 1511 (New Technology—Level 11 ($901–$1000)) with a payment rate of $950.50.

f. Cardiac Positron Emission Tomography (PET)/Computed Tomography (CT) Studies

Effective January 1, 2020, we have assigned three CPT codes (78431, 78432, and 78433) that describe the services associated with cardiac PET/CT studies to New Technology APCs. Table 13 reports code descriptors, status indicators, and APC assignments for these CPT codes. These codes were listed in Addendum B to the CY 2020 OPPS/ASC proposed rule as 78X32, 78X33, and 78X44. More information about CPT codes 78431, 78432, and 78433 can be found in section III. D. b. of this final rule.

Comment: Several commenters reported that certain societies submitted a new technology application to CMS for CPT codes 78431, 78432, and 78433 that details the costs associated with providing these services. For CPT code 78431, these same commenters disagreed with the proposed APC placement and recommended its reassignment from APC 5594 (Level 4 Nuclear Medicine and Related Services) with a proposed payment rate of $1,466.16 to APC 1522 (New Technology—Level 23 ($2501–$3000)) with a proposed payment rate of $2,750.50. They reported that, based on the resource cost of the service described by CPT code 78431, APC 1522 provides adequate reimbursement for the service. Similarly, for CPT codes 78432 and 78433, the commenters indicated that APC 5594 would not adequately cover the resource costs associated with these procedures, and recommended their reassignment to APC 1523 (New Technology—Level 23 ($2501–$3000)) with a proposed payment rate of $ 2,750.50

Response: Based on the information provided in the new technology application, and the comments received, we are revising the APC assignments for these codes. Specifically, we are revising the APC assignment for CPT code 78431 from APC 5594 to APC 1522, and reassigning CPT codes 78432 and 78433 from APC 5594 to APC 1523.

In summary, after consideration of the public comments for the new cardiac PET/CT 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 assigning CPT codes 78431, 78432, and 78433 to the final APCs listed in Table 14 below. Please refer to section III. D. b. of this final rule for more information on the finalized proposal to establish a payment rate for other new CPT codes associated with PET/CT studies. The final CY 2020 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 14.—CY 2020 OPPS APC AND STATUS INDICATOR FOR CPT CODES 78431, 78432, AND 78433 ASSIGNED TO NEW TECHNOLOGY APCS

CPT Code	CY 2020 OPPS/ASC Proposed Rule Placeholder Code	Long Descriptor	Proposed OPPS SI	Proposed OPPS APC	Final OPPS SI	Final OPPS APC
78431	78X32	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	5594	S	1522
78432	78X33	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	5594	S	1523
78433	78X34	Myocardial imaging, positron emission tomography (PET),	S	5594	S	1523

CPT Code	CY 2020 OPPS/ASC Proposed Rule Placeholder Code	Long Descriptor	Proposed OPPS SI	Proposed OPPS APC	Final OPPS SI	Final OPPS APC
		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				

g. V-Wave Interatrial Shunt Procedure

A randomized, double-blinded control IDE study is currently in progress for the V-Wave interatrial shunt procedure. All participants who passed initial screening for the study receive a right heart catherization 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 is 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)). Details about the temporary HCPCS code are shown in Table 15 below. The final CY 2020 payment rate for V-Wave interatrial shunt procedure can be found in Addendum B to this final rule with comment period (which is available via the internet on the CMS website).

TABLE 15.—CY 2020 OPPS APC AND STATUS INDICATOR FOR V-WAVE INTRATRIAL SHUNT PROCEDURE ASSIGNED TO A NEW TECHNOLOGY APC

HCPCS Code	IDE Name	Long Descriptor	Add Date	Jan 2020 OPPS SI	Jan 2020 OPPS APC	Jan 2020 ASC PI
C9758	Interatrial shunt IDE	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	01/01/2020	T	1589	X5

D. OPPS APC-Specific Policies

1. Barostim Neo™ System (APC 5464)

In CY 2019, CPT codes 0266T and 0268T were assigned to APC 5463 (Level 3 Neurostimulator and Related Procedures) with a payment rate of $18,707.16. For CY 2020, as listed in Addendum B to the CY 2020 OPPS/ASC proposed rule, we proposed to reassign both codes to APC 5464 (Level 4 Neurostimulator and Related Procedures) with a proposed payment rate of $29,025.99. Table 16 below lists the long descriptors, proposed status indicator (SI), and APC assignments for these codes. We note that both codes are associated with the Barostim Neo™ System.

Comment: A medical device company agreed with the reassignment for CPT codes 0266T and 0268T to APC 5464. The commenter stated that APC 5464 is the more appropriate assignment for these codes based on clinical and resource homogeneity, and encouraged CMS to finalize the APC assignment.

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.

Based on our analysis of the proposed rule claims data as well as clinical review of the services described, we proposed to revise the APC assignment for both CPT codes 0266T and 0268T to APC 5464. In our analysis of CPT code 0268T (which describes implantation/replacement of the pulse generator), we noticed that the APC assignment for CPT code 0266T (which describes the implantation or replacement of the complete system) was lower. We do not believe that the payment for the complete system (CPT code 0266T) should be less than the payment for the implantation/replacement of the pulse generator (CPT code 0268T) procedure. Consequently, we proposed to revise the APC assignment for CPT code 0266T to APC 5464. Although we had no claims data for CPT code 0266T, we believed it was necessary to revise the APC assignment to appropriately reflect the device cost associated with the procedure.

Similar to our findings for the proposed rule, based on updated claims data for this final rule with comment period, the geometric mean cost for CPT code 0268T supports its reassignment from APC 5463 to APC 5464. Specifically, our claims data show a geometric mean cost of approximately $25,558 for CPT code 0268T based on 6 single claims (out of 6 total claims), which is consistent with the geometric mean cost of approximately $28,491 for APC 5464, rather than the geometric mean cost of approximately $18,864 for APC 5463. Furthermore, as mentioned above, we are also assigning CPT code 0266T to APC 5464 even though we do not yet have claims data because we do not believe that the service for implantation of the entire system (CPT code 0266T) would be less resource intensive than the implantation of the pulse generator alone (CPT code 0268T).

In summary, after consideration of the public comment and analysis of the latest claims data, we are finalizing our proposal, without modification, to assign CPT codes 0266T and 0268T to APC 5464 for CY 2020. Table 16 below list the long descriptors for the codes and the final SI and APC assignments. The final CY 2020 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) assignments for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

TABLE 16.—FINAL SI AND APC ASSIGNMENTS FOR CPT CODES 0266T and 0268T FOR CY 2020

CPT Code	Long Descriptor	Proposed CY 2020 OPPS SI	Proposed CY 2020 OPPS APC	Final CY 2020 OPPS SI	Final CY 2020 OPPS APC
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)	J1	5464	J1	5464
0268T	Implantation or replacement of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)	J1	5464	J1	5464

2. Biomechanical Computed Tomography (BCT) Analysis (APCs 5521, 5523, and 5731)

The CPT Editorial Panel established five new codes, specifically, CPT codes 0554T, 0555T, 0556T, 0557T, and 0558T, to describe the services associated with biomechanical computed tomography (BCT) analysis effective July 1, 2019. Through the July 2019 OPPS quarterly update CR (Transmittal 4313, Change Request 11318, dated May 24, 2019), we assigned these new codes to appropriate interim status indicators (SI) and APCs. Table 17 below lists the long descriptors and proposed SI and APCs of the codes.

Comment: A commenter agreed with the SI and APC assignments and stated that the APC assignments for these codes are the best available placements. The commenter also noted that CMS did not assign the comprehensive code (CPT code 0554T) and the physician interpretation code (CPT code 0557T) to an APC because the codes represent physician services.

Response: We thank the commenter for its feedback. We are finalizing the SIs and APC assignments for the codes. Table 17 below list the long descriptors and final SIs and APCs. The final CY 2020 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 complete list of the OPPS payment status indicators and their definitions for CY 2020. Both Addendum B and Addendum D1 are available via the internet on the CMS website.

As we do for all codes, we will reevaluate the APC assignments for CPT codes 0555T, 0556T, and 0558T once we have claims data. 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.

TABLE 17.—FINAL SI AND APC ASSIGNMENTS FOR CPT CODES 0554T, 0555T, 0556T, 0557T, and 0558T FOR CY2020

CPT Code	Long Descriptor	Proposed CY 2020 OPPS SI	Proposed CY 2020 OPPS APC	Final CY 2020 OPPS SI	Final CY 2020 OPPS APC
0554T	Bone strength and fracture risk using finite element analysis of functional data, and bone-mineral density, utilizing data from a computed tomography scan; retrieval and transmission of the scan data, assessment of bone strength and fracture risk and bone mineral density, interpretation and report	M	N/A	M	N/A
0555T	Bone strength and fracture risk using finite element analysis of functional data, and bone-mineral density, utilizing data from a computed tomography scan; retrieval and transmission of the scan data	S	5731	S	5731
0556T	Bone strength and fracture risk using finite element analysis of functional data, and bone-mineral density, utilizing data from a computed tomography scan; assessment of bone strength and fracture risk and bone mineral density	S	5523	S	5523
0557T	Bone strength and fracture risk using finite element analysis of functional data, and bone-mineral density, utilizing data from a computed tomography scan; interpretation and report	M	N/A	M	N/A
0558T	Computed tomography scan taken for the purpose of biomechanical computed tomography analysis	S	5521	S	5521

3. Cardiac Magnetic Resonance (CMR) Imaging (APC 5572)

For CY 2020, we proposed to maintain the APC assignment for 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 rate of $373.45.

Comment: Some commenters expressed concern with the placement of CPT code 75561 in APC 5572, and stated that it is grouped with services that are not similar clinically or with respect to resource use. As an example, they observed that CPT code 75561 is unlike CT of the abdomen or pelvis or MRI of the neck and spine, and instead, is more similar to those services in APC 5573 (Level 3 Imaging with Contrast), with a proposed payment rate of $682.96.Another commenter expressed concern with the payment stability for CPT code 75561. The commenter noted that although the code is assigned to the same APC for CY 2020, the payment for the service is slated for another reduction. The commenter observed that the payment rate for the service has decreased in the last several years and noted the following yearly rates:

- CY 2017 OPPS payment rate: $426.52
- CY 2018 OPPS payment rate: $456.34

- CY 2019 OPPS payment rate: $385.88
- CY 2020 OPPS proposed payment rate: $373.45

This same commenter reported that the code was previously included in a nuclear medicine APC, which it maintained was appropriate based on its clinical and resource homogeneity to cardiovascular magnetic resonance and cardiac nuclear imaging services in the APC, and that, since its APC reassignment, the payment for the service has dropped. The commenter believed that the different cost reporting methods used by hospitals may contribute to the artificially low relative payment weights and payment amounts for CT and MR.

Response: For CY 2020, based on claims submitted between January 1, 2018 through December 30, 2018, that were processed on or before June 30, 2019, our analysis of the latest claims data for this final rule continues to support our proposal of assigning CPT code 75561 to APC 5572. Specifically, our claims data show a geometric mean cost of approximately $413 for CPT code 75561 based on 14,350 single claims (out of 18,118 total claims), which is comparable to the geometric mean cost of about $359 for APC 5572, rather than the geometric mean cost of approximately $660 for APC 5573. The geometric cost of approximately $413 for CPT code 75561 is also consistent with the costs for significant services in APC 5572, which range between about $269 (for CPT code 74174) to $515 (for CPT code 73525). Based on our analysis of the latest claims data, we believe that CPT code 75561 is appropriately assigned to APC 5572.

With regards to the issue of payment stability, we note that Section 1833(t)(9)(A) of the Act requires the Secretary to review, not less often than annually, and to revise the groups, 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. Therefore, every year we review and revise the APC assignments based on our evaluation of these factors using the latest OPPS claims data. While we recognize the concerns about payment stability, we note that changes made to payment rates are based on our calculations of geometric mean costs from the most recently available Medicare claims and cost report data analysis, which may or may not result in payment increases and/or reductions based on the most recent geometric mean costs available. We note that the geometric mean costs reflect the national average resources to furnish a service in the hospital outpatient setting. To the extent that costs decrease, so too, would the payment rate.

In addition, with regard to the issue of different hospital cost reporting methods, we are unable to determine whether hospitals are misreporting the procedure. It is generally not our policy to judge the accuracy of hospital charging and coding for purposes of ratesetting. We rely on hospitals to accurately report the use of HCPCS codes in accordance with their code descriptors and CPT and CMS instructions, and to appropriately report services on claims and charges and costs for the services on their Medicare hospital cost report. Also, we do not specify the methodologies that hospitals 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 hospitals report all HCPCS codes consistent with their descriptors; CPT and/or CMS instructions and correct coding principles, and all charges for all services they furnish, whether payment for the services is made separately paid or is packaged'' to enable CMS to establish future ratesetting for OPPS services.

Comment: One commenter who expressed concern with the APC assignment for CPT code 75561 also requested that we address in the final rule how we determine which services are clinically similar. The commenter noted that CMS has constructed many APCs with a mix of imaging services that are dissimilar and yet preserves the clinical homogeneity of some APCs, such as nuclear medicine services.

Response: Under the OPPS, each service is assigned to an APC based on the clinical and resource similarity to other services within the APC or family of APCS. The OPPS is a prospective payment system under which payment groupings (that is, APCs) are based on clinical and resource similarity rather than code-specific payment rates, which would result in a cost-based fee schedule. For example APCs 5111–5116, which are described as Levels 1 through 6 Musculoskeletal Procedures, all include services that involve musculoskeletal services/procedures and the various levels of that APC family differentiate such procedures based on resource homogeneity. That is, the descriptors for APCs 5111 through 5116 are general and broadly describe a variety of musculoskeletal procedures, and are differentiated by the various levels based on the geometric mean costs for each APC. Clinically, all the procedures in APCs 5111 through 5116 are similar in that they involve some form of musculoskeletal procedure. In addition, as stated in section III.B.2. (Application of the 2 Times Rule) of this final rule with comment, 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''). While it may seem appropriate to place one code in a specific grouping, based on our 2 times rule criteria, we must assign the code to the appropriate APC based on its geometric mean cost.

In summary, after consideration of the public comments, we are finalizing our proposal, without modification, to assign CPT code 75561 to APC 5572. The final CY 2020 payment rate for CPT code 75561 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.

4. CardioFlux™ Magnetocardiography (MCG) Myocardial Imaging (APC 5723)

For CY 2020, we proposed to maintain the APC assignment for CPT code 0541T to APC 5722 (Level 2 Diagnostic Tests and Related Services) with a proposed payment rate of $256.60. We also proposed to continue to assign CPT code 0541T, which is an add-on code, to status indicator ''N'' to indicate that the code is packaged and payment for it is included in the primary procedure or service. In this case, the payment for 0542T is included in CPT code 0541T. We note that CPT codes 0541T and 0542T are associated with the CardioFlux magnetocardiography imaging technology. Table 18 below lists the long descriptors for the codes as well as the proposed SI and APC assignments.

Comment: A commenter disagreed with the assignment to APC 5722 and reported that the service associated with CPT code 0541T is not clinically and resource comparable to the services in the APC. The commenter stated that the service is clinically comparable to the services that are assigned to APCs 5593 and 5724, specifically:

• APC 5593 (Level 3 Nuclear Medicine), with a proposed payment rate of $ 1,293.33, which includes—
+ CPT code 78451 (Myocardial perfusion imaging); and
+ CPT code 78452 (Myocardial perfusion imaging).
• APC 5724 (Level 4 Diagnostic Tests and Related Services), with a proposed payment rate of approximately $ 920.66, which includes—
+ CPT code 95965 (Magnetoencephalography (MEG)); and
+ CPT code 95966 (Magnetoencephalography (MEG)).

The commenter indicated that this new technology requires the use of very expensive capital equipment, and added that the CardioFlux System costs about $1.5 million with a useful life of seven years. The technology itself involves hospital site implementation and ongoing operation. The commenter stated that the proposed payment does not provide adequate payment for this novel technology. The commenter expressed concern that the proposed low payment rate will severely limit uptake of this new technology, and, consequently, urged CMS to reassign CPT code 0541T to either APC 5593 or APC 5724 to ensure patient access to this emerging technology and its potential for savings to the Medicare program.

Response: 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 our OPPS payments remain appropriate for procedures as they transition into mainstream medical practice.

In addition, we note this new technology is currently under clinical trial (ClinicalTrials.gov Identifiers: NCT03968809 and NCT04044391) and does not appear to be a service that is typically performed in an HOPD facility. Further, based on our clinical evaluation, we do not agree that CardioFlux MCG is similar to the MEG procedures described by CPT codes 95965 and 95966 since MEG procedures involve the brain while the CardioFlux technology involves imaging of the heart. Also, we do not agree that CardioFlux MCG is similar to the myocardial perfusion scans described by CPT codes 78451 and 78452 because these scans involve the use of radioactive tracers, specialized staff, and more time as the test generally takes two to four hours to complete. Furthermore, based on our findings, the CardioFlux MCG scan is unlike other cardiac imaging tests because it does not require or expose the patient to radiation, and takes about 90 seconds to perform with physician review and return of interpretation of the results in an estimated 5 minutes per patient.

However, based on our review of the issue and feedback from our medical advisors, as well as the anticipated operating costs per case derived from the public comment and publicly available information about the service, we believe that CPT code 0541T should be assigned to APC 5723 (Level 3 Diagnostic Tests and Related Services) rather than to APC 5722 (Level 2 Diagnostic Tests and Related Services). Because we have neither claims data nor specific HOPD costs, including the cost to perform each exam (other than the cost of the capital equipment that was supplied to us), we believe that APC 5723 is the most appropriate assignment at this time.

Therefore, after consideration of the public comment, we are finalizing our proposal, with modification, to assign CPT code 0541T to APC 5723. Table 18 list the long descriptors and final SI and APC assignments for both codes. The final CY 2020 payment rate for CPT code 0541T 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 18.—FINAL SI AND APC ASSIGNMENTS FOR CPT CODES 0541T AND 0542T FOR CY 2020

CY 2020 CPT Code	Long Descriptor	Proposed CY 2020 OPPS SI	Proposed CY 2020 OPPS APC	Final CY 2020 OPPS SI	Final CY 2020 OPPS APC
0541T	Myocardial imaging by magnetocardiography (MCG) for detection of cardiac ischemia, by signal acquisition using minimum 36 channel grid, generation of magnetic field time series images, quantitative analysis of magnetic dipoles, machine learning derived clinical scoring, and automated report generation, single study;	S	5722	S	5723
0542T	Myocardial imaging by magnetocardiography (MCG) for detection of cardiac ischemia, by signal acquisition using minimum 36 channel grid, generation of magnetic field time series images, quantitative analysis of magnetic dipoles, machine learning derived clinical scoring, and automated report generation, single study; interpretation and report	N	N/A	N	N/A

5. Cataract Removal With Endoscopic Cyclophotocoagulation (ECP) (APC 5492)

For CY 2020, the CPT Editorial Panel established two new codes to describe cataract removal with endoscopic cyclophotocoagulation (ECP), specifically, CPT codes 66987 and 66988. As listed in Table 19 below with the long descriptors, and also in Addendum B to the CY 2020 OPPS/ASC proposed rule, we proposed to assign CPT code 66987 and 66988 to APC 5491 (Level 1 Intraocular Procedures) with a proposed payment rate of $2,053.39. The codes were listed as 66X01 and 66X02 (the 5-digit CMS placeholder codes), respectively, in Addendum B with the short descriptors and again in Addendum O with the long descriptors. We also assigned the codes to comment indicator ''NP'' in Addendum B to indicate that they are new for CY 2020 and that public comments would be accepted on their proposed status indicator assignments. We note these codes will be effective January 1, 2020.

Comment: A commenter disagreed with the APC assignment and, based on their analysis of the combined geometric mean costs for the existing cataract and ECP procedures (CPT codes 66982, 66984, and 66711), believed the new codes should be reassigned to APC 5492 (Level 2 Intraocular Procedures) with a proposed payment rate of $3,867.16. Four professional ophthalmology organizations suggested that CMS should establish the payment rate for CPT code 66987 based on the combined costs of CPT codes 66711 and 66982, and, similarly, determine the payment rate for CPT code 66988 based on the combined costs of CPT codes 66711 and 66984. They expressed concern that the proposed payment rates for the codes do not adequately capture the resources hospitals will expend for each combined procedure.

Response: APC assignment for a code is not typically based on combined costs of existing HCPCS codes, rather, it is based on similarity to other codes within an APC based 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. Also, 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, with all new codes, 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.

Based on our analysis of the public comment and input from our medical advisors, we believe that we should

revise the APC assignment for these new cataract codes. We reviewed the components of the procedure associated with CPT codes 66987 and 66988, and after our analysis, we agree with commenters that the resources associated with the new codes are higher than the routine cataract and ECP procedures when performed by themselves. Therefore, we are reassigning the new codes from APC 5491 to APC 5492.

In summary, after consideration of the public comments, we are finalizing our proposal with modification, and revising the APC assignment for CPT codes 66987 and 66988 to APC 5492 for CY 2020. Table 19 lists the final SI and APC assignments for the two codes. The final CY 2020 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.

We note that we will reevaluate the APC assignments for CPT codes 66987 and 66988 once we have claims data. We review, on an annual basis, the APC assignments for all services and items paid under the OPPS based on the latest claims data that we have available.

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TABLE 19.— FINAL APC AND SI ASSIGNMENTS FOR CPT CODES 66987 and 66988 FOR CY 2020

CY 2020 HCPCS Code	CY 2020 OPPS/ASC Proposed Rule Placeholder Code	Long Descriptor	Proposed OPPS SI	Proposed OPPS APC	Final OPPS SI	Final OPPS APC
66987	66X01	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with endoscopic cyclophotocoagulation	J1	5491	J1	5492
66988	66X02	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification); with endoscopic cyclophotocoagulation	J1	5491	J1	5492

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6. Chimeric Antigen Receptor T-Cell (CAR T) Therapy (APCs 5694, 9035, and 9194)

Chimeric Antigen Receptor (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.

Two CAR T-cell therapies received FDA approval in 2017. KYMRIAH® (manufactured by Novartis Pharmaceuticals Corporation) was

approved for use in the treatment of patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse. In May 2018, KYMRIAH® received FDA approval for a second indication, treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL), high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma. YESCARTA® (manufactured by Kite Pharma, Inc.) was approved for use in the treatment of adult patients with relapsed or refractory large B-cell lymphoma and who have not responded to or who have relapsed after at least two other kinds of treatment.

The HCPCS code to describe the use of KYMRIAH® (HCPCS code Q2042) has been active since January 1, 2019 for OPPS, which replaced HCPCS code Q2040, active January 1, 2018 through December 31, 2018, as discussed in the CY2019 OPPS/ASC final rule with comment period. The HCPCS code to describe the use of YESCARTA® (HCPCS code Q2041) has been active since April, 1, 2018 for OPPS. The HCPCS Q-code for the currently approved CAR T-cell therapies include leukapheresis and dose preparation procedures because these services are included in the manufacturing of these biologicals. Both of these CAR T-cell therapies were approved for transitional pass-through payment status, effective April 1, 2018. The HCPCS codes that describe the use of these CAR T-cell therapies were assigned status indicator ''G'' in Addenda A and B to the CY2020 OPPS/ASC proposed rule.

As discussed in section V.A.4. (Drugs, Biologicals, and Radiopharmaceuticals with New or Continuing Pass-Through Payment Status in CY 2019) of this final rule with comment period, we are finalizing our proposal to continue pass-through payment status for HCPCS code Q2042 and HCPCS code Q2041 for CY 2020. In section V.A.4. of this final rule with comment period, we also are finalizing our proposal to determine the pass-through payment rate following the standard ASP methodology, updating pass-through payment rates on a quarterly basis if applicable information indicates that adjustments to the payment rates are necessary.

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, 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. Additionally, we 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 IV Drug Administration) for CY 2019. Additionally, the National Uniform Billing Committee (NUBC) established CAR T-cell related revenue codes and value code to be reportable on Hospital Outpatient Department (HOPD) claims effective for claims received on or after April 1, 2019.

As listed in Addendum B of the CY 2020 OPPS/ASC proposed rule, we proposed 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 assign CPT code 0540T to status indicator ''S'' (Procedure or Service, Not Discounted when Multiple) and APC 5694 (Level IV Drug Administration).

At the August 19, 2019 meeting, the HOP Panel recommended that CMS reassign the status indicator for the procedures described by the specific CPT codes 0537T, 0538T, and 0539T from ''B'' to ''Q1'' for CY2020.

Comment: Several commenters opposed our proposal to continue to assign status indicator ''B'' to CPT codes 0537T, 0538T, and 0539T for CY2020. Commenters proposed a variety of alternative status indicators including status indicators ''N'', ''S'', and ''Q1.'' Commenters believed that CPT codes 0537T, 0538T, and 0539T did not represent the steps required to manufacture the CAR T product as CMS has stated. Generally, those advocating for status indicator ''N'' (Items and Services Packaged into APC Rates) stated that this assignment would ease the billing burden and confusion experienced by providers under the current status indicator assignment of ''B''. Generally, those advocating for status indicator ''S'' (Procedure or Service, Not Discounted When Multiple) believed that separate payment is warranted for these services as they are distinct procedures and are ordered and performed by clinicians. Finally, generally those advocating for status indicator ''Q1'', indicating conditional separate payment, supported the HOP Panel's recommendation to assign this status indicator based on codes, such as CPT code 0565T (placeholder code 05X3T) (Autologous cellular implant derived from adipose tissue for the treatment of osteoarthritis of the knees; tissue harvesting and cellular implant creation). CPT code 0565T has a status indicator of ''Q1'' and commenters believe it is similar to the procedures described by CPT codes 0537T, 0538T, and 0539T, since CPT code 0565T involves the collection and harvest of cells, in the form of tissue, for the treatment of osteoarthritis of the knee. Additionally, commenters stated that the HCPCS drug Q-codes (Q2041 and Q2042) should be revised to eliminate the language referencing leukapheresis and dose preparation procedures.

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 CY2020. The existing CAR T-cell therapies on the market were approved as biologics and, therefore, provisions of the Medicare statute providing for payment for biological products apply. 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, and it 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 therapy drugs, HCPCS codes Q2041 and Q2042, include leukapheresis and dose preparation procedures as these services are including in the manufacturing of these biologicals. Therefore, payment for these services is incorporated into the drug Q-codes. We note that although there is no payment associated with 0537T, 0538T, and 0539T for reasons stated previously, these codes can still be reported to CMS for tracking purposes. Additionally, 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 Q-codes for CAR T-cell therapies to remove leukapheresis and dose preparation procedures, and we are not accepting the recommendations to revise the status indicators for procedures described by CPT codes 0537T, 0538T, and 0539T. We will continue to evaluate and monitor our payment for CAR T-cell therapies.

Comment: We note that commenters were supportive of the decision to continue the assignment of status indicator ''S'' (Procedure or Service, Not Discounted When Multiple) to CPT code 0540T.

Response: We thank commenters for their support and are finalizing our proposal to maintain status indicator ''S'' for CPT code 0540T.

Comment: Some commenters recommended CMS evaluate modifications to CAR T-cell payments for future rule making years, including strategies such as creating a new statutory benefit category for cell and gene therapies and value-based payment. Specifically, commenters suggested value-based payments could include milestone-based payments over time, indication-based pricing or combination-based pricing.

Response: We thank commenters for their feedback. Currently, the existing CAR T-cell therapies on the market were approved as biologics and, therefore, provisions of the Medicare statute providing for payment for biologicals apply. In regards to the creation of a new statutory benefit category, that is out of the scope of existing CMS statutory authority.

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 CY2020. Additionally, we are continuing our policy from CY2019 to assign status indicator ''S'' to CPT code 0540T for CY2020. Tables 20 and 21 below show the final SI and APC assignments for HCPCS codes Q2041, Q2042, 0537T, 0538T, 0539T, and 0540T for CY 2020. We refer readers to Addendum B to this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website. In addition, we refer readers to Addendum D1 to this final rule with comment period for the complete list of the OPPS payment status indicators and their definitions for CY2020.

Table 20.– FINAL SI AND APC ASSIGNMENT FOR HCPCS CODES Q2041 AND 2042 FOR CY 2020

HCPCS Code	Long Descriptors	CY 2019 SI	CY 2019 APC	Final CY 2020 SI	Final CY2020 APC
Q2041	Axicabtagene ciloleucel, up to 200 million autologous anticd 19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9035	G	9035
Q2042	Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9194	G	9194

Table 21.–FINAL SI AND APC ASSIGNMENTS FOR CPT CODES 0537T, 0538T, 0539T, AND 0540T FOR CY 2020

CPT Code	Long Descriptors	CY 2019 SI	CY 2019 APC	Final CY2020 SI	Final CY2020 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	N/A	B	N/A
0538T	Chimeric antigen receptor t-cell (car-t) therapy; preparation of blood-derived t lymphocytes for transportation (eg, cryopreservation, storage)	B	N/A	B	N/A
0539T	Chimeric antigen receptor t-cell (car-t) therapy; receipt and preparation of car-t cells for administration	B	N/A	B	N/A
0540T	Chimeric antigen receptor t-cell (car-t) therapy; car-t cell administration, autologous	S	5694	S	5694

7. Colonoscopy and Sigmoidoscopy With Endoscopic Mucosal Resection (EMR) (APC 5313)

For CY 2020, we proposed to continue to assign CPT codes 45349 and 45390 to APC 5312 (Level 2 Lower GI Procedures), with a proposed payment rate of $1,024.08. The long descriptors and proposed SI and APC assignments for both codes can be found in Table 22 below.

Comment: A commenter believed that the two procedures are different from the other procedures currently assigned to APC 5312, and stated they are more similar to these procedures that are assigned to APC 5313:

- 46610 (Anoscopy; with removal of single tumor, polyp, or other lesion by hot biopsy forceps or bipolar cautery);
- 46612 (Anoscopy; with removal of multiple tumors, polyps, or other lesions by hot biopsy forceps, bipolar cautery or snare technique); and
- 46615 (Anoscopy; with ablation of tumor(s), polyp(s), or other lesion(s) not amenable to removal by hot biopsy forceps, bipolar cautery or snare technique) where lesions are being removed by methods other than just the snare wire technique.

Based on clinical and resource homogeneity, the commenter requested a reassignment from APC 5312 to APC 5313 (Level 3 Lower GI Procedures), which had a proposed payment rate of $2,512.28, for CPT code 45349 and 45390

Response: Upon review of data available for this final rule with comment period, we agree with the commenter that the most appropriate assignment for both codes is APC 5313. Based on the latest hospital outpatient claims data used for this final rule with comment period, our analysis supports the reassignment for the codes to APC 5313. Specifically, our analysis of the claims data show a geometric mean cost of approximately $1,941 for CPT code 45349 based on 386 single claims (out of 387 total claims), and a geometric mean cost of about $2,039 for CPT code 45390 based on 10,212 single claims (out of 10,246). In both instances, the geometric mean cost for the codes are most compatible with APC 5313, whose geometric mean cost is approximately $2,294, compared to APC 5312, whose geometric mean cost is about $983. We believe that maintaining both codes in APC 5312 would underpay for the procedures. Therefore, we are reassigning the codes from APC 5312 to APC 5313 for CY 2020.

In summary, after consideration of the public comment, we are finalizing our proposal with modification, and revising the APC assignment for 45349 and 45390 from APC 5312 to APC 5313 for CY 2020. Table 22 lists the final SI and APC assignments for the two codes. The final CY 2020 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.

As we do every year, we will reevaluate the APC assignment for CPT codes 45349 and 45390 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.

TABLE 22.—FINAL APC AND SI ASSIGNMENTS FOR CPT CODES 45349 AND 45390 FOR CY2020

CPT Code	Long Descriptor	Proposed CY 2020 OPPS SI	Proposed CY 2020 OPPS APC	Final CY 2020 OPPS SI	Final CY 2020 OPPS APC
45349	Sigmoidoscopy, flexible; with endoscopic mucosal resection	T	5312	J1	5313
45390	Colonoscopy, flexible; with endoscopic mucosal resection	T	5312	J1	5313

8. Coronary Computed Tomographic Angiography (CCTA) (APC 5571)

For CY 2020, we proposed to continue to assign CPT codes 75572, 75573, and 75574 to APC 5571 (Level 1 Imaging with Contrast) with a proposed payment rate of $179.91. The long descriptors and proposed status indicator (SI) and APC assignments for the codes can be found in Table 23 below.

Comment: Many commenters expressed concern with the decreased reimbursement for the codes and stated that the proposed payment rate underestimates the resources necessary to provide the service. They noted this is the third consecutive year of decreased reimbursement for cardiac CT. Some commenters added that the exams described by CPT codes 75572, 75573, and 75574 require more resources than the contrast-enhanced studies in APC 5571 because they require more time, are performed by highly trained technologists, involve higher risk patients, require administration of vasoactive medications, and require close supervision of patients during and after the procedure. A commenter urged CMS to reassign the codes to a higher paying APC that is more resource intensive and includes procedures that share similar clinical characteristics, such as APC 5572 (Level 2 Imaging with Contrast), which had a proposed payment rate of $373.45, or APC 5573 (Level 3 Imaging with Contrast), which had a proposed payment rate of $682.96. Other commenters specifically requested a reassignment to APC 5573 based on clinical and resource homogeneity to these services that are assigned to the APC: Stress cardiac magnetic resonance imaging (CPT code 75563), stress echocardiography (HCPCS codes C8928, C8930), and nuclear SPECT MPI (CPT codes 78451, 78452). One commenter recommended the reassignment of CPT code 75574 to APC 5191 (Level 1 Endovascular Procedures) with a proposed payment rate of $2,899.34 and believed the service is very similar to a cardiac catheterization procedure that is described by CPT code 93455 (Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) including intraprocedural injection(s) for bypass graft angiography). This same commenter suggested that the less-intensive CPT codes 75572 and 75573 be reassigned to APC 5572.

Response: CPT codes 75572, 75573, and 75574 were effective January 1, 2010, and prior to that they were described by Category III CPT codes from January 1, 2006 through December 31, 2009; therefore, we have many years of claims data associated with these services. For this final rule with comment period, based on claims submitted between January 1, 2018 through December 30, 2018, that were processed on or before June 30, 2019, our analysis of the latest claims data for this final rule supports maintaining CPT codes 75572, 75573, and 75574 in APC 5571. Specifically, our claims data show a geometric mean cost of approximately $159 for CPT code 75572 based on 12,299 single claims (out of 23,902 total claims), $185 for CPT code 75573 based on 323 single claims (out of 466 total claims), and $196 for CPT code 75574 based on 25,434 single claims (out of 40,219 total claims). Because the geometric mean costs for the CCTA codes range are between $159 and $196, we believe it would be inappropriate to reassign the codes to these suggested APCs because their geometric mean costs are significantly higher:

- APC 5572 (with geometric mean cost of about $359)
- APC 5573 (with a geometric mean cost of approximately $660)
- APC 5191 (with a geometric mean cost of about $2,788)

In our analysis to determine the cause of the decreased payment rates for the last several years, we also reviewed our claims data to determine whether changes in payment for certain computed tomography (CT) services impacted the OPPS payment rates. Specifically, section 218(a)(1) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) amended section 1834 of the Act by establishing a new subsection 1834(p). Effective for services furnished on or after January 1, 2016, section 1834(p) of the Act reduces payment for the technical component (TC) of applicable CT services paid under the MPFS and applicable CT services paid under the OPPS, with a 5-percent reduction required in 2016 and a 15-percent reduction required in 2017 and subsequent years. The applicable CT services are identified by HCPCS codes 70450 through 70498; 71250 through 71275; 72125 through 72133; 72191 through 72194; 73200 through 73206; 73700 through 73706; 74150 through 74178; 74261 through 74263; and 75571 through 75574 (and any succeeding codes) for services furnished using equipment that does not meet each of the attributes of the National Electrical Manufacturers Association (NEMA) Standard XR–29–2013, entitled ''Standard Attributes on CT Equipment Related to Dose Optimization and Management.''

In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70470), we established a new ''CT'' modifier to be used on claims that include CT services furnished using equipment that does not meet each of the attributes of NEMA Standard XR–29–2013. Hospitals are required to report the ''CT'' modifier on claims for CT scans described by any of the HCPCS codes we identified (and any

successor codes) that are furnished on non-NEMA Standard XR–29–2013-compliant CT scanners. The use of this modifier results in the applicable payment reduction for the CT service, as specified under section 1834(p) of the Act.

Based on our analysis, we observed declining use of the CT modifier in both billing volume and the number of providers using the modifier over the past several years. Further, we note that the payment reduction required by section 1834(p), as amended by section 218(a)(1) of PAMA, does not directly affect the geometric mean costs under the OPPS, because we do not use payment rates to establish CCRs, rather we use the charges submitted by hospitals on claims and costs estimated through applying the cost report CCRs for modeling purposes. The application of the payment reductions associated with the CT modifier only occurs after the prospective OPPS payments are already calculated.

Comment: Some commenters recommended the establishment of a new cost center specific to CCTA. They noted that hospitals currently do not submit any cost center data for cardiac CT services.

Response: We thank the commenters for their suggestion. CMS is currently reviewing non-standard cost centers used frequently in the Medicare cost report in order to establish additional standardized reporting. We will consider the establishment of a new cost center specific to cardiac CT services in our review.

In summary, after consideration of the public comments and after our analysis of the latest claims data, we are finalizing our proposal, without modification, to assign CPT codes 75572, 75573, and 75574 to APC 5571 for CY 2020. Table 23 lists the final SI and APC assignments for the three codes. The final CY 2020 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).

As we do every year, we will reevaluate the APC assignment for CPT codes 75572, 75573, and 75574 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.

TABLE 23.—FINAL APC AND SI ASSIGNMENTS FOR CPT CODES 75572, 75573, and 75574 FOR CY2020

CPT Code	Long Descriptor	Proposed CY 2020 OPPS SI	Proposed CY 2020 OPPS APC	Final CY 2020 OPPS SI	Final CY 2020 OPPS APC
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)	S	5571	S	5571
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)	S	5571	S	5571
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)	S	5571	S	5571

9. Deep Brain Stimulation (DBS) Programming (APC 5742)

In CY 2018, the DBS programming codes were described by CPT code 95978 (first 60 minutes), which was assigned to APC 5742, with a payment of $115.18, and CPT code 95979 (each additional 30 minutes), which was assigned to SI ''N'' to indicate that the code is packaged since it is an add-on code. For CY 2019, the CPT Editorial Panel deleted CPT code 95978 and replaced it with CPT code 95983 (first 15 minutes) effective January 1, 2019. Similarly, CPT code 95979 was deleted and replaced with CPT code 95984 (each additional 15 minutes) effective January 1, 2019. As a result of this coding change, we assigned the 15-minute CPT code 95983 to APC 5741 (Level 1 Electronic Analysis of Devices) with a payment rate of $37.16, and assigned CPT code 95984 to ''N'' to indicate that the code is packaged because it describes an add-on service, which is similar to the SI for its predecessor code (CPT code 95979). Table 24 below list the long descriptors and proposed SI and APC assignments for CPT codes 95983 and 95984.

At the August 21, 2019 HOP Panel Meeting, a presenter requested that the 15-minute CPT code 95983 be reassigned to APC 5742. The presenter added that the cost of providing the service from 2018 to 2019 has not changed but the reimbursement has reduced the hospital payment by about $100. The presenter requested an APC modification for CPT code 95983 from APC 5741 to APC 5742 so that hospitals receive adequate payment for providing the service. Based on the information presented at the meeting, the HOP Panel recommended a reassignment to APC 5742 for CPT code 95983. Specifically, the Panel recommended that ''CMS move HCPCS code 95983, Electronic analysis of implanted neurostimulator pulse generator/transmitter (*e.g.,* contact group[s], interleaving, amplitude, pulse width, frequency [hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, first 15 minutes face-to-face time with physician or other qualified health care professional, to APC code 5472, Level II Electronic Analysis of Devices, if the final data that are available in time for consideration of the Final Rule are consistent with preliminary data.''

For CY 2020, we proposed to continue to assign CPT code 95983 to APC 5741 (Level 1 Electronic Analysis of Devices) with a proposed payment rate of $36.81. In addition, we proposed to continue to assign CPT code 95984 to status indicator (SI) ''N'' to indicate that the code is an add-on that is packaged and payment for it is included in the primary service. In this case, the payment for the add-on code is included in CPT code 95983.

Comment: Several commenters requested the reassignment of CPT code 95983 to APC 5742. One commenter stated that the assignment of the primary CPT code 95983 to the lower level APC 5741 is not appropriate because the overall time and resources expended by a hospital when furnishing this service in the HOPD setting remains the same, even if the units are billed differently. This same commenter indicated that, based on the coding descriptor for the replacement codes with the primary service described as the first 15-minutes and the secondary service as each additional 15-minutes, hospitals will continue to receive a single line-item payment for the service, with the payment for the add-on CPT code packaged into it, regardless of the number of units billed. Another commenter stated that reassigning the code from APC 5741 to APC 5742 will have no effect on the geometric mean cost of either APC. Another commenter requested the reassignment based on the geometric mean cost of approximately $109 for the predecessor code (CPT code 95978) and the Panel's recommendation at the August 19, 2019 HOP Panel Meeting.

Response: As noted above, the predecessor CPT code 95978 described a 60-minute service, while the replacement code—CPT code 95983—describes a 15-minute service. Based on the new time specified in the descriptor for CPT code 95983, we believed that assigning the replacement code to APC 5741 was appropriate. However, at the August 21, 2019 HOP Panel meeting, the presenter indicated that the service of providing DBS programming during 2018 and 2019 are the same, but because of the coding change that packages any service after each additional 15 minutes, the maximum payment that a hospital would receive for the service is a single unit of the code. The presenter recommended a change in the APC assignment to APC 5742 so that hospitals receive adequate payment for the service based on the coding structure of the replacement codes.

As recommended by the HOP Panel, we reviewed the claims data associated with the predecessor code (CPT code 95978). Based on the latest hospital outpatient claims data used for this final rule with comment period, our analysis reveals a geometric mean cost of approximately $109 for the code, which is consistent with the geometric mean cost of about $111 for APC 5742 compared to APC 5741 whose geometric mean cost is about $35. Based on the information presented at the HOP Panel Meeting, the Panel's recommendation, as well as the final rule claims data, we agree with the commenters that APC 5741 may not adequately reflect the resources to provide the service described by CPT code 95983 and are, therefore, modifying the assignment for CPT code 95983 to APC 5742.

In summary, after consideration of the public comments and the presentation at the August 21 HOP Panel Meeting, we are finalizing our proposal, with modification, and revising the APC assignment for CPT code 95983 to APC 5742 for CY 2020. Table 24 list the final SI and APC assignments for CPT code 95983 and 95984. The final CY 2020 payment rate for CPT code 95983 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 95983 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.

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TABLE 24.— FINAL APC AND SI ASSIGNMENTS FOR CPT CODES 95983 AND 95984 FOR CY 2020

CY 2020 HCPCS Code	Long Descriptor	Proposed OPPS SI	Proposed OPPS APC	Final OPPS SI	Final OPPS APC
95983	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, first 15 minutes face-to-face time	S	5741	S	5742

CY 2020 HCPCS Code	Long Descriptor	Proposed OPPS SI	Proposed OPPS APC	Final OPPS SI	Final OPPS APC
	with physician or other qualified health care professional				
95984	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, each additional 15 minutes face-to-face time with physician or other qualified health care professional (list separately in addition to code for primary procedure)	N	N/A	N	N/A

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10. Extracorporeal Shock Wave Lithotripsy (ESWL) (APC 5374)

For the CY 2019 OPPS/ASC final rule, we reviewed all of the procedures assigned to the Urology Procedures APCs, specifically, APCs 5371 through 5377, and made some modifications to more appropriately reflect the resource costs and clinical characteristics of the services within each APC grouping. Specifically, we revised the APC assignment of the procedures assigned to the family of Urology APCs to more appropriately reflect a prospective payment system that is based on payment groupings and not code-specific payment rates, while maintaining clinical and resource homogeneity. As we stated in the CY 2019 OPPS/ASC final rule (83 FR 58900), this modification was based on public comments we received in response to the CY 2019 OPPS/ASC proposed rule on the proposed APC assignments for certain urology procedures.

We received many comments on the APC reassignment for the extracorporeal shock wave lithotripsy (ESWL) procedure, which is described by CPT code 50590 (Lithotripsy, extracorporeal shock wave), in the CY 2019 OPPS/ASC final rule with comment period. The commenters indicated there was no discussion in the preamble on the reassignment of the code from APC 5375 (Level 5 Urology and Related Services) to APC 5374 (Level 4 Urology and Related Services), and they disagreed with the revision and believed that APC 5375 was the more appropriate assignment for the code. We remind the commenters that, as we have stated in every OPPS/ASC proposed and final rules, 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. Based on updated claims data for the final rule for CY 2019, we found that the geometric mean cost of approximately $3,265 for CPT code 50590 did not support its continued assignment to APC 5375, which had a geometric mean cost of about $4,055. We believed that we would have significantly overpaid for the procedure had we maintained the assignment to APC 5375. Consequently, we revised the APC assignment for CPT code 50590 to APC 5374, which had a geometric mean cost of approximately $2,952 for CY 2019.

We note that the SI and APC assignment for CPT code 50590 were subject to comment in the CY 2019 OPPS/ASC proposed rule but not in the CY 2019 OPPS/ASC final rule with comment period. Nevertheless, we received comments on this specific issue in response to the CY 2019 OPPS/ASC final rule with comment period. Because CPT code 50590 was not assigned to comment indicator ''NI'' in the final rule because it was not a new code for CY 2019, and therefore, the comments received related to this code

were out-of-scope. Nonetheless, we discuss above to provide some clarity to this issue.

For CY 2020, as listed in Addendum B to the proposed rule, we proposed to maintain the APC assignment for CPT code 50590 to APC 5374 with a proposed payment rate of $3,059.21.

Comment: Some commenters requested that we restore the code to APC 5375 where it had been placed for several years prior to CY 2019. The commenters indicated that CPT code 50590 is similar to two ureteroscopy with lithotripsy (URSL) procedures that are assigned to APC 5375, specifically:

- CPT code 52353 (Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy (ureteral catheterization is included)); and
- CPT code 52356 (Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy including insertion of indwelling ureteral stent (*e.g.,* gibbons or double-j type)).

In addition, some commenters suggested that placing the three procedures in two separate APCs may create an unintended consequence of unplanned admissions to the hospital. Specifically, the commenters indicated that if the proposed assignment for CPT code 50590 is finalized in APC 5374, while CPT codes 52353 and 52356 are finalized in APC 5375, hospitals might discontinue ESWL services (described by CPT code 50590) which would make it less accessible to Medicare beneficiaries and, ultimately, encourage hospitals to perform more URSL procedures, which, according to the commenter, have higher complication rates compared to ESWL. These commenters asserted that 90 percent of Medicare patients require an indwelling ureteral stent after a URSL procedure (described by CPT codes 52353 and 52356), and that the stents lead to infection, visits to the ER, and unplanned admissions. Hence, the commenters requested an APC reassignment to APC 5375 for CPT code 50590 to eliminate any unintended consequences.

Further, the commenters noted that because of the capital equipment expense associated with purchasing ($500,000) and maintaining ($65,000 per year) a lithotripter, hospitals rarely own their own lithotripter and generally contract under arrangement with suppliers to provide the service. Alternatively, the commenter asserted that all URSL equipment is owned by the hospitals furnishing the service and that the hospitals are therefore able to train clinicians on the equipment.

Response: As discussed above, we revised the APC assignment for CPT code 50590 based on our analysis of the latest claims data for the CY 2019 final rule. For this final rule with comment period, which is based on claims submitted between January 1, 2018 through December 30, 2018, that were processed on or before June 30, 2019, our findings do not support a reassignment to APC 5375. Instead, our analysis supports retaining CPT code 50590 in APC 5374. Specifically, our data reveal a geometric mean cost of approximately $3,247 for CPT code 50590 based on 40,009 single claims (out of 40,351 total claims). The geometric mean cost for APC 5374 is about $2,953 while APC 5375 shows a geometric mean cost of approximately $4,140. Based on the geometric mean cost, we believe that maintaining CPT code in APC 5374 is more appropriate than reassigning it to APC 5375, based on the geometric mean cost of CPT code 50590 relative to that of APCs 5374 and 5375.

In addition, we note that the resource costs associated with the URSL procedures (CPT codes 52353 and 52356) are higher than that of ESWL (CPT code 50590). Specifically, the geometric mean cost for CPT code 50590 for CY 2020 is $3,247 while the geometric mean cost for CPT codes 52353 and 52356 are $3,740 and $4,361, respectively. The geometric mean cost of $3,247 for CPT code 50590 falls within APC 5374, whose geometric mean costs for the significant procedures range between $2,495 (for CPT code 52351) and $3,472 (for CPT code 52318), while the geometric mean costs of $3,740 and $4,361 for CPT codes 52353 and 52356, respectively, fall within APC 5375, whose geometric mean costs for the significant procedures range between $3,575 (for CPT code 52630) and $5,655 (for CPT code 55875). Although all three procedures are used for the treatment of kidney stones, we disagree that CPT codes 50590, 52353, and 52356 are similar based on resource and clinical homogeneity. With regards to unintended consequences as a result of the assignment to APC 5374 for CPT code 50590, we rely on physicians to provide appropriate care based on the needs of their patients. While the payment rate for services assigned to APC 5375 is higher than that of APC 5374, it is based on the relative resources associated with furnishing the services assigned to that APC. While each of the lithotripsy procedures have some clinical similarity, as the commenters pointed out, they have clinical differences. While the commenters expected that these clinical differences may result in similar or higher resources for CPT code 50590 compared to CPT codes 52353 and 52356, that has not been borne out in the Medicare data we have available. As we do every year, we will review the claims data associated with CPT code 50590 to determine its appropriate APC placement for the next rulemaking update.

Comment: Some commenters suggested, based on their analysis of the OPPS Limited Data Sets (LDS) for the CY 2018 OPPS/ASC final rule, the CY 2019 OPPS/ASC final rule, and the CY 2020 OPPS/ASC proposed rule, that the methodology formula that was supplied with the LDS materials was flawed and, therefore, they were unable to validate CMS's calculation or the accuracy of the cost data upon which CMS relied to determine the payment rates. In addition, these same commenters suggested that because hospitals do not generally own lithotripters, they would not be surprised if the cost reports for CPT code 50590 were inaccurate.

Response: It is generally not our policy to judge the accuracy of hospital coding and charging for purposes of ratesetting. We rely on hospitals 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. We do not specify the methodologies that hospitals use to set charges for this or any other service. In addition, we state in Chapter 4 of the Medicare Claims Processing Manual that ''it is extremely important that hospitals report all HCPCS codes consistent with their descriptors; CPT and/or CMS instructions and correct coding principles, and all charges for all services they furnish, whether payment for the services is made separately paid or is packaged'' to enable CMS to establish future ratesetting for OPPS services.

Comment: To pay appropriately for CPT code 50590, some commenters suggested adding the cost of a ureteral stent in calculating the geometric mean cost since some procedures (less than 20 percent) require the device. They noted that the URSL procedure described by CPT code 52356 requires the insertion of a ureteral stent that costs $609.16.

Response: Geometric mean costs are determined based on the costs reported on the claim. If the CPT code descriptor describes the insertion of a device, we would expect the device cost to be packaged into the cost of the procedure

since the charges associated with the device and its insertion should be reflected in claims submitted to Medicare. We note that the CPT code descriptor for the URSL procedures (CPT codes 52353 and 52356) describes the use of stents, consequently, the geometric mean cost for the procedures include the packaged cost of the devices. However, the CPT code descriptor for the ESWL procedure does not describe the use of a ureteral stent, so we disagree that device costs for a ureteral stent should be included in CPT code 50590. If a ureteral stent were involved in an ESWL procedure, HOPDs should report the CPT code that appropriately describes the procedure performed. Moreover, as we have stated previously, we rely on HOPDs to accurately report all HCPCS codes consistent with their descriptors; CPT and/or CMS instructions and correct coding principles, and all charges for all services they furnish, whether payment for the services is made separately paid or is packaged.

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 continue to assign CPT code 50590 to APC 5374 for CY 2020. The final CY 2020 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 always, we will reevaluate the APC assignment for CPT code 50590 for the next rulemaking cycle. As stated above, we review, on an annual basis, the APC assignments for all services and items paid under the OPPS.

11. Extravascular Implantable Cardioverter Defibrillator (EV ICD)

As displayed in Table 25 and in Addendum B to the CY 2020 OPPS/ASC proposed rule, we proposed to assign CPT codes 0571T through 0580T to status indicator (SI) ''E1'' to indicate that the codes are 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. The codes were listed as 06X0T through and 07X4T (the 5-digit CMS placeholder codes) in Addendum B with the short descriptors, and again in Addendum O with the long descriptors. We also assigned the codes to comment indicator ''NP'' in Addendum B to indicate that they are new for CY 2020 and that public comments would be accepted on their proposed status indicator assignments. We note that these codes will be effective January 1, 2020.

Comment: A commenter reported that the device associated with these codes is in a clinical trial and also received FDA approval with an IDE Category B designation. The commenter added that they are currently in the process of applying for Medicare national coverage for the clinical trial as a Category B IDE study. The commenter requested that we crosswalk the new codes to the SIs and APC assignments of comparable procedures involving ICD placement so that appropriate hospital outpatient payment may be made in the event the Category B IDE study is approved for Medicare coverage. The commenter listed the comparable codes with the SI and APCs assignments.

Response: Based on our review, the clinical trial has not met Medicare's standards for coverage, nor does it appear on the CMS Approved IDE List, which can be found at this CMS website: *https://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies.html.* Because the clinical trial associated with these codes has not been approved for Medicare coverage, we believe we should continue to assign CPT codes 0571T through 0580T to status indicator ''E1'' for CY 2020. If Medicare approves the clinical trial as a Category B IDE study, we will reassess the SI and APC assignments for the codes.

Therefore, after consideration of the public comment received, we are finalizing our proposal without modification for CPT codes 0571T through 0580T. The final status indicator assignments for both codes are listed in Table 25 below. We refer readers to Addendum D1 of this final rule with comment period for the complete list of the OPPS payment status indicators and their definitions for CY 2020. Addendum D1 is available via the internet on the CMS website.

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TABLE GX25.—FINAL STATUS INDICATOR (SI) ASSIGNMENT FOR THE EXTRAVASCULAR IMPLANTABLE CARDIOVERTER DEFIBRILLATOR CPT CODES FOR CY 2020

CY 2020 HCPCS Code	CY 2020 OPPS/ASC Proposed Rule Placeholder Code	Long Descriptor	Proposed OPPS SI	Final OPPS SI
0571T	06X0T	Insertion or replacement of implantable cardioverter defibrillator system, with substernal electrode(s), including all imaging guidance and electrophysiological evaluation (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters), when performed	E1	E1
0572T	06X1T	Insertion of substernal implantable defibrillator electrode	E1	E1
0573T	06X2T	Removal of substernal implantable defibrillator electrode	E1	E1
0574T	06X3T	Repositioning of previously implanted substernal implantable defibrillator-pacing electrode	E1	E1
0575T	06X4T	Programming device evaluation (in person) of implantable cardioverter defibrillator system with substernal electrode, with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional	E1	E1
0576T	06X5T	Interrogation device evaluation (in person) of implantable cardioverter defibrillator system with substernal	E1	E1

		electrode, with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter		
0577T	06X6T	Electrophysiological evaluation of implantable cardioverter defibrillator system with substernal electrode (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters)	E1	E1
0578T	07X2T	Interrogation device evaluation(s) (remote), up to 90 days, substernal lead implantable cardioverter defibrillator system with interim analysis, review(s) and report(s) by a physician or other qualified health care professional	E1	E1
0579T	07X3T	Interrogation device evaluation(s) (remote), up to 90 days, substernal lead implantable cardioverter defibrillator system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results	E1	E1
0580T	07X4T	Removal of substernal implantable defibrillator pulse generator only	E1	E1

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12. Genicular and Sacroiliac Joint Nerve Injections/Procedures (APCs 5442 and 5431)

For CY 2020, the CPT Editorial Panel established four new codes to describe genicular and sacroiliac joint nerve injections and procedures. As listed in Table 26 below with the long descriptors, and also in Addendum B to the CY 2020 OPPS/ASC proposed rule, we proposed to assign CPT codes 64451 and 64454 to APC 5442 (Level 2 Nerve Injections) with a proposed payment rate of $627.39. We note both CPT codes 64451 and 64454 describe therapeutic and/or diagnostic injection procedures. We also proposed to assign CPT code 64624 to APC 5443 (Level 3 Nerve Injections) with a proposed payment rate of $808.58. In addition, we proposed to assign CPT code 64625 to APC 5431 (Level 1 Nerve Procedures) with a proposed payment rate of $1,747.26. CPT codes 64451, 64454, 64624, and 64625 were listed as 6XX00, 64XX0, 64XX1, and 6XX01 (the 5-digit CMS placeholder codes), respectively, in Addendum B with the short descriptors, and again in Addendum O with the long descriptors. We also assigned these codes to comment indicator ''NP'' in Addendum B to indicate that the codes are new for CY 2020 and that public comments would be accepted on their proposed status indicator assignments. We note that these codes will be effective January 1, 2020.

Comment: Several commenters disagreed with the APC assignment for CPT code 64624 (shown in the proposed rule with placeholder code 64XX1) and suggested that it would be more appropriate, based on clinical homogeneity, to assign it to APC 5431, where similar radiofrequency ablation procedures are assigned, specifically, CPT codes 64633 (Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or ct); cervical or thoracic, single facet joint), 64635 (Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance

(fluoroscopy or ct); lumbar or sacral, single facet joint), and new CPT code 64625. Several commenters reported that, unlike CPT code 64640 (Destruction by neurolytic agent; other peripheral nerve or branch) which only involves one nerve, the procedure described by CPT code 64624 requires more expensive medical equipment and supplies and involves the destruction of three nerves. Most commenters agreed that the procedure is not a nerve injection. One commenter explained that the procedure describes the destruction of three nerve branches at three locations in the knee, and the destruction is typically done via radiofrequency ablation similar to those procedures described by CPT codes 64633 and 64635 that are assigned to APC 5431. Another commenter suggested that reassigning CPT code 64624 to APC 5431, similar to new CPT code 64625, would provide adequate reimbursement for the procedure and enable providers to offer patients with chronic knee pain an effective alternative to systemic opioids.

Response: After consideration of the public comments, and based on the characteristics of the procedure, as well as input from our medical advisors, we believe that it would be appropriate to revise the APC assignment for CPT code 64624 from APC 5443 to APC 5431. We agree with the commenters that this new procedure shares similar characteristics with CPT codes 64633 and 64635 that are assigned to APC 5431.

Comment: A commenter agreed with the proposed APC assignments for CPT codes 64451, 64454, and 64425.

Response: We thank the commenter for their feedback and are finalizing the APC assignments for these codes.

In summary, after consideration of the public comments, we are finalizing our proposal with modification. Specifically, we are finalizing the APC assignments for CPT codes 64451, 64454, and 64425 to the APCs listed in Table 26. In addition, we are revising the APC assignment for CPT code 64624 from APC 5443 to APC 5431. Table 26 lists the long descriptors for the codes, as well as the final APC and SI assignments for all four codes. The final CY 2020 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.

As always, we will reevaluate the APC assignment for these codes once we have claims data. We review, on an annual basis, the APC assignments for all services and items paid under the OPPS based on the latest claims data that we have available.

TABLE 26.— FINAL APC AND SI ASSIGNMENTS FOR CPT CODES 64451, 64454, 64624, AND 64625 FOR CY 2020

CY 2020 CPT Code	Placeholder Code	Long Descriptor	**Proposed OPPS SI**	**Proposed OPPS APC**	**Final OPPS SI**	**Final OPPS APC**
64451	6XX00	Injection(s), anesthetic agent(s) and/or steroid; nerves innervating the sacroiliac joint, with image guidance (ie, fluoroscopy or computed tomography)	T	5442	T	5442
64454	64XX0	Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed	T	5442	T	5442
64624	64XX1	Destruction by neurolytic agent, genicular nerve branches, including imaging guidance, when performed	T	5443	J1	5431
64625	6XX01	Radiofrequency ablation, nerves innervating the sacroiliac joint, with image guidance (ie, fluoroscopy or computed tomography)	J1	5431	J1	5431

13. FemBloc® and FemChec®

For CY 2020, the CPT Editorial Panel established two new codes to describe FemBloc (0567T) and FemChec (0568T). As listed in Table 27 with the long descriptors, and in Addendum B to the CY 2020 OPPS/ASC proposed rule, we proposed to assign CPT code 0567T to APC 5414 (Level 4 Gynecologic Procedures) and status indicator (SI) ''J1'' (Hospital Part B services paid through a comprehensive APC) with a payment rate of $2,564.60. In addition, we proposed to assign new CPT code 0568T to APC 5732 (Level 2 Minor Procedures) and status indicator ''Q1'' (conditionally packaged) with a payment rate of $34.33. The codes were listed as 05X1T and 05X2T (the 5-digit CMS placeholder codes), respectively, in Addendum B with the short descriptors, and again in Addendum O with the long descriptors. We also assigned these codes to comment indicator ''NP'' in Addendum B to indicate that the codes are new for CY 2020 and that public comments would be accepted on their proposed status indicator assignments. We note these codes will be effective January 1, 2020.

Comment: A medical technology company disagreed with the proposed APC assignment for CPT code 0567T and suggested that we reassign the procedure code from APC 5414 to APC 5415 (Level 5 Gynecologic Procedures) with a proposed payment rate of $4,426.45. The commenter noted that the single-use, disposable device associated with the code contains two deployable and retractable balloon catheters and a biopolymer that retails for $1,800. The commenter believes the procedure more appropriately fits in APC 5415 based on its similarity to CPT code 58565 (Hysteroscopy, surgical; with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants). Specifically, the commenter explained that in both procedures, specifically CPT codes

58565 and 0567T, the entrances to the fallopian tubes are accessed and a device is placed that causes permanent occlusion of the tubes.

Response: Based on our findings associated with FemBloc, the procedure is currently in clinical trial with an estimated study completion date of September 2022 (*ClinicalTrials.gov* Identifier: NCT03067272). Because the FemBloc device has not received FDA approval, we believe that we should reassign CPT code 0567T to status indicator ''E1'' to indicate that the code is not payable by Medicare when submitted on outpatient claims (any outpatient bill type). If FDA approves the device, we will reassess the code and determine the appropriate SI and APC assignments.

Comment: The same commenter for FemBloc also requested an APC modification for the code associated with FemChec. Specifically, the commenter requested the reassignment for CPT code 0568T from APC 5732 (Level 2 Minor Procedures) to APC 5523 (Level 3 Imaging without Contrast) with a proposed payment rate of $231.28. The commenter reported that the code is more clinically related to one of the procedures assigned to APC 5523, specifically, CPT code 76831 (Saline infusion sonohysterography (sis), including color flow doppler, when performed). Both CPT codes 0568T and 76831 require ultrasound and saline to study the uterus.

Response: Our findings reveal that the clinical study associated with FemBloc also applies to FemChec. Based on the clinical study (*ClinicalTrials.gov* Identifier: NCT03067272), FemChec will be used with FemBloc. Because the FemBloc device has not received FDA approval, we believe that we should reassign CPT code 0568T to status indicator ''E1'' to indicate that the code is not payable by Medicare when submitted on outpatient claims (any outpatient bill type). If FDA approves FemBloc, we will reassess the code associated with FemChec and determine the appropriate OPPS SI and APC assignments for CPT code 0568T.

Therefore, after consideration of the public comments, we are revising the SI and APC assignments for CPT codes 0567T and 0568T. The final status indicator assignments for both codes are listed in Table 27 below. We refer readers to Addendum D1 of this final rule with comment period for the complete list of the OPPS payment status indicators and their definitions for CY 2020. Addendum D1 is available via the internet on the CMS website.

TABLE 27.— FINAL SI AND APC ASSIGNMENTS FOR CPT CODES 0567T AND 0568T FOR CY 2020

CY 2020 CPT Code	CY 2020 OPPS/ASC Proposed Rule Placeholder Code	Long Descriptor	Proposed OPPS SI	Proposed OPPS APC	Final OPPS SI	Final OPPS APC
0567T	05X1T	Permanent fallopian tube occlusion with degradable temporary biopolymer implant, transcervical approach, including transvaginal ultrasound	J1	5414	E1	N/A
0568T	05X2T	Occlusion of fallopian tube(s) by device (eg, band, clip, falope ring) vaginal or suprapubic approach	Q1	5732	E1	N/A

14. 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 procedures. Specifically, CMS established HCPCS code C9754 for the Ellipsys® System and C9755 for the WavelinQ™ System effective January 1, 2019. Both HCPCS codes were assigned to APC 5193 (Level 3 Endovascular Procedures) with a payment rate of 9,669.04 for CY 2019.

At the August 21, 2019 HOP Panel Meeting, a presenter requested that we reassign the WavelinQ procedure to APC 5194. The presenter indicated that the APC payment associated with HCPCS code C9755 is inadequate to cover the cost of the procedure. According to the presenter, the conservative cost estimate for the procedure is over $12,500. The presenter also reported that their HOPD facility performed 35 procedures between October 2018 to July 31, 2019, and the average payment for each procedure ranged between $3,410 and $11,247. Based on the information presented at the meeting, the HOP Panel made no recommendation to CMS on the APC assignment for the WavelinQ procedure.

For CY 2020, as listed in Table 28 below with the long descriptors and proposed SI and APC assignments, we

proposed to continue to assign HCPCS codes C9754 and C9755 to APC 5193 with a proposed payment rate of $10,013.25. We received several comments related to this proposal. Below are the comments and our responses.

Comment: Several physicians stated that the current payment rate does not cover the cost of the procedure and requested the reassignment of both HCPCS code C9754 and C9755 to APC 5194 (Level 4 Endovascular Procedures) with a proposed payment rate of $16,049.73. A physician association explained that the new technologies describe innovative new procedures that increase options for dialysis patients to have a successful arteriovenous fistula for dialysis access, and that the procedures are important in making fistula access possible for patients that either refuse open surgery or where skilled surgeons are not readily available. However, they expressed concern that the procedures may not be available to patients if the costs are higher than the payment, and requested that CMS carefully examine the most recent claims to determine if they should be reclassified to APC 5194.

Response: After consideration of the public comments received and based on input from our medical advisors, as well as our review of the latest claims data available to us, we believe that we should revise the APC assignment for HCPCS code C9754 and C9755 to APC 5194 for CY 2020.

Comment: A medical device company requested an APC reassignment based on data presented at the August 21, 2019 HOP Panel Meeting. They indicated that their analysis of the 1Q2019 Medicare Limited Data Set (LDS) Standard Analytic File (SAF) for HCPCS code C9755 showed a geometric mean cost of $12,960, and suggested reassigning the code to APC 5194. They also reminded CMS that the reassignment to APC 5194 is in line with various HHS initiatives, such as the HHS Initiative on ''Advancing American Kidney Health'' since the payment rate for the procedure would improve access to the service.

Response: As stated above, we believe that it is appropriate to revise the APC assignment for HCPCS code C9754 and C9755. Consequently, we are reassigning both codes from APC 5193 to APC 5194 for CY 2020.

Comment: A commenter representing 13 different health systems suggested that CMS adopt the recommendation they made at the August 21, 2019 HOP Panel Meeting. Specifically, they recommended the reassignment of HCPCS code C9755 from APC 5193 to APC 5194.

Response: Although there was a presentation at the August 21, 2019 meeting on HCPCS code C9755 with a request to reassign the code to APC 5194, the HOP Panel made no recommendation to CMS. We note that the August 21, 2019, HOP Panel recommendations are posted online and can be found on this CMS website: *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html.* Although the HOP Panel made no recommendation to CMS, based on the proposed rule comments, and our review of the issue, we are revising the APC assignment for HCPCS code C9755 to APC 5194 for CY 2020.

Comment: A commenter stated that it was brought to their attention that other comments related to the WavelinQ procedure may urge CMS to revisit the APC assignment for HCPCS code C9755. The commenter indicated that if CMS were to revisit the issue and reassign the APC assignment for the WavelinQ procedure, it should also apply the same consideration to the Ellipsys procedure (C9754).

Response: We agree that the services described by HCPCS codes C9754 and C9755 are clinically similar and, therefore, we are revising the APC assignment for both HCPCS code C9754 and C9755 to APC 5194 for CY 2020. However, we note that claims data upon which we could determine the geometric mean costs associated with each procedure are not yet available for ratesetting but once such data become available, we will be able to determine whether the two services are similar in terms of resources. In addition, as has been our practice since the implementation of the OPPS in 2000, we review, on an annual basis, the APC assignments for the procedures and services paid under the OPPS. Consequently, we will review the cost data associated with HCPCS codes C9754 and C9755 for the next annual rulemaking.

In summary, after consideration of the public comments, we are finalizing our proposal with modification. Specifically, we are reassigning HCPCS codes C9754 and C9755 from APC 5193 to APC 5194 for CY 2020. The final CY 2020 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 28 lists the final SI and APC assignments for HCPCS codes C9754 and C9755.

TABLE 28.— FINAL SI AND APC ASSIGNMENTS FOR HCPCS CODES C9754 AND C9755 FOR CY 2020

HCPCS CODE	Long Descriptor	Proposed OPPS SI	Proposed OPPS APC	Final OPPS SI	Final OPPS APC
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 (that is, transluminal balloon angioplasty, coil embolization, when performed)	J1	5193	J1	5194
C9755	Creation of arteriovenous fistula, percutaneous using magnetic-guided arterial and venous catheters and radiofrequency energy, including flow-directing procedures (that is, 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	J1	5193	J1	5194

15. Hemodialysis Duplex Studies (APCs 5522 and 5523)

For CY 2020, the CPT Editorial Panel established two new codes to describe hemodialysis duplex studies, specifically, CPT codes 93985 and 93986. The new codes replace HCPCS code G0365 (Vessel mapping of vessels for hemodialysis access (services for preoperative vessel mapping prior to creation of hemodialysis access using an autogenous hemodialysis conduit, including arterial inflow and venous outflow)). HCPCS code G0365 was assigned to status indicator ''D'' in the proposed rule to indicate that the code would be deleted on December 31, 2019.

As listed in Table 29 below with the long descriptors, and also in Addendum B to the CY 2020 OPPS/ASC proposed rule, we proposed to assign CPT code 93985 and 93986 to APC 5522 (Level 2 Imaging without Contrast) with a proposed payment rate of $111.04. The codes were listed as 93X00 and 93X01 (the 5-digit CMS placeholder codes), respectively, in Addendum B with the short descriptors, and again in Addendum O with the long descriptors. We also assigned these codes to comment indicator ''NP'' in Addendum B to indicate that the codes are new for CY 2020 and that public comments would be accepted on their proposed status indicator assignments. We note that these codes will be effective January 1, 2020.

Comment: Several commenters recommended a reassignment of CPT code 93985 from APC 5522 to APC 5523 (Level 3 Imaging without Contrast) with a proposed payment rate of $231.28. They indicated that the code represents a bilateral study, and as such, should be assigned to APC 5523 with similar bilateral/complete duplex studies.

Response: Based on the public comments that we received, our review of the procedure associated with CPT code 93985 and advice from our medical advisors, we agree that the code fits more appropriately in APC 5523 based on its clinical homogeneity and resource use to the other procedures in the APC. Therefore, we are reassigning the code to APC 5523. We received no comments on CPT code 93986. Consequently, we are finalizing its APC assignment to APC 5522.

In summary, after consideration of the public comments, we are finalizing our proposal with modification. Specifically, we are finalizing our proposal for CPT code 93986 to APC 5522, and reassigning CPT code 93985 to APC 5523. Table 29 below lists the long descriptors for the three codes and the final SI and APC assignments for CY 2020. The final CY 2020 OPPS payment rates 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 2020. Both Addendum B and Addendum D1 are available via the internet on the CMS website.

TABLE 29.— FINAL SI AND APC ASSIGNMENTS FOR HCPCS CODE G0365, CPT CODE 93985, AND CPT CODE 93986 FOR CY 2020

CY 2020 HCPCS Code	CY 2020 OPPS/ASC Proposed Rule Placeholder Code	Long Descriptor	Proposed OPPS SI	Proposed OPPS APC	Final OPPS SI	Final OPPS APC
G0365	N/A	Vessel mapping of vessels for hemodialysis access (services for preoperative vessel mapping prior to creation of hemodialysis access using an autogenous hemodialysis conduit, including arterial inflow and venous outflow)	D	N/A	D	N/A
93985	93X00	Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete bilateral study	S	5522	S	5523
93986	93X01	Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete unilateral study	S	5522	S	5522

16. Intraocular Procedures (APCs 5491 Through 5494)

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 is discussed in more detail in section III.C.2. of the proposed rule.

In the CY 2019 OPPS/ASC proposed rule, we proposed to reassign CPT code 0308T from APC 5495 to APC 5493 (Level 3 Intraocular Procedures), based on the data for two claims available for ratesetting for the proposed rule, and to delete APC 5495 (83 FR 37096 through 37097). However in the CY 2019 OPPS/ASC final rule with comment period, based on updated data on a single claim available for ratesetting for the final rule, we modified our proposal and reassigned 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 higher than the OPPS payments for the same service because of the intersection of the 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 reviewing the claims data available for the proposed rule for CY 2020 OPPS ratesetting, we found several claims reporting the procedure described by CPT code 0308T. Based on the claims data, the procedure would have a geometric mean cost of $28,122.51 and a median cost of $19,864.38. These cost statistics are significantly higher than the geometric mean cost of the other procedure assigned to APC 5494, that is, the procedure described by CPT code 67027 (Implant eye drug system), which has a geometric mean cost of $12,296.27. In addition, if we continued to assign the procedure described by CPT code 0308T to APC 5494 (the Level 4 Intraocular Procedures APC), the discrepancy between payments within the OPPS and the ASC payment system would also continue to exist. As a result, we proposed to reestablish APC 5495 (Level 5 Intraocular Procedures) because we believe that the procedure described by CPT code 0308T would be most appropriately placed in this APC based on its estimated cost. Assignment of the procedure to the Level 5 Intraocular Procedures APC is 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, based on data available for the proposed rule, the proposed payment rate for this procedure when performed in an ASC, as discussed in more detail in section XIII.D.1.c. of the proposed rule, would be no higher than the OPPS payment rate for this procedure when performed in the hospital outpatient setting. We will continue to monitor the volume of claims data available for the procedure for ratesetting purposes.

Therefore, for CY 2020, we proposed to reestablish APC 5495 (Level 5 Intraocular Procedures) and reassign the procedure described by CPT code 0308T from APC 5494 to APC 5495. Under this proposal, the proposed CY 2020 OPPS payment rate for the service would be established based on its 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.

Comment: Several commenters expressed support for our proposal to assign the HCPCS code 0308T to APC 5495 (Level 5 Intracoular Procedures).

Response: We thank commenters for their support.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to assign HCPCS code CPT 0308T to APC 5495 for the CY 2020 OPPS.

17. Long-Term Electroencephalogram (EEG) Monitoring Services (APCs 5722, 5723, and 5724)

For CY 2020, the CPT Editorial Panel deleted four existing long-term EEG monitoring services, specifically, CPT codes 95950, 95951, 95953, and 95956, and replaced them with 23 new CPT codes that consisted of 10 professional component (PC) codes and 13 technical component (TC) codes. As listed in Table 30 below with the long descriptors, and also in Addendum B to the CY 2020 OPPS/ASC proposed rule, we proposed to assign the 13 technical component codes, specifically, CPT codes 95700 through 95716, to either APC 5722 (Level 2 Diagnostic Tests and Related Services) with a proposed payment rate of $256.60 or APC 5723 (Level 3 Diagnostic Tests and Related Services) with a proposed payment rate of $486.65. The codes were listed as 95X01 through and 95X13 (the 5-digit CMS placeholder codes) in Addendum B with the short descriptors, and again in Addendum O with the long descriptors. In addition, we proposed to assign the 10 professional component codes, specifically, CPT codes 95717 through 95726, to status indicator ''M'' to indicate that the services are not paid under the OPPS since they describe physician services. These codes were listed were listed as 95X14 through 95X23 (the 5-digit CMS placeholder codes) in Addendum B with the short descriptors, and again in Addendum O with the long descriptors. We assigned these 23 codes to comment indicator ''NP'' in Addendum B to indicate that the codes are new for CY 2020 and that public comments would be accepted on their proposed status indicator assignments. We note these codes will be effective January 1, 2020.

Comment: Many commenters expressed concern with the proposed APC assignments for CPT codes 95712, 95713, 95715, and 95716 and stated that the proposed payment rates for the codes do not provide adequate reimbursement. A commenter indicated that the proposed APC assignments for the EEG monitoring services for 2 to 12 hours does not appropriately reflect the resources and time required to monitor complex epilepsy patients. Several other commenters recommended the reassignment of CPT codes 95712 and 95713 to APC 5723 and stated they should be paid approximately half the rate of the 24-hour video EEG services. These same commenters stated that the reassignment of CPT codes 95715 and 95716 to APC 5724, which had a proposed payment rate of $920.66, would be appropriate since patients being tested may be classified as observation stays and will not be admitted to the hospital. The commenters added that these codes were previously described by predecessor CPT code 95951 (24 hour VEEG), which was assigned to APC 5724 (Level 4 Diagnostic Tests and Related Services).

Response: With respect to CPT codes 95712 (2–12 hours VEEG with intermittent monitoring) and 95713 (2–12 hours VEEG with continuous monitoring), we believe that the resources and time associated with intermittent monitoring (CPT code 95712) are less than that of continuous monitoring (CPT code 95713), and therefore, believe they should be assigned to different APCs. Based on input from our medical advisors that intermittent monitoring involves checking the patient every two hours rather than the full 12 hours, we believe it would be appropriate to modify the APC assignment for the continuous monitoring code (CPT code 95713) to APC 5723. Applying this same concept to the 12–24 VEEG technical component codes, we believe that the resources associated with the intermittent monitoring code (CPT code 95715) are not the same as the continuous monitoring code (CPT code 95716). Therefore, we are reassigning the APC assignment for CPT code 95716 to APC 5724. Although the commenters indicated that the predecessor code for 95715 and 95716 was CPT code 95951, we are uncertain whether the predecessor code describes continuous or intermittent monitoring since the code descriptor lacks this specificity.

Comment: Some commenters urged CMS not to finalize the policies proposed in the PFS or OPPS proposed rules. They indicated that the policies would dramatically reduce reimbursement for EEG and VEEG services and instead, suggested that we

appropriately value these services so that people with epilepsy have access and can be diagnosed and treated in a timely manner.

Response: We believe these commenters did not fully understand our APC proposal. Because the existing EEG and VEEG CPT codes will be deleted on December 31, 2019, if we do not finalize our proposal for the 13 technical codes that will be effective January 1, 2020, there would be no codes to report the services associated with EEG and VEEG.

In summary, after consideration of the public comments, we are finalizing our proposal, with modification. Specifically, we are finalizing our proposal to assign CPT codes 95700 through 95712, 95714, and 95715 to the APCs listed in Table 30 below. In addition, we are modifying our proposal for CPT codes 95713 and 95716, and revising their APC assignments to APC 5723 and APC 5724, respectively. Further, we are finalizing our proposal to assign CPT codes 95717 through 95726 to status indicator ''M''. These codes, along with the deleted codes, are listed in Table 30. The final CY 2020 payment rate for these codes can be found in Addendum B to this final rule with comment period (which is available via the internet on the CMS website).

As always, we will reevaluate the APC assignment for these codes once we have claims data. We review, on an annual basis, the APC assignments for all services and items paid under the OPPS based on the latest claims data that we have available.

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TABLE 30.— FINAL APC AND SI ASSIGNMENTS FOR CPT CODE 95700 THROUGH 95726 FOR CY 2020

CY 2020 HCPCS Code	Proposed Rule Placeholder Code	Short Descriptor	Proposed OPPS SI	Proposed OPPS APC	Final OPPS SI	Final OPPS APC
95950	N/A	Ambulatory eeg monitoring	D	N/A	D	N/A
95951	N/A	Eeg monitoring/videorecord	D	N/A	D	N/A
95953	N/A	Eeg monitoring/computer	D	N/A	D	N/A
95956	N/A	Eeg monitor technol attended	D	N/A	D	N/A
95700	95X01	Eeg cont rec w/vid eeg tech	S	5722	S	5722
95705	95X02	Eeg w/o vid 2-12 hr unmntr	S	5722	S	5722
95706	95X03	Eeg wo vid 2-12hr intmt mntr	S	5722	S	5722
95707	95X04	Eeg w/o vid 2-12hr cont mntr	S	5722	S	5722
95708	95X05	Eeg wo vid ea 12-26hr unmntr	S	5723	S	5723
95709	95X06	Eeg w/o vid ea 12-26hr intmt	S	5723	S	5723
95710	95X07	Eeg w/o vid ea 12-26hr cont	S	5723	S	5723
95711	95X08	Veeg 2-12 hr unmonitored	S	5722	S	5722

CY 2020 HCPCS Code	Proposed Rule Placeholder Code	Short Descriptor	Proposed OPPS SI	Proposed OPPS APC	Final OPPS SI	Final OPPS APC
95712	95X09	Veeg 2-12 hr intmt mntr	S	5722	S	5722
95713	95X10	Veeg 2-12 hr cont mntr	S	5722	S	5723
95714	95X11	Veeg ea 12-26 hr unmntr	S	5723	S	5723
95715	95X12	Veeg ea 12-26hr intmt mntr	S	5723	S	5723
95716	95X13	Veeg ea 12-26hr cont mntr	S	5723	S	5724
95717	95X14	Eeg phys/qhp 2-12 hr w/o vid	M	N/A	M	N/A
95718	95X15	Eeg phys/qhp 2-12 hr w/veeg	M	N/A	M	N/A
95719	95X16	Eeg phys/qhp ea incr w/o vid	M	N/A	M	N/A
95720	95X17	Eeg phy/qhp ea incr w/veeg	M	N/A	M	N/A
95721	95X18	Eeg phy/qhp>36<60 hr w/o vid	M	N/A	M	N/A
95722	95X19	Eeg phy/qhp>36<60 hr w/veeg	M	N/A	M	N/A
95723	95X20	Eeg phy/qhp>60<84 hr w/o vid	M	N/A	M	N/A
95724	95X21	Eeg phy/qhp>60<84 hr w/veeg	M	N/A	M	N/A
95725	95X22	Eeg phy/qhp>84 hr w/o vid	M	N/A	M	N/A
95726	95X23	Eeg phy/qhp>84 hr w/veeg	M	N/A	M	N/A

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18. Musculoskeletal Procedures (APCs 5111 Through 5116)

Prior to the 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 provided 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 2020 OPPS/ASC proposed rule, we continue 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 2020 OPPS update.

We note that this is the first year for which claims data are available for the total knee arthroplasty procedure described by CPT code 27447, which was removed from the inpatient only list in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59382 through 59385). Based on approximately 60,000 hospital outpatient claims reporting the procedure that were available for ratesetting in the proposed rule, the geometric mean cost was approximately $12,472.05, which is similar to the geometric mean cost for APC 5115 (Level 5 Musculoskeletal Procedures) of $11,879.66, and within a range of the lowest geometric mean cost of the significant procedure costs of $9,969.37 and the highest geometric mean cost of the significant procedure costs of $12,894.18. Therefore, we believed that the assignment of the procedure described by CPT code 27447 in the Level 5 Musculoskeletal Procedures APC series remains appropriate and, therefore, we proposed to continue to assign CPT code 27447 to APC 5115 (Level 5 Musculoskeletal Procedures) for CY 2020.

We also proposed to remove the procedure described by CPT code 27130 (Total hip arthroplasty) from the CY 2020 OPPS inpatient only list. Based on the estimated costs derived from in the available claims data, as well as the 50th percentile IPPS payment for TKA/THA procedures without major complications or comorbidities (MS–DRG 470) of approximately $11,900 for FY 2020 when the procedure is performed on an inpatient basis, we believed that it was appropriate to assign the procedure described by CPT code 27130 to the Level 5 Musculoskeletal Procedures APC series, which had a geometric mean cost of $11,879.66. Therefore, for CY 2020, we also proposed to assign the procedure described by CPT code 27130 to APC 5115. We noted that we will monitor the claims data reflecting these procedures as they become available. For a more detailed discussion of the procedures that were proposed to be removed from the inpatient only (IPO) list for CY 2020 under the OPPS, we refer readers to section IX. of the proposed rule.

Table 31 displays the CY 2020 Musculoskeletal Procedures APC series' structure and APC geometric mean costs.

TABLE 31.--FINAL MUSCULOSKELETAL PROCEDURES APCs FOR CY 2020

APC	Group Title	HCPCS Codes Assigned to APC in the CY 2020 OPPS/ASC Final Rule	CY 2019 Final APC Geometric Mean Cost	CY 2020 Final APC Geometric Mean Cost
5111	Level 1 Musculoskeletal Procedures	102	$227.04	$210.99
5112	Level 2 Musculoskeletal Procedures	133	$1,324.69	$1,326.17
5113	Level 3 Musculoskeletal Procedures	401	$2,646.02	$2,678.42
5114	Level 4 Musculoskeletal Procedures	328	$5,748.86	$5,852.95
5115	Level 5 Musculoskeletal Procedures	69	$10,806.47	$11,644.09
5116	Level 6 Musculoskeletal Procedures	14	$15,535.58	$15,602.23

Comment: Several commenters requested that CMS reconsider the proposal to assign 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, and instead allow the code to remain in APC 5116, where it has been historically placed. They believed that the proposal to move the APC was based on inaccurate data, due to one hospital incorrectly reporting its costs and charges. They noted that the influence of that inaccurate data would be short term and that the claims would eventually support the higher placement, as the reporting issues were corrected. We also note that the HOP Panel made a recommendation that CMS examine the claims data for CPT code 22869 and determine an appropriate APC placement.

Response: While we recognize the concerns that the commenters have described, it is generally not our policy to judge the accuracy of hospital coding and charging for purposes of ratesetting. We rely on hospitals 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. However, we do not specify the methodologies that hospitals use to set charges for this or any other service. In addition, we state in Chapter 4 of the Medicare Claims Processing Manual that ''it is extremely important that hospitals report all HCPCS codes consistent with their descriptors; CPT and/or CMS instructions and correct coding principles, and all charges for all services they furnish, whether payment for the services is made separately paid

or is packaged'' to enable CMS to establish future ratesetting for OPPS services.

After consideration of the public comments we received, we are finalizing the proposed six level Musculoskeletal Procedures APC structure. We also are finalizing the proposed assignment of the procedure described by CPT codes 22869 to APC 5115. As discussed in section IX. of this final rule, we are also finalizing the proposal to remove the procedure described by CPT code 27130 from the inpatient only list and to assign it to APC 5115 for the CY 2020 OPPS.

19. Nuclear Medicine Services

a. Cardiac Positron Emission Tomography (PET) Studies (APCs 5593 and 5594)

For CY 2020, we proposed to continue to assign CPT code 78459 (Myocardial imaging, positron emission tomography (pet), metabolic evaluation) to APC 5593 (Level 3 Nuclear Medicine and Related Services) with a proposed payment rate of $1,293.33. Similarly, we proposed to maintain the APC assignments for CPT codes 78491 (Myocardial imaging, positron emission tomography (pet), perfusion; single study at rest or stress) and 78492 (Myocardial imaging, positron emission tomography (pet), perfusion; multiple studies at rest and/or stress) to APC 5594 (Level 4 Nuclear Medicine and Related Services) with a proposed payment rate of $1,466.16.

Comment: Commenters agreed with the APC assignments for CPT codes 78459, 78491, and 78492 and stated they are placed appropriately in APCs 5593 and 5594. Some commenters added that the cost associated with CPT code 78492, which describes a wall motion and ejection fraction, supports its maintenance in APC 5594.

Response: We thank the commenters for their feedback and will finalize the APC assignments for CPT code 78459 to APC 5593, and for CPT codes 78491 and 78492 to APC 5594.

b. Cardiac Positron Emission Tomography (PET)/Computed Tomography (CT) Studies (APCs 1522, 1523, and 5594)

For CY 2020, the CPT Editorial established six new codes to describe the services associated with cardiac PET/CT studies, specifically, CPT codes 78429, 78430, 78431, 78432, 78433, and 78434. These codes were listed in Addendum B to the CY 2020 OPPS/ASC proposed rule as 78X29, 78X31, 78X32, 78X33, 78X34, and 78X35 (the 5-digit CMS placeholder codes), respectively, in Addendum B with the short descriptors, and again in Addendum O with the long descriptors. We also assigned these codes to comment indicator ''NP'' in Addendum B to indicate that the codes are new for CY 2020 and that public comments would be accepted on their proposed status indicator assignments. We note that these codes will be effective January 1, 2020. Table 32 below list the placeholder codes, long descriptors, and proposed SI and APC assignments.

Comment: Several commenters opposed the APC assignment for CPT code 78429 (placeholder code 78X29) and recommended its reassignment from APC 5593 to APC 5594. They stated that APC 5593 does not recognize the additional cost associated with the CT scan that is included in the service, and requested revising the code to APC 5594.

Response: Based on the commenters' feedback and our review of the components of this new service, we agree with the commenters that APC 5594 is the more appropriate assignment for CPT code 78429. Therefore, we will reassign CPT code 78429 from APC 5593 to APC 5594.

Comment: Several commenters agreed with the APC placement for CPT code 78430 (placeholder code 78X31) in APC 5594. They stated that APC 5594 allows adequate payment for the CT scanner that that is a component of this service.

Response: We thank the commenters for their feedback and are finalizing the APC assignment for CPT code 78430 to APC 5594.

Comment: Several commenters reported that certain societies submitted a new technology application to CMS for CPT codes 78431 (placeholder code 78X32), 78432 (placeholder code 78X33), and 78433 (placeholder code 78X34) that details the costs associated with providing the services. For CPT code 78431, these same commenters disagreed with the proposed APC placement and recommended its revision from APC 5594 (Level 4 Nuclear Medicine and Related Services) with a proposed payment rate of $1,466.16 to APC 1522 (New Technology—Level 23 ($2501–$3000)) with a proposed payment rate of $2,750.50. They reported that, based on the resource cost of the service described by CPT code 78431, APC 1522 provides adequate reimbursement for the service. Similarly, for CPT codes 78432 and 78433, the commenters indicated that APC 5594 would not adequately reimburse the resource costs associated with providing these services, and recommended their reassignment to APC 1523 (New Technology—Level 23 ($2501–$3000)) with a proposed payment rate of $ 2,750.50

Response: Based on our assessment of the information provided in the new technology application and the public comments received, we are revising the APC assignments for these codes. Specifically, we are revising the APC assignment for CPT code 78431 from APC 5594 to APC 1522, and reassigning CPT codes 78432 and 78433 from APC 5594 to APC 1523.

In summary, after consideration of the public comments for the new cardiac PET/CT codes, and based on our evaluation of the new technology application that provided the estimated costs for the services and described the components and characteristics of the new codes, we are finalizing our proposal, with modification, to assign CPT codes 78429, 78431, 78432, and 78433 to the final APCs listed in Table 32 below. In addition, we are finalizing our proposal, without modification, for CPT codes 78430 and 78434. In Table 32 below we list the long descriptors and final SI and APC assignments for the codes. The final CY 2020 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).

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TABLE 32.—FINAL APC AND SI ASSIGNMENTS FOR CPT CODES 78429, 78430, 78431, 78432, 78433, AND 78434 FOR CY 2020

CPT Code	CY 2020 OPPS/ASC Proposed Rule Placeholder Code	Long Descriptor	Proposed OPPS SI	Proposed OPPS APC	Final OPPS SI	Final OPPS APC
78429	78X29	Myocardial imaging, positron emission tomography (PET), metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), single study; with concurrently acquired computed tomography transmission scan	S	5593	S	5594
78430	78X31	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); single study, at rest or stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan	S	5594	S	5594
78431	78X32	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular	S	5594	S	1522

CPT Code	CY 2020 OPPS/ASC Proposed Rule Placeholder Code	Long Descriptor	Proposed OPPS SI	Proposed OPPS APC	Final OPPS SI	Final OPPS APC
		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				
78432	78X33	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	5594	S	1523
78433	78X34	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	5594	S	1523
78434	78X35	Absolute quantitation of myocardial blood flow	N		N	

CPT Code	CY 2020 OPPS/ASC Proposed Rule Placeholder Code	Long Descriptor	Proposed OPPS SI	Proposed OPPS APC	Final OPPS SI	Final OPPS APC
		(AQMBF), positron emission tomography (PET), rest and pharmacologic stress (List separately in addition to code for primary procedure)				

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c. Single-Photon Emission Computed Tomography (SPECT) Studies (APCs 5591, 5593, and 5594).

For CY 2020, we proposed to continue to assign CPT codes 78800 and 78801 to APC 5591 with a proposed payment rate of $372.69, CPT codes 78802 and 78804 to APC 5593 with a proposed payment rate of $1,293.33), and CPT code 78803 to APC 5592 with a proposed payment rate of $482.38.

We also proposed to assign new CPT codes 78830 and 78831 to APC 5593, and 78832 to APC 5594 with a proposed payment rate of $1,466.16. In addition, we proposed to assign new CPT code 78835 to status indicator ''N'' because it is an add-on code that is packaged and payment for it is included in the primary service. Table 33 below list the long descriptors and their proposed SI and APC assignments for these codes.

Comment: Some commenters agreed with the proposed APC assignments for CPT codes 78800, 78801, and 78802.

Response: We thank the commenters for their feedback and are finalizing the APC assignments for these codes.

Comment: Several commenters disagreed with the assignment for CPT codes 78803 and requested a modification from APC 5592 to APC 5593 because this one code will replace seven SPECT codes that will be deleted on December 31, 2019. Specifically, they reported that the seven CPT codes listed in Figure 34 will be deleted. Several commenters indicated that APC 5592 would not account for the deleted SPECT codes and recommended using a weighted average to determine an appropriate geometric mean cost for 78803. Based on their calculation, the geometric mean cost for the code should be $784.18, which is higher than the approximately $462 geometric mean cost for APC 5592, and is more consistent with the geometric mean cost for APC 5593.

Response: Based on our analysis of the latest claims data for this final rule with comment period, and as listed in the Figure 33 below, the range of geometric mean cost for CPT code 78803 and the seven deleted codes is between $433 and $1,417. 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 reassign CPT code 78803 from APC 5592 to APC 5593.

Table 33.--GEOMETRIC MEAN COSTS FOR CPT CODE 78803 AND THE DELETED CPT CODES

CPT Code	Status	Long Descriptor	SI	APC	Geo Mean Cost
78205	DELETED	Liver imaging; with vascular flow	S	5593	$456.39
78206	DELETED	Liver imaging (spect);	S	5592	$525.39
78320	DELETED	Bone and/or joint imaging; tomographic (spect)	S	5592	$432.59
78607	DELETED	Brain imaging, tomographic (spect)	S	5593	$1,416.71
78647	DELETED	Cerebrospinal fluid flow, imaging (not including introduction of material); tomographic (spect)	S	5593	$440.05
78710	DELETED	Kidney imaging morphology; tomographic (spect)	S	5592	$493.61
78803	ACTIVE	Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); tomographic (spect)	S	5592	$598.29
78807	DELETED	Radiopharmaceutical localization of inflammatory process; tomographic (spect)	S	5592	$660.98

Comment: Some commenters disagreed with the assignment of CPT code 78804 to APC 5593, and stated that the APC assignment does not adequately capture the cost of multiple SPECTs provided. The commenters indicated that it would not make sense to continue to assign single and full sets of studies to the same APC and urged CMS to reassign the code to APC 5594.

Response: For CY 2020, based on claims submitted between January 1, 2018 and December 30, 2018 that were processed on or before June 30, 2019, our analysis of the latest claims data for this final rule supports maintaining CPT code 78804 in APC 5593. Specifically, our claims data show a geometric mean cost of approximately $1,298 for CPT code 78804 based on 1,656 single claims (out of 2,961 total claims), which is more appropriate in APC 5593 whose geometric mean cost is about $1,245 compared to the geometric mean cost of approximately $1,412 for APC 5594.

Comment: Some commenters agreed with the APC assignment for new CPT codes 78830 and 78832 to APC 5593 and APC 5594, respectively.

Response: We appreciate the commenters' feedback and are finalizing the APC assignment for CPT code 78830 to APC 5593 and for CPT code 78832 to APC 5594.

Comment: Several commenters opposed the APC assignment for CPT code 78831 to APC 5593. They indicated that the proposed APC assignment for CPT code 78831 does not adequately capture the resources required to perform the procedure and should be reassigned to APC 5594.

Response: We believe that new CPT code 78831 shares similar characteristics and resources to existing CPT code 78804. Consequently, we assigned the new code to APC 5593, which is the same APC assignment for CPT 78804. We note that once we have claims data for CPT code 78831, we will assess and determine whether a reassignment is necessary. As always, we review the APC assignments for all services under the OPPS based on the latest claims data.

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 codes 78800, 78801, 78802, 78804, 78830, 78831, 78832, and 78835. However, we are finalizing our proposal, with modification, for CPT code 78803 and reassigning the code from APC 5592 to APC 5593 for CY 2020. Table 34 below list the long descriptors for these codes and their final SI and APC assignments. The final CY 2020 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).

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TABLE 34.—FINAL SI AND APC ASSIGNMENTS FOR CPT CODES 78800, 78801, 78802, 78803, 78804, 78830, 78831, 78832, AND 78835 FOR CY2020

CPT Code	CY 2020 OPPS/ASC Proposed Rule Placeholder Code	Long Descriptor	Proposed OPPS SI	Proposed OPPS APC	Final OPPS SI	Final OPPS APC
78800	N/A	Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); limited area	S	5591	S	5591
78801	N/A	Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); multiple areas	S	5591	S	5591

CPT Code	CY 2020 OPPS/ASC Proposed Rule Placeholder Code	Long Descriptor	Proposed OPPS SI	Proposed OPPS APC	Final OPPS SI	Final OPPS APC
78802	N/A	Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); whole body, single day imaging	S	5593	S	5593
78803	N/A	Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); tomographic (spect)	S	5592	S	5593
78804	N/A	Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); whole body, requiring 2 or more days imaging	S	5593	S	5593
78830	788X0	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT) with concurrently acquired computed tomography (CT) transmission scan for anatomical review, localization and determination/detection of pathology, single area (eg, head, neck, chest, pelvis), single day of imaging	S	5593	S	5593

CPT Code	CY 2020 OPPS/ASC Proposed Rule Placeholder Code	Long Descriptor	Proposed OPPS SI	Proposed OPPS APC	Final OPPS SI	Final OPPS APC
78831	788X1	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT), minimum 2 areas (eg, pelvis and knees, abdomen and pelvis), single day of imaging, or single area of imaging over 2 or more days	S	5593	S	5593
78832	788X2	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT) with concurrently acquired computed tomography (CT) transmission scan for anatomical review, localization and determination/detection of pathology, minimum 2 areas (eg, pelvis and knees, abdomen and pelvis), single day of imaging, or single area of imaging over 2 or more days imaging	S	5594	S	5594
78835	788X3	Radiopharmaceutical quantification measurement(s) single area	N		N	

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20. Radiofrequency Spectroscopy

As displayed in Table 8 and Addendum B to the CY 2020 OPPS/ASC proposed rule, we proposed to assign CPT code 0546T (Radiofrequency spectroscopy, real time, intraoperative margin assessment, at the time of partial

mastectomy, with report) to status indicator (SI) ''N'' to indicate that the code is packaged and payment for it is included in the primary surgical procedure. Specifically, payment for the codes assigned to status indicator ''N'' is made through the payment for the separately payable, independent services with which they are billed. No separate payment is made for services that we have assigned to status indicator ''N.'' We note that CPT code 0546T is associated with the MarginProbe procedure.

Comment: Several commenters requested separate payment for CPT code 0546T. One commenter stated that the code should be adequately valued and removed from packaging. Another commenter stated that packaging the code will limit the number of Medicare beneficiaries who will benefit from the procedure. Still another commenter suggested a modification in the status indicator from ''N'' to ''J1'' (comprehensive APC) but did not suggest any specific APC to which they believed the code should be assigned. Another commenter stated that assigning separate payment for CPT code 0546T is in line with CMS' objectives of reducing the number of repeat surgical excisions.

Response: As noted in the code descriptor, CPT code 0546T describes an intraoperative procedure that is performed at the time of partial mastectomy. As specified in 42 CFR 419.2(b)(14), intraoperative items and services are packaged under the OPPS. By definition, a service that is performed intraoperatively is provided during and, therefore on the same date of service, as another procedure that is separately payable under the OPPS. Because intraoperative services support the performance of an independent procedure and they are provided in the same operative session as the independent procedure, we have packaged the payment for the radiofrequency spectroscopy into the OPPS payment for the primary surgical procedure with which it is reported. In this case, the payment for CPT code 0546T is included in the breast mastectomy codes that are reported with the procedure.

We note that since 2008, intraoperative services have been packaged under the OPPS, however, packaging has always been a primary component of the OPPS since its implementation in 2000. As we state in section II.A.3. (Changes to Packaged Items and Services) of this final rule, because packaging encourages efficiency and is an essential component of a prospective payment system, packaging payment 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.

Comment: A medical device company stated that although CPT code 0546T is a procedure provided during an operative session, it is a distinct procedure with a beginning, middle, and end. The commenter reported that the cost of the procedure is not included in the primary surgical procedure. The same commenter pointed out that based on the language below from the CY 2008 OPPS/ASC final rule (72 FR 66621), it believed CMS has the discretion not to package an intraoperative service:

> ''To the extent that a service for which New Technology APC status is being requested is ancillary and supportive of another service, for example, a new intraoperative service or a new guidance service, we might not consider it to be a complete service because its value is as part of an independent service. However, if the entire, complete service, including the guidance component of the service, for example, is 'truly new,' as we explained that term at length . . . we would consider the new complete procedure for New Technology APC assignment.''

The commenter also indicated that, at its September 2018 meeting, the CPT Editorial Panel determined that radiofrequency spectroscopy is a stand-alone service and, therefore, issued a unique code, specifically, CPT code 0546T to be effective July 1, 2019. The commenter noted that until July 1, 2019 there was no code available to adequately describe the service, therefore, the procedure could not be represented in the claims data upon which CMS has established the CY 2020 OPPS payment determinations. Consequently, the commenter requested that CMS assign CPT code 0546T to New Technology APC 1518 (New Technology—Level 18 ($1601-$1700)) with a proposed payment rate of $1,650.50, and indicated that the payment would reflect the cost of the sterile, disposable, radiofrequency spectroscopy probe and supplies. The commenter asserted that assigning separate payment for the procedure would alleviate the barrier to access to care for the service.

Response: We note that the establishment of a new CPT code does not indicate that a code is always a stand-alone procedure or service. The current CPT code set lists hundreds of add-on codes that do not describe stand-alone services. For the list of add-on codes, refer to Appendix D (Summary of CPT Add-on Codes) of the latest CPT code book. We note that the CPT Editorial Panel does not establish new CPT codes because the service or procedure is considered stand-alone, rather they establish new codes for procedures and services that are not described by any existing code and have met their application criteria.

As stated above, CPT code 0546T is associated with the MarginProbe procedure. CPT code 0546T describes an intraoperative procedure that is performed at the time of partial mastectomy. As specified in 42 CFR 419.2(b)(14), intraoperative items and services are packaged under the OPPS.

We also disagree with the commenter's statement that CMS has the discretion not to package an intraoperative procedure. As noted above, 42 CFR 419.2(b)(14) states that intraoperative items and services are packaged under the OPPS. We do not agree that MarginProbe, for which CPT code 0546T was established, is a new, standalone procedure for which separate payment should be made. We note that the preamble language the commenter quoted only applies for services that are truly new and a complete service and, as mentioned in the quoted language, with respect to an ancillary service, which may include a new intraoperative service or a new guidance service, we might not consider it to be a complete service because its value is as part of an independent service. MarginProbe, received Premarket Approval (PMA) from the FDA on December 27, 2012, and has been on the market since February 2013, however, FDA approval alone does not compel a determination under Medicare that the technology represents a separate standalone service that would qualify for New Technology APC assignment.

Finally, because CPT code 0546T describes an intraoperative service that is performed during a mastectomy procedure, we are finalizing our proposal to assign the code to status indicator ''N''. Therefore, after consideration of the public comments received, we are finalizing our proposal without modification for CPT code 0546T. The final status indicator assignment for the code is listed in Addendum B to this final with comment period. We refer readers to Addendum D1 of this final rule with comment period for the complete list of the OPPS payment status indicators and their definitions for CY 2020. Both Addendum B and Addendum D1 are available via the internet on the CMS website.

21. Reflectance Confocal Microscopy (RCM)

For CY 2020, we proposed to continue to assign CPT code 96932 to status indicator ''Q1'' (conditionally packaged) and APC 5731 (Level 1 Minor Procedures) with a proposed payment rate of $23.57. We note that the CPT Editorial Panel established six (6) CPT codes to describe the services associated with RCM. These codes are shown in Table 35 with the long descriptors and proposed status indicator assignments.

Comment: A commenter stated that the low payment rate for this service under the OPPS is based on misreporting of charges by a hospital. The commenter explained that based on their review and analysis of the OPPS claims, only two hospitals in the country are performing this imaging test, and that the proposed payment rate is based primarily on one hospital's charges. The same commenter stated that the cost of performing the imaging service is about $128, which is more than the proposed payment rate of $23.57. To correct the low payment for the test, the commenter suggested that CMS use its equitable adjustment authority to set an appropriate payment for 96932 and also recommended that we do one of the following:

- Reassign the code to APC 5522 (Level 1 Imaging without Contrast) with a proposed payment rate of $111.04;
- Reassign the code to New Technology APC 1503 (New Technology—Level 3 ($101–$200) with a proposed payment rate of $150.50; or
- Assign an unconditionally packaged (''N'') or non-payable status indicator to the code, similar to the other RCM codes.

The commenter also expressed concern that the low payment rate under the OPPS significantly impacts the payment for the service under the PFS. The commenter added that RCM is primarily performed in the physician office setting, however, because of the low payment rate established under the OPPS, the payment for the service is inadequate. To correct the low payment rate, the commenter suggested that CMS revise the status indicator of CPT code 96932 to identify the service as packaged or non-payable, and, therefore, not have a published OPPS payment rate for the code. The commenter believed that packaging the code or assigning it as non-payable will correct the payment rate and provide adequate payment for the service.

Response: Section 5102(b) of the Deficit Reduction Act of 2005 (DRA) amended the PFS 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. CPT code 96932 is designated as a DRA imaging code whose payment under the PFS is capped at the OPPS rate even when performed in a physician office setting. Based on our review of the issue, we believe that we should revise the OPPS status indicator assignment for CPT code 96932 from ''Q1'' to ''N'', similar to the status indicator assignment for several other RCM codes. Since CPT code was low volume under the OPPS, it may be inappropriate to establish an OPPS payment rate by which the PFS rate would be capped. Accordingly, this change will allow there not to be an OPPS cap for the service.

In summary, after consideration of the public comment, we are finalizing our proposal with modification and revising the status indicator assignment for CPT code 96930 to ''N'' for CY 2020. Table 35 below lists the long descriptors and final status indicator assignments for the six (6) codes that describe the services associated with RCM. We refer readers to Addendum D1 of this final rule with comment period for the complete list of the OPPS payment status indicators and their definitions for CY 2020. Addendum D1 is available via the internet on the CMS website.

TABLE 35.—FINAL SI ASSIGNMENTS FOR THE REFLECTANCE CONFOCAL MICROSCOPY (RCM) CPT CODES FOR CY 2020

CY 2020 HCPCS Code	Long Descriptor	Proposed OPPS SI	Final OPPS SI
96931	Reflectance confocal microscopy (rcm) for cellular and sub-cellular imaging of skin; image acquisition and interpretation and report, first lesion	M	M
96932	Reflectance confocal microscopy (rcm) for cellular and sub-cellular imaging of skin; image acquisition only, first lesion	Q1	N
96933	Reflectance confocal microscopy (rcm) for cellular and sub-cellular imaging of skin; interpretation and report only, first lesion	B	B
96934	Reflectance confocal microscopy (rcm) for cellular and sub-cellular imaging of skin; image acquisition and interpretation and report, each additional lesion (list separately in addition to code for primary procedure)	N	N
96935	Reflectance confocal microscopy (rcm) for cellular and sub-cellular imaging of skin; image acquisition only, each additional lesion (list separately in addition to code for primary procedure)	N	N
96936	Reflectance confocal microscopy (rcm) for cellular and sub-cellular imaging of skin; interpretation and report only, each additional lesion (list separately in addition to code for primary procedure)	N	N

22. remedē® System—Transvenous Phrenic Nerve Stimulation Therapy (APCs 5461–5464, 5724, and 5742)

For the CY 2020 update, we proposed to modify the APC assignment for certain CPT codes associated with the Transvenous Phrenic Nerve Stimulation Therapy or remedē® System. Of the 13 codes, we received a comment on the APC assignment for three codes, specifically, CPT codes 0426T, 0427T, and 0431T. As shown in Table 36 below with the long descriptors, and also in Addendum B to the CY 2020 OPPS/ASC proposed rule, we proposed to reassign CPT codes 0426T and 0431T from APC 5463 (Level 3 Neurostimulator and Related Procedures) to APC 5464 (Level 4 Neurostimulator and Related Procedures) with a proposed payment rate of $29,025.99. In addition, we proposed to continue to assign CPT code 0427T to APC 5463 ((Level 3 Neurostimulator and Related Procedures) with a proposed payment rate of $19,370.82.

Comment: A device company suggested that we maintain the current assignment and not revise the APC assignment to APC 5464 for CPT code 0426T. The commenter stated that the resources required for the procedure are more closely aligned with the procedures in APC 5463.

Response: Based on our evaluation of the procedure associated with CPT code 0426T, we agree that the procedure described by the code appropriately fits in APC 5463 based on its clinical similarity to other procedures in the APC. CPT code 0426T describes the insertion or replacement of the stimulation lead associated with a neurostimulator system for the treatment of central sleep apnea, and APC 5463 includes other procedures that involve the insertion or replacement of a stimulation lead for a neurostimulator system. Therefore, we will maintain the APC assignment for CPT code 0426T to APC 5463 for CY 2020.

Comment: The same device company that commented on CPT code 0426T also commented on the APC assignment for CPT code 0427T. According to the commenter, the procedure describes the initial insertion of the implantable pulse generator when the full system cannot be implanted for a patient, and added that the procedure does not occur frequently.

The commenter also noted that the hospital resources associated with CPT code 0427T are very similar to CPT code 0431T, which is assigned to APC 5464, and recommended the assignment of both procedures to APC 5464.

Response: Based on our review of the two procedures, we agree that the resources associated with inserting or replacing a pulse generator for a neurostimulator system that is described by CPT code 0427T are very similar to removing and replacing a pulse generator for a neurostimulator system that is described by CPT code 0431T. Consequently, we are modifying our

proposal and reassigning CPT code 0427T to APC 5464.

Comment: The same device company that commented on CPT codes 0426T and 0427T also commented on CPT code 0431T. Specifically, the commenter concurred with the APC reassignment for the code to APC 5464.

Response: As indicated above, based on our review of the two procedures, we agree that the resources associated with inserting or replacing a pulse generator for a neurostimulator system that is described by CPT code 0427T are very similar to removing and replacing a pulse generator for a neurostimulator system that is described by CPT code 0431T. Therefore, we are finalizing our proposal for CPT code 0431T and assigning the code to APC 5464.

In summary, after consideration of the public comment, we are finalizing our proposal with modification. Specifically, we are finalizing our APC proposal for CPT code 0431T to APC 5464, however, we are maintaining the APC assignment for CPT code 0426T to APC 5463, and reassigning CPT code 0427T to APC 5464. We note that the final CY 2020 OPPS payment rates for all the codes associated with the Transvenous Phrenic Nerve Stimulation Therapy or remedē® System can be found in Addendum B of this final rule with comment period. Table 36 below lists the long descriptors for all 13 codes and the final APC and SI assignments for CY 2020. 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 2020. Both Addendum B and Addendum D1 are available via the internet on the CMS website.

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TABLE 36.—FINAL SI AND APC ASSIGNMENTS FOR THE TRANSVENOUS PHRENIC NERVE STIMULATION THERAPY CODES FOR CY 2020

CY 2020 HCPCS Code	Long Descriptor	Proposed OPPS SI	Proposed OPPS APC	Final OPPS SI	Final OPPS APC
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)	J1	5464	J1	5464
0425T	Insertion or replacement of neurostimulator system for treatment of central sleep apnea; sensing lead only	J1	5462	J1	5462
0426T	Insertion or replacement of neurostimulator system for treatment of central sleep apnea; stimulation lead only	J1	5464	J1	5463
0427T	Insertion or replacement of neurostimulator system for treatment of central sleep apnea; pulse generator only	J1	5463	J1	5464
0428T	Removal of neurostimulator system for treatment of central sleep apnea; pulse generator only	J1	5461	J1	5461
0429T	Removal of neurostimulator system for treatment of central sleep apnea; sensing lead only	J1	5461	J1	5461
0430T	Removal of neurostimulator system for treatment of central sleep apnea; stimulation lead only	J1	5461	J1	5461
0431T	Removal and replacement of neurostimulator system for treatment of central sleep apnea, pulse generator only	J1	5464	J1	5464

CY 2020 HCPCS Code	Long Descriptor	Proposed OPPS SI	Proposed OPPS APC	Final OPPS SI	Final OPPS APC
0432T	Repositioning of neurostimulator system for treatment of central sleep apnea; stimulation lead only	J1	5461	J1	5461
0433T	Repositioning of neurostimulator system for treatment of central sleep apnea; sensing lead only	J1	5461	J1	5461
0434T	Interrogation device evaluation implanted neurostimulator pulse generator system for central sleep apnea	S	5742	S	5742
0435T	Programming device evaluation of implanted neurostimulator pulse generator system for central sleep apnea; single session	S	5742	S	5742
0436T	Programming device evaluation of implanted neurostimulator pulse generator system for central sleep apnea; during sleep study	S	5724	S	5724

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23. Surgical Pathology Tissue Exam (APC 5673)

In CY 2019, CPT code 88307 (Level V—surgical pathology, gross and microscopic examination) was assigned to APC 5673 (Level 3 Pathology) with a payment rate of $274.22. For CY 2020, we proposed to reassign the code to APC 5672 (Level 2 Pathology) with a proposed payment rate of $148.62.

Comment: A commenter disagreed with the proposed reassignment and urged CMS to continue to assign CPT code 88307 to APC 5673. This same commenter reported that the service includes complex Level V surgical pathology specimens and the proposed change represents a 46 percent decrease in the payment amount. The commenter added that the proposed reassignment creates a resource cost rank order anomaly with other physician services and the technical costs will not be fully recovered from each unit of service. In addition, the commenter believed that the data do not identify actual costs for specific procedures, and stated that the cost associated with CPT code 88307 is greater than six times the cost of the services assigned to APC 5672 (Level 2 Pathology) based on physician fee schedule technical component cost differences. The commenter also believed that the data leading to the APC reassignment must be flawed and added that charge-based cost data were neither designed nor intended to be an accurate estimate of service/procedure level costs at the CPT code level. The commenter stated that the hospital charge-based cost data used for OPPS rate-setting allows CMS to estimate costs for purposes of grouping a number of services or procedures (multiple distinct codes) into appropriate clinically and economically homogeneous APCs.

Response: As stated in section III.B. (Final OPPS Changes—Variations Within APCs) of this final rule with comment period, payments for OPPS services and procedures are based on our analysis of the latest claims data. For the proposed rule, the OPPS proposed payment rates were based on claims data that were submitted between January 1, 2018 through December 31, 2018, that were processed on or before December 31, 2018. However, for the final rule, the OPPS final payment rates are based on claims that were submitted between January 1, 2018 through December 31, 2018, that were processed on or before June 30, 2019. Based on the latest hospital outpatient claims data used for this final rule with comment period, we agree with the commenter that the code should continue to be assigned to APC 5673 for CY 2020. Specifically, CPT code 88307 shows a geometric mean cost of approximately $219, which is more appropriate in APC 5673 whose geometric cost is approximately $277 compared to the geometric mean cost of about $140 for APC 5672. Consequently, we are revising our proposal and maintaining the APC assignment for CPT code 88307 to APC 5673 for CY 2020.

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 with modification. Specifically, we are revising the APC assignment for CPT code 88307 to APC 5673 for CY 2020. The final CY 2020 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 88307 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.

24. Urology Procedures

a. HIFU Procedure—High-Intensity Focused Ultrasound of the Prostate (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 made no change to the APC assignment and continued to assign 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.

For CY 2020, we proposed to continue to assign HCPCS code C9747 to APC 5375 with a proposed payment rate $4,286.06.

Comment: Several commenters disagreed with the APC assignment for HCPCS code C9747 and recommended a reclassification to APC 5376 because they believed 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 placed in APC 5376 (Level 6 Urology and Related Services), with a proposed payment rate of $8,193.30. The commenters believed that the geometric mean cost, and ultimately, the APC determination for the prostate HIFU procedure was based on inaccurate hospital costs. They believed that the average cost of the procedure should be approximately $6,250, and requested a reassignment to APC 5376 to enable Medicare beneficiaries to continue to receive the treatment. They stated based on their projections that maintaining the APC assignment to APC 5375 for the procedure will decrease the number of Medicare beneficiaries receiving the treatment by 75 percent if the CY 2020 payment rate is finalized.

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 2020, based on claims submitted between January 1, 2018 through December 30, 2018, that were processed on or before June 30, 2019, 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 $5,850 for HCPCS code C9747 based on 264 single claims (out of 268 total claims), which is comparable to the geometric mean cost of about $4,140 for APC 5375, rather than the geometric mean cost of approximately $7,894 for APC 5376.

Also, we do not agree that the resource costs associated with the prostate HIFU procedure are similar to those of cryoablation of the prostate. Our claims data for the CY 2020 update shows a geometric mean cost of about $8,152 based on 1,417 single claims (out of 1,429 total claims) for cryoablation of the prostate. The geometric mean cost for CPT code 55873 is reasonably consistent with APC 5376, whose geometric mean cost is approximately $7,894.

With respect to the issue of inaccurate hospital cost reporting for HCPCS code C9747, based on our analysis of the CY 2020 hospital outpatient claims data used for this final rule with comment period, we are unable to determine whether hospitals are misreporting the procedure. It is generally not our policy to judge the accuracy of hospital coding and charging for purposes of ratesetting. We rely on hospitals 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 do not specify the methodologies that hospitals 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 hospitals report all HCPCS codes consistent with their descriptors; CPT and/or CMS instructions and correct coding principles, and all charges for all services they furnish, whether payment for the services is made separately paid or is packaged'' to enable CMS to establish future ratesetting for OPPS services.

Comment: A commenter reported that the prostate HIFU procedure (C9747) and cryoablation of the prostate (55873) are two clinically similar procedures for the ablation of prostate for cancer, and are the only two acknowledged treatments for radiorecurrent, non-metastatic prostate cancer. This same commenter requested that we either create a new APC group specific to prostate ablation procedures or modify the organization of HCPCS codes within the urology family of APCs. The commenter specifically noted that a reorganization for APCs 5374 through 5376 would be appropriate but added that there are other inconsistencies across procedures within the urology APCs. The commenter also mentioned that CPT codes 50555 (Renal endoscopy through established nephrostomy or pyelostomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with biopsy) and 50557 (Renal endoscopy through established nephrostomy or pyelostomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with fulguration and/or incision, with or without biopsy) are assigned to two different APCs, however, their APC assignments appear reversed. The commenter further suggested updating the procedures within APCs 5374, 5375, and 5376 so that the geometric mean costs for the procedure fall into the following ranges:

APC	Low Geometric Mean Cost	High Geometric Mean Cost
5374	$1,800	$3,000
5375	$3,001	$5,500
5376	$5,501	$10,500

Response: We appreciate the commenter's suggestions and may consider a reorganization of the procedures in the urology APCs in future rulemaking. 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. For CY 2020, based on our analysis of the latest claims data for this final rule, we do not believe that establishing a new APC specific to prostate ablation procedures is necessary, nor do we believe that modifying the HCPCS codes within the urology family APCs is appropriate at this time.

With respect to CPT codes 50555 and 50557, based on our review of the claims data for this final rule with comment period, we revised the APC assignment for CPT code 50555 from APC 5375 to APC 5376, and maintained the APC assignment for CPT code 50557 in APC 5376. Specifically, our claims data show a geometric about $7,327 for CPT code 50555 and approximately $6,224 for CPT code 50557, which are more comparable with the geometric cost for APC 5376 of about $7,894 unlike that of APC 5375 whose geometric mean cost is approximately $4,140.

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 continue to assign HCPCS code C9747 to APC 5375 for CY 2020. The final CY 2020 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.

b. ProACT Procedure—Transperineal Periurethral Adjustable Balloon Continence Device Procedure (APCs 5371, 5374, 5375, and 5376)

In 2017, CMS received a new technology application for the transperineal periurethral adjustable balloon continence device procedure, which is associated with ProACT Therapy, and established a new code, specifically, HCPCS code C9746. Based on the estimated cost for the bilateral placement of the balloon continence devices, we assigned the code to APC 5377 (Level 7 Urology and Related Services) with a payment rate of $14,363.61 effective July 1, 2017. We announced the new code, and 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 C9746 to APC 5377 with a payment rate of $15,697.82. 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. Since HCPCS code C9746 was established on July 1, 2017, we had no claims data for the procedure for use in ratesetting in CY 2018.

For the CY 2019 update, we again had no claims data for the code so we made no change to the APC assignment and continued to assign HCPCS code C9746 to APC 5377 with a payment rate of $16,319.55. 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.

In July 2019, the CPT Editorial Panel established four new codes to describe the transperineal periurethral adjustable balloon continence device procedure, specifically, CPT codes 0548T, 0549T, 0550T, and 0551T. In the July 2019 quarterly update to the OPPS (Transmittal 4313, Change Request 11318, dated May 24, 2019), we listed the temporary APC assignments for the new codes in the July 2019 OPPS Update CR and announced the deletion of HCPCS code C9746 on June 30, 2019, since it was replaced with CPT code 0548T effective July 1, 2019. These codes are listed in Table 37 along with their long descriptors and proposed SI and APC assignments.

For CY 2020, we proposed to revise the APC assignment for new CPT code 0548T, which was previously described by HCPCS code C9746. In addition, we proposed to assign CPT codes 0549T, 0550T, and 0551T to APCs 5375, 5374, and 5371, respectively.

Comment: A medical device company suggested that CPT code 0548T remain in APC 5377, consistent with the APC assignment for the predecessor code (HCPCS code C9746). This commenter indicated that the calculated geometric mean cost does not accurately reflect the actual cost of the procedure. The commenter noted there were only two billings identified in the CMS data—one billing at the correct cost of $16,250 and one billing incorrectly recorded at $0. The commenter stated that the resulting calculation of the geometric mean cost of $8,125 does not accurately represent the actual cost of the bilateral procedure for CPT code 0548T. In addition, the same commenter requested a reassignment from APC 5375 to APC 5376 for CPT code 0549T.

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 2020, based on claims submitted between January 1, 2018 through December 30, 2018, that were processed on or before June 30, 2019, our analysis of the latest claims data for this final rule supports revising the APC assignment for CPT code 0548T (which was previously described by predecessor HCPCS code C9746) from APC 5377 to APC 5376 (Level 6 Urology and Related Services). Specifically, our claims data shows a geometric mean cost of approximately $9,504 for HCPCS code C9746 based on 7 single claims (out of 7 total claims), which is most comparable to the geometric mean cost of about $7,894 for APC 5376, rather than the geometric mean cost of approximately $17,195 for APC 5377. We believe that assigning CPT code 0548T to APC 5377 would significantly overpay for the procedure.

In addition, based on the geometric mean cost for the placement of the bilateral balloon continence devices (CPT code 0548T), we do not agree that we should revise the APC assignment for CPT code 0549T, which represents

the unilateral placement of the balloon continence device, from APC 5375 to APC 5376. We believe that the cost associated with CPT code 0549T should be less than that of CPT code 0548T since CPT code 0549T describes the use of only one device.

Moreover, we rely on hospitals to accurately report the use of HCPCS codes in accordance with their code descriptors and CPT and CMS instructions, and to appropriately report services on claims and charges and costs for the services on their Medicare hospital cost report. However, we do not specify the methodologies that hospitals use to set charges for this or any other service. We also state in Chapter 4 of the Medicare Claims Processing Manual that ''it is extremely important that hospitals report all HCPCS codes consistent with their descriptors; CPT and/or CMS instructions and correct coding principles, and all charges for all services they furnish, whether payment for the services is made separately paid or is packaged'' to enable CMS to establish future ratesetting for OPPS services.

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 CPT codes 0548T, 0549T, 0550T, and 0551T to the APCs listed in Table 37 below. The final CY 2020 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 37.—FINAL APC AND SI ASSIGNMENTS FOR CPT CODES 0548T, 0549T, 0550T, and 0551T FOR CY2020

HCPCS Code	Long Descriptor	Proposed OPPS SI	Proposed OPPS APC	Final OPPS SI	Final OPPS APC
C9746	Transperineal implantation of permanent adjustable balloon continence device, with cystourethroscopy, when performed and/or fluoroscopy, when performed	D	N/A	N/A	N/A
0548T	Transperineal periurethral balloon continence device; bilateral placement, including cystoscopy and fluoroscopy	J1	5376	J1	5376
0549T	Transperineal periurethral balloon continence device; unilateral placement, including cystoscopy and fluoroscopy	J1	5375	J1	5375
0550T	Transperineal periurethral balloon continence device; removal, each balloon	J1	5374	J1	5374
0551T	Transperineal periurethral balloon continence device; adjustment of balloon(s) fluid volume	T	5371	T	5371

c. Rezum Procedure—Transurethral High Energy Water Vapor Thermal Therapy of the Prostate (APC 5373)

In late 2017, CMS received a new technology application for the transurethral radiofrequency generated water vapor thermal therapy of the prostate, also known as the Rezum procedure, and established a new code, specifically, HCPCS code C9748 (Transurethral destruction of prostate tissue; by radiofrequency water vapor (steam) thermal therapy) effective January 1, 2018. Based on the estimated cost of the procedure, we assigned the new code to APC 5373 (Level 3 Urology and Related Services) with a payment rate of $1,695.68 effective January 1, 2018. The new code appeared in both the OPPS Addendum B of the CY 2018 OPPS/ASC final rule and the January 2018 OPPS Update CR (Transmittal 3941, Change Request 10417, dated December 22, 2017).

For the CY 2019 update, the CPT Editorial Panel established a new code to describe the Rezum procedure, specifically, CPT code 53854 (Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy) effective January 1, 2019. We deleted HCPCS code C9748 on December 31, 2018 because it was replaced with CPT code 53854 and assigned the new code to APC 5373, which was the same APC assignment for the predecessor code, with a payment rate of $1,739.75. We note that payment rates for the CY 2019 update were based on claims submitted between January 1, 2017 and December 30, 2017 that were processed on or before June 30, 2018.

For the CY 2020 update, we proposed to maintain the APC assignment for CPT code 53854 to APC 5373 with a proposed payment rate of $1,797.97.

Comment: Several commenters requested a reclassification for CPT code 53854 from APC 5373 to APC 5374 (Level 4 Urology and Related Services) with a proposed payment rate of $3,059.21. The commenters reported that the Rezum procedure is most clinically similar to the transurethral microwave therapy (TUMT), which is described by CPT code 53850 (Transurethral destruction of prostate tissue; by microwave thermotherapy), and transurethral needle (radiofrequency) ablation (TUNA), which is described by CPT code 53852

(Transurethral destruction of prostate tissue; by radiofrequency thermotherapy). Some commenters reported that the primary difference between each of these codes is the energy source used to destroy or shrink the prostate tissue, specifically, CPT code 53850 uses microwave energy, 53852 uses radiofrequency energy, and 53854 uses radiofrequency generated water vapor thermotherapy. Apart from the energy source, the commenters indicated that the procedures and resources used in these procedures are similar. Consequently, they recommended that all three procedures be placed in APC 5374.

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 2020, based on claims submitted between January 1, 2018 through December 30, 2018, that were processed on or before June 30, 2019, our analysis of the latest claims data for this final rule supports maintaining the APC assignment for CPT code 53854 (which was previously described by predecessor HCPCS code C9748) to APC 5373. Our claims data show a geometric mean cost of approximately $1,899 for the predecessor HCPCS code C9748 based on 191 single claims (out of 192 total claims). The geometric mean cost for the Rezum procedure is more in line with the geometric mean cost of about $1,733 for APC 5373 rather than with APC 5374 whose geometric mean cost is approximately $2,953.

In addition, based on our analysis of the claims data, the resource costs associated with the TUMT and TUNA procedures are not similar to the Rezum procedure. While all three procedures treat the same indication and utilize the same type of technology, time, set up, and planning, their resource costs vary. Our claims data show a geometric mean cost of approximately $2,851 for the TUMT procedure (CPT code 53850) based on 41 single claims (out of 41 total claims), and about $3,027 for the TUNA procedure (CPT code 53852) based on 513 single claims (out of 514 total claims). In both cases, the resource costs for the TUMT and TUNA procedures are much higher than those for the Rezum procedure.

Therefore, 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, and assigning CPT code 53854 to APC 5373. Table 38 below list the final APC assignments for CPT code 58350 (TUMT), 53852 (TUNA) and 53854 (Rezum). In addition, the final CY 2020 payment rates for these procedures can be found in Addendum B to this final rule with comment period. Further, 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 always, we will reevaluate the APC assignment for CPT code 53854 in the next rulemaking cycle. As stated above, we review, on an annual basis, the APC assignments for all services and items paid under the OPPS.

TABLE 38.—FINAL SI AND APC ASSIGNMENTS FOR CPT CODES 53850, 53852, and 53854 FOR CY2020

HCPCS Code	Long Descriptor	Proposed OPPS SI	Proposed OPPS APC	Final OPPS SI	Final OPPS APC
53850	Transurethral destruction of prostate tissue; by microwave thermotherapy	J1	5374	J1	5374
53852	Transurethral destruction of prostate tissue; by radiofrequency thermotherapy	J1	5374	J1	5374
53854	Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy	J1	5373	J1	5373

d. VaporBlate Procedure—Transurethral Radiofrequency Generated Water Vapor Thermal Therapy of the Prostate

As displayed in Addendum B to the CY 2020 OPPS/ASC proposed rule, we proposed to assign the procedure described by CPT code 0582T (Transurethral ablation of malignant prostate tissue by high-energy water vapor thermotherapy, including intraoperative imaging and needle guidance) to status indicator ''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 by Medicare, or are not reasonable and necessary. The code was listed as 0X76T (the 5-digit CMS placeholder code) in Addendum B with the short descriptor, and again in Addendum O with the long descriptor. We also assigned the code to comment indicator ''NP'' in Addendum B to indicate that the code is new for CY 2020 and that public comments would be accepted on the proposed status indicator assignment. We note that the code will be effective January 1, 2020.

Comment: A medical device company reported that the technology associated with this new code received FDA approval as an IDE. Specifically, the VaporBlate technology was designated by the FDA as a Category B IDE on August 29, 2019. The commenter also

stated that they are in the process of applying for Medicare coverage of the Category B IDE clinical trial. In the event the clinical trial is approved by Medicare, the commenter suggested assigning the code to one of the following APCs:

- APC 1590 (New Technology—Level 39 ($15,001-$20,000)) with a proposed payment rate of $ 17,500.50; or
- APC 5377 (Level 7 Urology and Related Services) with a proposed payment rate of $17,465.94.

The commenter explained that the VaporBlate procedure involves the transurethral ablation of malignant prostate tissue by high-energy water vapor thermotherapy, which is unlike that of the Rezum procedure that involves transurethral radiofrequency generated water vapor thermal therapy for benign prostatic hyperplasia (BPH). The commenter added that the resource costs associated with the VaporBlate procedure are significantly higher than those for the Rezum procedure. The Rezum generator (capital equipment) used in CPT code 53854 costs $32,500 and the Rezum supply kit (disposables) costs between $1,000 and $1,500, while the VaporBlate generator (capital equipment) used to perform the procedure described by the VaporBlate procedure costs $80,000 and the supply kits (disposables) cost $12,500 each. Based on the clinical and cost differences, the commenter stated that CPT code 0582T should not be assigned to the same APC as CPT code 53854 (Rezum procedure).

Response: Based on our understanding of the procedure, we found that the service associated with CPT code 0582T is currently in clinical trial (Study Title: ''Ablation of Prostate Tissue in Patients With Intermediate Risk Localized Prostate Cancer''; *ClinicalTrials.gov* Identifier: NCT04087980). Further review of the clinical trial revealed that the clinical study has not yet met CMS' standards for coverage, nor does it appear on the CMS Approved IDE List, which can be found at this CMS website: *https://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies.html*. Because the VaporBlate technology has not been approved for Medicare coverage as a Category B IDE, we believe that we should continue to assign CPT code 0582T to status indicator ''E1''. If this technology later meets CMS' standards for coverage, we will reassess the APC assignment for the code in a future quarterly update and/or rulemaking cycle.

Therefore, after consideration of the public comment, we are finalizing our proposal, without modification, to assign CPT code 0582T to status indicator ''E1''. We refer readers to Addendum D1 of this final rule with comment period for the complete list of the OPPS payment status indicators and their definitions for CY 2020. Addendum D1 is 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 is one device category eligible for pass-through payment: C1823 Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads), which was established effective January 1, 2019. The pass-through payment status of the device category for HCPCS code C1823 will end on December 31, 2021. HCPCS code C1823 will continue to receive pass-through status in CY 2020.

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, in section IV.A.4. of the CY 2020 OPPS/ASC proposed rule, we proposed an alternative pathway that would grant 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 the CY 2020 OPPS/ASC proposed rule for a complete discussion on this proposal.

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 approval or clearance (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 approval or clearance, if required, unless there is a documented, verifiable delay in U.S. market availability after FDA approval or clearance 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 costs 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).

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.

b. Applications Received for Device Pass-Through Payment for CY 2020

We received seven complete applications by the March 1, 2019 quarterly deadline, which was the last quarterly deadline for applications to be received in time to be included in the CY 2020 OPPS/ASC proposed rule. We received one of the applications in the second quarter of 2018, three of the applications in the fourth quarter of 2018, and three of the applications in the first quarter of 2019. None of the applications were approved for device pass-through payment during the quarterly review process.

Applications received for the later deadlines for the remaining 2019 quarters (June 1, September 1, and December 1), if any, will be presented in the CY 2021 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, 2019 deadline is presented below.

(1) Surefire® Spark™ Infusion System

TriSalus Life Sciences submitted an application for a new device category for transitional pass-through payment status for the Surefire® Spark™ Infusion System. The Surefire® Spark™ Infusion System is described as a

flexible, ultra-thin microcatheter with a self-expanding, nonocclusive one-way microvalve at the distal end. The applicant stated that it has designed the Pressure Enabled Drug Delivery™ technology of the Surefire® Spark™ Infusion System to overcome intratumoral pressure in solid tumors and improve distribution and penetration of therapy during Transcatheter Arterial Chemoembolization (TACE) procedures. TACE is a minimally invasive, image-guided procedure used to infuse a high dose of chemotherapy into liver tumors. According to the applicant, the pliable, one-way valve at the distal tip of the Surefire® Spark™ Infusion System creates a temporary local increase in pressure during infusion, opening up collapsed vessels in tumors, which enables perfusion and therapy delivery in areas inaccessible to the systemic circulation, a positive hydrostatic pressure gradient, and restores convective flow to enable therapy to penetrate deeper into the tumor. During the TACE procedure, the physician first gains catheter access into the arterial system of the hepatic arteries through a small incision in the groin or the wrist. The applicant stated that the physician then uses real-time fluoroscopic guidance to navigate the Surefire® Spark™ Infusion System into the blood vessels feeding the tumors, infusing the chemotherapy and embolic materials through the Surefire® Spark™ Infusion System until the tumor bed is completely saturated.

With respect to the newness criterion at § 419.66(b)(1), FDA granted 510(k) premarket clearance as of April 3, 2018. The application for a new device category for transitional pass-through payment status for the Surefire® Spark™ Infusion System was received on November 29, 2018, which is within 3 years of the date of the initial FDA approval or clearance. We invited public comments on whether the Surefire® Spark™ Infusion System meets the newness criterion.

Comment: The manufacturer of Surefire® Spark™ Infusion System believed this device meets the eligibility criteria for device pass-through payment under the regulation at § 419.66, which includes the newness criterion.

Response: We appreciate the commenter's input. After consideration of the public comments we received and based on the fact that the Surefire® Spark™ Infusion System application was received within 3 years of FDA approval, we believe that the Surefire® Spark™ Infusion System meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the use of the Surefire® Spark™ Infusion System is integral to the service of providing delivery of chemotherapy into liver tumors, 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 the Surefire® Spark™ Infusion System meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or items for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. We invited public comments on whether the Surefire® Spark™ Infusion System meets the eligibility criteria at § 419.66(b).

Comment: The manufacturer of Surefire® Spark™ Infusion System believed that that the Surefire® Spark™ Infusion System met the eligibility criteria at § 419.66(b).

Response: We appreciate the commenter's input. Based on the information we have received and our review of the application, we have determined that Surefire® Spark™ Infusion System meets the eligibility criterion at § 419.66(b)(3) and (b)(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 identified several existing pass-through payment categories that may be applicable to the Surefire® Spark™ Infusion System. The Surefire® Spark™ Infusion System may be described by HCPCS code C1887 (Catheter, guiding (may include infusion/perfusion capability)). The applicant describes the Surefire® Spark™ Infusion System as a device used in vascular interventional procedures to deliver diagnostic and therapeutic agents in the peripheral vasculatures. The CMS List of Device Category Codes for Present or Previous Pass-Through Payment and Related Definitions describes HCPCS code C1887 as intended for the introduction of interventional/diagnostic devices into the coronary or peripheral vascular systems. In the CY 2020 OPPS/ASC proposed rule, we also stated that the Surefire® Spark™ Infusion System may also be described by HCPCS code C1751 (Catheter, infusion, inserted peripherally, centrally or midline (other than hemodialysis)). The applicant describes the Surefire® Spark™ Infusion System as being inserted through a small incision in the groin or the wrist. We invited public comments on this issue.

Comment: The manufacturer of the device does not believe there is an existing pass-through payment category that describes the Surefire® Spark™ Infusion 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 C1887 Catheter, guiding (may include infusion/perfusion capability) and C1751 Catheter, infusion, inserted peripherally, centrally or midline (other than hemodialysis)—do not appropriately describe catheters with a pressure-enabled drug delivery (PEDD) valve, a key mechanism of action of the Surefire® Spark™ Infusion System. The manufacturer stated that the PEDD valve is closely associated with differential and improved outcomes as compared to catheters without PEDD valves and is not appropriately described by existing categories.

Response: We appreciate the commenter's input. After consideration of the public comments we received, we believe there is no existing pass-through payment category that appropriately describes the Surefire® Spark™ Infusion System, due to the pressure-enabled drug delivery (PEDD) valve which offers a unique mechanism for therapy delivery. Based on this information, we believe that the Surefire® Spark™ Infusion System meets the eligibility criterion.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines 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. With respect to this criterion, the applicant submitted four studies to support the claim that their technology represents a substantial clinical improvement over existing technologies. The applicant asserts that the Surefire® Spark™ Infusion System represents a substantial clinical improvement over existing technologies because it offers a treatment option that no other catheters currently available can provide. The manufacturer notes that the self-expanding, nonocclusive, one-way valve can infuse therapy at pressure higher

than the baseline mean arterial pressure, and this pressurized delivery opens up collapsed vessels in tumors and enables perfusion and therapy delivery into hypoxic areas of the liver tumors. The applicant also believes that the Surefire® Spark™ Infusion System represents a substantial clinical improvement because the technology has shown improved tumor response rates in hepatocellular carcinoma, as well as a decrease in the rate of disease recurrence and the need for subsequent treatment.

The first pilot study of nine patients being treated for hepatocellular carcinoma, who received infusions via both a conventional end-hole catheter and an antireflux microcatheter, demonstrated statistically significant reductions in downstream distribution of embolic particles with the antireflux catheter and increases in tumor deposition ($p < 0.05$).[13] The second singlecenter retrospective study was conducted with 22 patients treated for hepatocellular carcinoma with the Surefire® Spark™ Infusion System and TACE. As assessed by MRI, there appeared to be overall disease response in 91 percent of patients and 85 percent of lesions and complete response in 32 percent of patients and 54 percent of lesions.[14] In the first study for a case-control series, 19 patients undergoing treatment using SIS–TACE had a statistically significant improvement in disease response rate compared to 19 patients treated with end-hole microcatheters, 78.9 percent compared to 36.8 percent for initial overall response rate ($p = 0.008$).[15] In the second study, a multi-center registry of 72 patients demonstrated high response rate when compared to historical control at 6 months follow-up.[16]

Based on the information submitted by the applicant, one concern was that large-scale studies with long-term follow-up were limited. Also, the majority of studies presented had a sample size of less than 25 and the highest sample size presented was less than 100 patients. Additionally, patient follow-up occurred mostly within a 3 to 6 month timeframe with few studies occurring beyond this range. Another concern was that none of the studies presented improvements in mortality with the use of the Surefire® Spark™ Infusion System. Outcomes focused primarily on tumor response rates and lesion size, based upon imaging. We noted additional data on mortality endpoints would be helpful to fully assess substantial clinical improvement. We invited public comments on whether the Surefire® Spark™ Infusion System meets the substantial clinical improvement criterion.

Comment: The manufacturer responded to several statements regarding Surefire® Spark™ Infusion System and substantial clinical improvement in the CY 2020 OPPS/ASC proposed rule, and asserted that Spark™ Infusion System meets the substantial clinical improvement criterion. The manufacturer stated that the population size in the studies submitted to CMS are normal for a new and innovative technology, noting that the studies are methodologically rigorous and show statistically significant differentiation from comparators. The manufacturer also noted that overall survival is not an appropriate endpoint for hepatocellular carcinoma. They cited National Comprehensive Cancer Network (NCCN) guidelines, noting that tumor necrosis and pathologic response are primary predictors of success in these cases and locoregional therapy should be viewed as a way to transition patients to transplant or resection. The manufacturer also suggested that CMS should consider that clinical improvements vary based on the therapeutic agent being delivered by the Spark™ Infusion System and that these agents are approved on a variety of endpoints.

Response: We appreciate the response to the questions we had regarding Spark™ Infusion System. After reviewing the information provided in the public comment, we agree that while the opportunity for large-scale studies with long-term follow-up is limited for a new technology, the existing studies show statistically significant improvements. Additionally, with regard to our questions about impacts on mortality, we accept the applicant's statement that there are other key clinical endpoints, such as tumor necrosis and progression-free survival, that can be used to assess improvements from the Spark™ Infusion System.

Comment: Multiple commenters supported granting Spark™ Infusion System transitional pass-through payment status. Many of the commenters mentioned that Spark™ Infusion System provides substantial clinical benefit over conventional therapy and urged CMS to approve the transitional pass-through payment to reduce cost burden and increase patient access.

Response: We appreciate the additional information that the commenters provided on the performance and the benefits of Spark™ Infusion System.

After consideration of the public comments we received, we have determined that Spark™ Infusion System does meet 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 the Surefire® Spark™ Infusion System would be reported with CPT code 37243, which is assigned to APC 5193 (Level 3 Endovascular 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 5193, which has a CY 2019 payment rate of $9,669.04. 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 37243 had a device offset amount of $3,894.69 at the time the application was received. According to the applicant, the cost of the Surefire® Spark™ Infusion System is $7,750.

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 $7,750 for the Surefire® Spark™ Infusion System is

[13] Pasciak AS, McElmurray JH, Bourgeois AC, Heidel RE, Bradley YC. Impact of an antireflux catheter on target volume particulate distribution in liver-directed embolotherapy: a pilot study. J Vasc Interv Radiol. 2015 May;26(5):660–9.

[14] Kim AY, Frantz S, Krishnan P, DeMulder D, Caridi T, Lynskey GE, et al. (2017) Short-term imaging response after drug-eluting embolic trans-arterial chemoembolization delivered with the Surefire Infusion System® for the treatment of hepatocellular carcinoma. PloS one 12.9 (2017): e0183861.

[15] N Apseloff, J Keung, T Caridi, D Buckley, G Lynskey, A Kim. Case-control evaluation of endhole microcatheter versus Surefire Infusion System for use during transarterial chemoembolization for hepatocellular carcinoma. Conference abstract presented at 2017 Society of Intervention Radiology Annual Congress, March 8, 2017.

[16] Kapoor B, Contreras F, Katz M, Arepally A, Fischman A, Rose S, Kim A, Ferraro J. Surefire Infusion System (SIS) hepatocellular carcinoma registry study interim results: A multicenter study of the safety, feasibility, and outcomes of the SIS expandable-tip microcatheter in DEB–TACE. Conference abstract presented at 2018 Society of Intervention Radiology Annual Congress, March 19, 2017.

80.2 percent of the applicable APC payment amount for the service related to the category of devices of $9,669.04 ($7,750/$9,669.04 × 100 = 80.2 percent). Therefore, we believe the Surefire® Spark™ Infusion 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 $7,750 for the Surefire® Spark™ Infusion System exceeds the cost of the device-related portion of the APC payment amount for the related service of $3,894.69 by 199 percent ($7,750 − $3,894.69) × 100 = 198.99 percent). Therefore, we believe that the Surefire® Spark™ Infusion 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 $7,750 for the Spark™ Infusion System and the portion of the APC payment amount for the device of $3,894.69 exceeds the APC payment amount for the related service of $9,669.04 by 40 percent (($7,750 − $3,894.69)/$9,669.04) × 100 = 39.87 percent). Therefore, we believe that the Surefire® Spark™ Infusion System meets the third cost significance requirement.

We invited public comments on whether the Surefire® Spark™ Infusion System meets the device pass-through payment criteria discussed in this section, including the cost criterion.

Comment: The manufacturer of the Surefire® Spark™ Infusion 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, we believe that Surefire® Spark™ Infusion System meets the cost criterion for device pass-through payment status.

After consideration of the public comments we received, we are approving the Surefire® Spark™ Infusion System for device pass-through payment status beginning in CY 2020.

(2) TracPatch

According to the applicant, TracPatch is a wearable device that utilizes an accelerometer, temperature sensor and step counter to allow the surgeon and patient to monitor recovery and help ensure critical milestones are being met. The applicant states that TracPatch utilizes wearable monitoring technology and methods in an effort to enhance the rehabilitation experience for both patients and physicians. Accelerometers are utilized to recognize and record the results when patients perform standard physical therapy exercises, in addition to providing standard step count and high-acceleration events that may indicate a fall. A temperature sensor monitors the skin temperature near the joint.

TracPatch is described by the applicant as a 24/7 remote monitoring wearable device that captures a patient's key daily activities: such as range of motion progress, exercise compliance, and ambulation. TracPatch is used for pre- and post-operative patient monitoring, patient engagement, data analytics and post-op cost reduction.

According to the applicant, the wearable devices stick on the skin above and below the knee. The wearables are applied before total knee surgery to determine a patient's baseline activity levels, and then again after surgery to allow the patient and surgeon to monitor activity, pain, range of motion and physical therapy. The use of the Bluetooth connectivity allows the device to be paired with any smartphone and the TracPatch cloud allows for unlimited data collection and storage. The applicant states that TracPatch includes a web dashboard and computer application, which permit a health care provider to monitor a patient's recovery in real-time, allowing for immediate care adjustments and the ability for providers and patients to respond to issues that may occur during recovery from surgery.

With respect to the newness criterion at § 419.66(b)(1), the applicant stated that TracPatch does not need FDA clearance because it is a Class I device that would be assigned to a generic category of devices described in 21 CFR parts 862 through 892 that is exempt from FDA premarket notification. However, the applicant did not identify which category of exempted devices that TracPatch would be assigned. The applicant also stated that TracPatch will be introduced into the market in 2019, which would be within 3 years of the device pass-through payment application for TracPatch that was received in March 2019. We invited public comments on whether the TracPatch is exempt from FDA clearance and if the TracPatch meets the newness criterion.

Comment: One commenter, the manufacturer, stated that they had registered TracPatch as a Class I Exempt goniometer with FDA which was listed on the Global Unique Device Identification Database (GUDID) as of August 28, 2019.

Response: We thank the manufacturer for clarifying that TracPatch is now registered with FDA as a Class I Exempt goniometer as of August 28, 2019.

After consideration of the public comments, we have determined that TracPatch meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), the applicant claimed that the TracPatch is an integral part of monitoring the range of motion for a knee prior to and after total knee arthroplasty, is used for one patient only, and is placed on the skin above and below the knee and secured by Velcro strips. The applicant stated that the device is not surgically implanted or inserted into the patient and is not applied in or on a wound or other skin lesion. We stated concerns in the proposed rule with TracPatch's eligibility with respect to the criterion at § 419.66(b)(3) because to be eligible for pass-through payment a device must be surgically implanted or inserted into the patient or applied in a wound or on other skin lesions. In addition, the applicant stated that the TracPatch 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. We determined that TracPatch was not a material or supply furnished incident to a service. We invited public comments on whether the TracPatch meets the eligibility criterion.

Comment: One commenter, the manufacturer, provided more information on whether TracPatch meets the eligibility criterion. The manufacturer states that the device is adhered to a patient's skin using a medical adhesive patch and not Velcro strips and that the device is placed near a wound (which we assume is the incision for the associated knee surgery) in a sterile setting. The placement of the device near the wound allows real time monitoring of changes to the wound and complications and abnormalities that may arise. Also the device placement is important to perform measurements related to the knee's range of motion.

Response: The commenter did not state or provide evidence either in its device pass-through application or in its comment on the CY 2020 OPPS/ASC proposed rule, that the TracPatch device is surgically implanted or inserted into a patient or is applied in a wound or on other skin lesions. In fact, the description of the Class I Exempt goniometer on the FDA product classification web page states that the goniometer is not an implantable device. To be considered for device pass-through payment, a device must meet this part of the eligibility criterion.

After consideration of all of the information we have received, we have determined that TracPatch is not surgically implanted or inserted into a patient or applied in a wound or on other skin lesions, and the product thus does not meet the eligibility criterion for device pass-through payment status. Because we have determined that TracPatch does not meet the basic eligibility criterion for transitional pass-through payment status, we have not evaluated this product to determine whether it meets the other criteria required for transitional pass-through payment for devices; that is the substantial clinical improvement criterion, and the cost criterion.

Comment: Multiple commenters, including physicians and patients, described the benefits of TracPatch and how it helped either them or their patients with their recoveries from knee surgery.

Response: We appreciate the comments we received about the benefits of TracPatch. However, we did not evaluate substantial clinical improvement for TracPatch because it did not meet the eligibility criterion.

After consideration of the public comments we received, we are not approving device pass-through payment status for TracPatch for CY 2020.

(3) Vagus Nerve Stimulation (VNS) Therapy® System for Treatment Resistant Depression (TRD)

LivaNova USA Inc. submitted an application for the Vagus Nerve Stimulation (VNS) Therapy® System for Treatment Resistant Depression (TRD). According to the applicant, the VNS Therapy® System consists of two implantable components: A programmable electronic pulse generator and a bipolar electrical lead that is connected to the programmable electronic pulse generator. The applicant stated that the surgical procedure to implant the VNS Therapy® System involves subcutaneous implanting of the pulse generator in the intraclavicular region as well as insertion of the bipolar electrical lead which entails wrapping two spiral electrodes around the cervical portion of the left vagus nerve within the carotid sheath.

According to the applicant, following implant and recovery, the physician programs the pulse generator to intermittently stimulate the vagus nerve at a level that balances efficacy and patient tolerability. The pulse generator delivers electrical stimulation via the bipolar electrical lead to the cervical portion of the left vagus nerve within the carotid sheath thereby relaying information to the brain stem modulating structures relevant to depression. Stimulation typically consists of a 30-second period of ''on time,'' during which the device stimulates at a fixed level of output current, followed by a 5-minute ''off time'' period of no stimulation.

The applicant states that a hand-held programmer is utilized to program the pulse generator stimulation parameters, including the current charge, pulse width, pulse frequency, and the on/off stimulus time, which is also known as the on/off duty cycle. Initial settings can be adjusted to enhance the tolerability of the device as well as its clinical effects on the patient. The generator runs continuously, but patients can temporarily turn off the device by holding a magnet over it. The generator can also be turned on and off by the programmer.

The applicant states that the VNS Therapy® System provides indirect modulation of brain activity through the stimulation of the vagus nerve. The vagus nerve, the tenth cranial nerve, has parasympathetic outflow that regulates the autonomic (that is, involuntary) functions of heart rate and gastric acid secretion, and also includes the primary functions of sensation from the pharynx, muscles of the vocal cords and swallowing. It is a nerve that carries both sensory and motor information to and from the brain. Importantly, the vagus nerve has influence over widespread brain areas and it is believed that electrical stimulation of the vagus nerve alters various networks of the brain in order to treat psychiatric disease.

With respect to the newness criterion at § 419.66(b)(1), the applicant received FDA clearance for the VNS Therapy® System for TRD through the premarket approval (PMA) process on July 15, 2005, and the VNS Therapy® for TRD device was introduced to the market in September 2005. However, on May 4, 2007, a national coverage determination (NCD 160.18) was released prohibiting Medicare from covering the use of the VNS Therapy® System for TRD. This NCD remained in effect until February 15, 2019, when CMS determined that the VNS Therapy® for TRD could receive payment if the service was performed in CMS-approved coverage with evidence development (CED) studies. Although the VNS Therapy® System for TRD was introduced to the market in September 2005, Medicare has only covered it for slightly more than 1½ years. However, § 419.66(b)(1) states that a pass-through payment application for a device must be received within 3 years of when the device either received FDA approval or was introduced to the market. The applicant stated that the VNS Therapy® System for TRD was introduced to the market in September 2005, which means the device pass-through payment application would have needed to have been submitted to CMS by September 2008. However, the pass-through application for the device was not received by CMS until March 2019.

In addition, it appeared that the neurostimulator device for the VNS Therapy® System for TRD is the same device that has been used since 1997 to treat epilepsy.[17] The applicant stated the following three differences between the two devices: (1) How the device is programmed to treat epilepsy versus TRD; (2) how the external magnets of the device are used for epilepsy treatment as compared to TRD treatment; and (3) that the battery life of the device to treat epilepsy is different than the battery life of the device when treating TRD. However, it was not clear that these differences demonstrate that the actual device used to treat TRD is any different than the device used to treat epilepsy.

Based on the information presented, we invited public comments on whether the VNS Therapy® System for TRD meets the newness criterion.

Comment: One commenter, the manufacturer, made additional arguments for why the VNS Therapy® System for TRD meets the newness criterion. The manufacturer stated that there were 22 months between the FDA approval of the associated procedure to treat TRD in July 2005 and CMS' issuance of the national determination of non-coverage on May 4, 2007. The manufacturer asserts that during those 22 months the VNS Therapy® System for TRD was ''realistically not available'' because of concerns about covering the TRD treatment procedure during the period between FDA approval and the national determination of non-coverage.

[17] Current Behavioral Neuroscience Reports. 2014 Jun; 1(2): 64–73.

In another part of the manufacturer's comment, they state that the uncertainty of coverage for the TRD treatment procedure meant that the treatment was not available to patients during the July 2005 to May 2007 time period.

The manufacturer believes the most equitable reading of the rule that is consistent with the intent of the criterion when it was established in the CY 2016 OPPS final rule (80 FR 70418 through 70420) is that the 3-year period for newness from when the VNS Therapy® System for TRD was introduced into the market in July 2015 should have been held in suspension from May 4, 2007 when the original national determination of non-coverage by CMS until the subsequent national determination allowing coverage of the VNS Therapy® System for TRD with coverage with evidence development (CED) was released on February 15, 2019.

The manufacturer cites CMS statements from the CY 2016 OPPS final rule supporting this reading, including that device pass-through payment is for devices that are truly new and do not have sufficient claims data for CMS to analyze, and that market availability for a device could be considered to be after its FDA approval or clearance date where there is a national coverage determination of non-coverage of the device within the Medicare population. The manufacturer asserts that the reason that the newness criterion does not address the market availability situation faced by the VNS Therapy® System for TRD is that CMS simply did not envision that such a situation would occur. The manufacturer asserts that the VNS Therapy® System for TRD neurostimulator device has not been available in the market for 3 full years, and therefore still meets the newness criterion.

Response: We disagree with the commenter's conclusion. The manufacturer did not provide evidence to establish that the neurostimulator device for the VNS Therapy® System for TRD was not similar to the neurostimulator device that has been used since 1997 to treat epilepsy. With no evidence to the contrary, it appears the neurostimulator device for the VNS Therapy® System for TRD has been on the market continuously since 1997 and therefore fails the newness criterion.

However, even if we were to assume the neurostimulator device for the VNS Therapy® System for TRD was a new device upon FDA approval for the TRD treatment procedure in July 2005, the device would still not meet the newness criterion. The manufacturer's comment about suggesting an equitable reading of the newness criterion consistent with what it believed was our intent in the CY 2016 OPPS final rule (80 FR 70418 through 70420) implied that, for a device to meet the newness standard, it had to be available in the market for less than three years and that the availability period would be suspended if the device was unavailable in the market due to national non-coverage. This comment does not align with the language of § 419.66(b)(1), which states that the application for device pass-through payment must be received within 3 years from the date of market availability and makes no exception for periods of national non-coverage. As we stated in the proposed rule, based on information provided in the original device pass-through application, the device pass-through application had to be submitted by September 2008 to meet the newness requirement.

Comment: One commenter stated that it did not believe that the VNS Therapy® System for TRD meets the newness criterion for device pass-through payment. The commenter states that while there have been technical improvements with the VNS Therapy® System for TRD, the commenter believes these are typical upgrades of an existing technology and not evidence of a new device.

Response: We appreciate the feedback from the commenter, including their concern that the differences cited by the manufacturer between the neurostimulator VNS device to treat epilepsy and the neurostimulator VNS device to treat TRD are not substantial enough to establish the VNS Therapy® System for TRD neurostimulator device as a new device that meets the newness criterion. A device also will fail the newness criterion if, as noted above, it is on the market more than three years, based either on its FDA clearance or approval date or the date of U.S. market availability.

After consideration of all of the information we have received, we have determined that the VNS Therapy® System for TRD does not meet the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), the applicant claimed that the VNS Therapy® System for TRD is an integral part of a procedure to provide adjunctive treatment of chronic or recurrent depression in adult patients that have failed four or more antidepressant treatments. The VNS Therapy® System for TRD is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted into the patient. In addition, the applicant stated that the VNS Therapy® System for TRD 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. We determined that the VNS Therapy® for TRD was not a material or supply furnished incident to a service. We invited public comments on whether the VNS Therapy® for TRD meets the eligibility criterion.

Comment: One commenter, the manufacturer, claimed that the VNS Therapy® for TRD device meets the basic eligibility criteria for pass-through status. The device is an integral part of the service provided which is the adjunctive treatment of TRD. The device is used by one patient, comes in contact with human tissue and is surgically implanted. The manufacturer also asserts that the device is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered. The manufacturer states that the device is not a material or supply furnished incident to a service.

Response: We appreciate the additional comments from the manufacturer. After consideration of all of the information we have received, we have determined that the VNS Therapy® System for TRD does meet the device eligibility criterion as described by § 419.66(b)(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 describes the device used for the VNS Therapy® System for TRD, the applicant suggested a category descriptor of ''Generator, neurostimulator (implantable), treatment resistant depression, non-rechargeable.'' However, the device category represented by HCPCS code C1767 is described as ''Generator, neurostimulator (implantable), non-rechargeable,'' which appears to encompass the device category descriptor for the VNS Therapy® System for TRD suggested by the applicant. The applicant asserts that the device category descriptor for HCPCS code C1767 is overly broad and noted the establishment of HCPCS code C1823 (Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation

leads), effective January 1, 2019, as an example of where a new device category for a nonrechargeable neurostimulation system to treat central sleep apnea was carved out from the broad category described by HCPCS code C1767.

The applicant believes its proposed category for the device for the VNS Therapy® System for TRD should similarly qualify as a new category. However, HCPCS code C1823 was established due to specific device features which distinguish that device category from HCPCS code C1767. The applicant for the VNS Therapy® System for TRD requested a new device category based on a beneficiary's diagnosis, but OPPS does not differentiate payment by diagnosis.

Comment: The applicant asserts that the VNS Therapy® for TRD device is not described by any of the existing device categories in the OPPS and that the associated service was not paid as an outpatient service as of December 31, 1996.

Response: We do not agree with the applicant's assertion. We believe the VNS Therapy® for TRD device is described by existing HCPCS code C1767 (Generator, neurostimulator (implantable), non-rechargeable) and does not meet the criterion that is described by § 419.66(c)(1) because the device is described by an existing device category. As stated in the proposed rule, OPPS does not differentiate payment by diagnosis and therefore cannot establish new device categories based solely on a previously described device being used to treat a new indication. In the original pass-through application, the applicant cited the example of the establishment of a new category code, HCPCS code C1823 (Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads), for the remede system even though that device is a non-rechargeable neurostimulator and initially appeared to be covered by HCPCS code C1767, like the VNS Therapy® for TRD device. However, as we stated in the proposed rule, HCPCS code C1823 was established due to specific device features that distinguish that device category from HCPCS code C1767. The applicant has not identified any device features of the VNS Therapy® for TRD device that distinguish it from the category described by HCPCS code C1767.

After consideration of all of the information we have received, we have determined that the VNS Therapy® System for TRD is described by either an existing category or by a category previously in effect and does not meets the requirements of § 419.66(c)(1) and the device category eligibility criterion.

Because we have determined that the VNS Therapy® System for TRD does not meet either the newness criterion or the device category eligibility criterion for transitional pass-through payment status, we have not evaluated this device to determine whether it meets the other criteria required for transitional pass-through payment for devices; namely, the substantial clinical improvement criterion and the cost criterion.

Comment: A commenter supported giving pass-through status for the VNS Therapy® System for TRD because the commenter believes the clinical benefits of the VNS Therapy® System for TRD have been demonstrated by the studies submitted for the recent national coverage determination that established coverage with evidence development for the procedure.

Response: We appreciate the comment in support of the clinical benefits of the VNS Therapy® System for TRD. However, we did not evaluate substantial clinical improvement for the VNS Therapy® System for TRD because this device does not meet the newness criterion or the device category eligibility criterion.

After consideration of the public comments we received, we are not approving VNS Therapy® System for TRD device pass-through payment status for CY 2020.

(4) Optimizer® System

Impulse Dynamics submitted an application for a new device category for transitional pass-through payment status for the Optimizer® System. According to the applicant, the Optimizer® System is an implantable device that delivers Cardiac Contractility Modulation (CCM) therapy for the treatment of patients with moderate to severe chronic heart failure. CCM therapy is intended to treat patients with persistent symptomatic heart failure despite receiving guideline directed medical therapy (GDMT). The applicant stated that the Optimizer System consists of the Optimizer Implantable Pulse Generator (IPG), Optimizer Mini Charger, and Omni II Programmer with Omni Smart Software. Lastly, the applicant stated that the Optimizer® System delivers CCM signals to the myocardium. CCM signals are nonexcitatory electrical signals applied during the cardiac absolute refractory period that, over time, enhance the strength of cardiac muscle contraction.

With respect to the newness criterion at § 419.66(b)(1), the applicant received a Category B–3 Investigational Device Exemption (IDE) from FDA on April 6, 2017. Subsequently, the applicant received its premarket approval (PMA) application from FDA on March 21, 2019. We received the application for a new device category for transitional pass-through payment status for the Optimizer® System on February 26, 2019, which is within 3 years of the date of the initial FDA approval or clearance. We invited public comments on whether the Optimizer® System meets the newness criterion.

Comment: The manufacturer believes that the Optimizer® System meets the newness criterion.

Response: We appreciate the commenter's input. After consideration of the public comment we received, we believe that the Optimizer® System meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the Optimizer® System is integral to the CCM therapy 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 stated that the Optimizer® System meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or items for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service.

We did not receive any public comments regarding whether Optimizer® System meets the eligibility criterion. Based on the information we have received, we have determined that Optimizer® System meets the eligibility criterion.

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. For the proposed rule, we had not identified an existing pass-through payment category that describes the Optimizer® System.

Comment: The manufacturer of the Optimizer® System indicated that there is not an existing pass-through payment category that describes the device.

Response: We appreciate the commenter's input. After consideration of the public comment we received, we believe that the Optimizer® System meets the device category eligibility criterion.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines 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. The applicant stated that the use of CCM significantly improves clinical outcomes for a patient population compared to currently available treatments. With respect to this criterion, the applicant submitted studies that examined the impact of CCM on quality of life, exercise tolerance, hospitalizations, and mortality.

The applicant noted that the use of the Optimizer® System significantly improves clinical outcomes for patients with moderate-to-severe chronic heart failure, and specifically improves exercise tolerance, quality of life, and functional status of patients that are otherwise underserved. The applicant claims that the Optimizer® System fulfills an unmet need because there is currently no therapeutic medical device therapies available for the 70 percent of heart failure patients who have New York Heart Association (NYHA) Class III heart failure, normal QRS duration and reduced ejection fraction (EF). FDA approved the Optimizer® System for NYHA Class III heart failure patients who remain symptomatic despite guideline directed medical therapy, who are in normal sinus rhythm, are not indicated for Cardiac Resynchronization Therapy, and have a left ventricular ejection fraction ranging from 25 percent to 45 percent.[18]

The applicant presented several studies to support these claims. According to the applicant, the results of a randomized clinical study in which patients with NYHA functional Class III, ambulatory Class IV heart failure despite OMT, an EF from 25–45 percent, or a normal sinus rhythm with QRS duration <130ms (n = 160) were randomized to continued medical therapy (n = 86) or CCM with the Optimizer® System (n = 74) for 24 weeks showed a statistically significant improvement in the primary endpoint of peak oxygen consumption (pVO2 = 0.84, 95 percent Bayesian credible interval 0.123 to 1.52) compared with the patients who were randomized to continued medical therapy.[19] The secondary endpoint of quality of life, measured by Minnesota Living with Heart Failure Questionnaire (MLWHFQ) (p<0.001), 6-minute hall walk test (p = 0.02), and an NYHA function class assessment (p<0.001) were better in the treatment group versus control group. The secondary endpoint of heart failure-related hospitalizations was lowered from 10.8 percent to 2.9 percent (p = 0.048). The applicant also reported a registry study of 140 patients with a left ventricular ejection fraction from 25–45 percent receiving CCM therapy with a primary endpoint of comparing observed survival to Seattle Heart Failure Model (SHFM) predicted survival over 3 years of follow-up. All patients implanted with the Optimizer® System at participating centers were offered participation and 72 percent of patients agreed to enroll in the registry. There were improvements in quality of life markers (MLWHFQ) and a 75-percent reduction in heart failure hospitalizations (p<0.0001). Survival at 3 years was similar between the two study arms with CCM at 82.8 percent [73.4 percent-89.1 percent] and SHFM at 76.7 percent (p = 0.16). However, for patients with a left ventricular ejection fraction from 35–45 percent receiving CCM therapy, the 3-year mortality for CCM therapy was significantly better than predicted with 88 percent for CCM compared to 74.7 percent for SHFM (p = 0.0463).[20] The applicant presented a randomized, double blind, crossover study of CCM signals with 164 patients with EF ≤35 percent and NYHA Class II (24 percent) or III (76 percent) symptoms who received a CCM pulse generator. After the 6-month treatment period, results indicated statistically significantly improved peak VO2 and MLWHFQ (p = 0.03 for each parameter), concluding that CCM signals appear to be safe for patients and that exercise tolerance and quality of life were significantly better while patients were receiving active CCM treatment.[21]

A study was conducted with 68 consecutive heart failure patients with NYHA Class II or III symptoms, QRS duration ≤130 ms, and who had been implanted with a CCM device between May 2002 and July 2013 in Germany. Based upon pre-implant SHFM survival rates, 4.5 years mean follow-up, and an average patient age of 61 years old, the study found lower mortality rates for CCM therapy group with 0 percent at 1 year, 3.5 percent at 2 years, and 14.2 percent at 5 years, compared to 6.1 percent, 11.8 percent, and 27.7 percent predicted by SHFM, respectively (p = 0.007).[22] In a study on long-term outcomes, 41 consecutive heart failure patients with left ventricular ejection fraction (EF) < 40 percent receiving CCM therapy were compared to a control group of 41 similar heart failure patients and primarily evaluated for all-cause mortality, as well as heart failure hospitalization, cardiovascular death, and a death and heart failure hospitalization composite. After 6 years of follow-up, the results showed that all-cause mortality was lower for the CCM group as compared to the control group (39 percent versus 71 percent respectively, p = 0.001), especially among patients with EF ≥ 25–40 percent with 36 percent for the CCM group versus 80 percent for the control group (p <0.001). Although heart failure hospitalization was similar between the treatment and control cohorts, there was a significantly lower heart failure hospitalization rate for CCM patients with EF ≥ 25–40 percent (36 percent versus 64 percent respectively, p = 0.005).[23] The applicant also presented additional studies[24] [25] that presented similar conclusions to the studies discussed above, noting that CCM therapy provided improvements in quality of life, exercise capacity, NYHA class, and mortality rates.

[18] *https://www.accessdata.fda.gov/cdrh_docs/pdf18/P180036B.pdf.*

[19] Abraham, W. T., Kuck, K. H., Goldsmith, R. L., Lindenfeld, J., Reddy, V. Y., Carson, P. E., . & Wiegn, P. (2018). A randomized controlled trial to evaluate the safety and efficacy of cardiac contractility modulation. JACC: Heart Failure, 6(10), 874–883.

[20] Anker, S. D., Borggrefe, M., Neuser, H., Ohlow, M. A., Röger, S., Goette, A., . & Rousso, B. Cardiac contractility modulation improves long-term survival and hospitalizations in heart failure with reduced ejection fraction. *Eur J Heart Fail* .2019 Jan 16. doi: 10.1002/ejhf.1374. [Epub ahead of print]

[21] Borggrefe MM, Lawo T, Butter C, Schmidinger H, Lunati M, Pieske B, Misier AR, Curnis A, Bocker D, Remppis A, Kautzner J, Stuhlinger M, Leclerq C, Taborsky M, Frigerio M, Parides M, Burkhoff D and Hindricks G. Randomized, double blind study of non-excitatory, cardiac contractility modulation electrical impulses for symptomatic heart failure. *Eur Heart J.* 2008;29:1019–28.

[22] Kloppe A, Lawo T, Mijic D, et al. Long-term survival with Cardiac Contractility Modulation in patients with NYHA II or III symptoms and normal QRS duration. *Int J Cardiol.* 2016 Apr 15;209:291–5.

[23] Liu M, Fang F, Luo XX, Shlomo BH, Burkhoff D, Chan JY, Chan CP, Cheung L, Rousso B, Gutterman D, Yu CM. Improvement of long-term survival by cardiac contractility modulation in heart failure patients: A case-control study. *Int J Cardiol.* 2016 Mar 1;206:122–6.

[24] Müller D, Remppis A, Schauerte P, et al. Clinical effects of long-term cardiac contractility modulation (CCM) in subjects with heart failure caused by left ventricular systolic dysfunction. *Clin Res. Cardiol. 2017 Nov 1;106(11):893–904.*

[25] Kuschyk J, Roeger S, Schneider R, et al. Efficacy and survival in patients with cardiac contractility modulation: Long-term single center experience in 81 patients. *Int J Cardiol.* 2015;183C:76–81.

We noted several concerns with the studies presented by the applicant. One concern regarding the evidence for the Optimizer® System involves the mixed mortality outcomes presented. Three studies showed significantly lower mortality rates with the use of CCM compared to controls or predicted mortality. Each of these studies focused on slightly different mortality outcomes, including all-cause mortality, a composite of death and heart failure hospitalization, and cardiac mortality rates from 1 to 5 years. Two studies show mixed results. For the first, 3-year survival was not significant for the overall population, despite a significantly higher survival rate found in a subpopulation. For the second, mortality rates were significant compared to predictions at 1 year, but not 3 years. The final study did not report significance in its overall survival at 2 years. Although the studies and trials presented show improvements in mortality when evaluating CCM therapy with comparators, the studies have small sample sizes and limited timeframes for measuring survival. Additionally, three studies compared observed mortality rates to statistically projected mortality rates. In the two studies with observed mortality rates, the overall improvement in mortality was not significant, despite some significance found in subanalyses. These issues raise concerns about the strength of the conclusions related to the use of CCM therapy improving patient outcomes.

Another concern with the studies presented for the Optimizer® System is that the included study population may not be necessarily representative of the Medicare beneficiary population. Several studies had a predominantly white, male patient population, which could make generalization of study results to a more diverse Medicare population difficult. Additionally, the average age of patients for several studies was under 65 years old, which may also be a limitation in applying these study results to the Medicare population.

Overall, we were concerned that there was a lack of evidence from large trials for the CCM therapy provided by the Optimizer® System. The studies presented had sample sizes fewer than 500 patients. Other limitations include the potential placebo effects and selection bias that may have impacted study results. Only two studies presented were randomized and only one of those two was a double-blinded study. For the remaining studies, no blinding occurred to minimize potential biases, which indicates that patients and researchers knew they were receiving CCM therapy. This is a limitation because observed outcomes may be impacted by the placebo effect. Although most studies matched participants for similar demographics, there could be systematic differences and unmeasured bias between the two groups beyond the similarities addressed in the study that could affect outcomes. The lack of randomization may have implications for the strength of the studies' conclusions.

Based upon the evidence presented, we invited public comments on whether the Optimizer® System meets the substantial clinical improvement criterion.

Comment: The manufacturer responded to several statements regarding Optimizer® System and substantial clinical improvement in the CY 2020 OPPS/ASC proposed rule, and asserted that Optimizer® System meets the substantial clinical improvement criterion. The manufacturer noted that a mortality benefit cannot be claimed based on currently published data but that the Optimizer® System does not appear to have a negative impact on mortality. The manufacturer acknowledged that male patients and those that identify as white were prevalent in the Optimizer System studies but contended that for clinical trials in general, and for heart failure specifically, these groups are typically over-represented. They presented several examples of cardiac device and pharmaceutical clinical trials for the treatment of heart failure, where a similar mix of patients in terms of gender and race existed across unrelated trials and therapies. In response to the concern that the average age of patients for several studies was under 65 years old, limiting the application of the study results to the Medicare population, the manufacturer conducted additional analyses on patients aged 65 and older. The analysis showed that the two populations were not dissimilar, and the manufacturer believes the clinical trial results are applicable to the Medicare patient population.

The manufacturer presented data to demonstrate that the Optimizer® System delivers substantial clinical improvement in terms of improved functional status, quality of life, and exercise tolerance. In response to the concern regarding clinical trials enrolling sample sizes fewer than 500 patients, the manufacturer noted that there were 638 subjects enrolled and implanted with the Optimizer System in the U.S. randomized trials and that trials of this size are common in Class III medical device trials, which are tailored for gathering the required evidence to support FDA approval of novel technology. Regarding the concern about the lack of randomization and blinding in studies presented, the manufacturer noted that four out of the six studies were randomized, and two of the four were also blinded with both the control and the treatment group receiving the device.

Response: We appreciate the response to the questions we had regarding Optimizer® System. After reviewing the additional information provided during the public comment period, we agree that, for patients with NYHA Class III heart failure patients who remain symptomatic despite guideline directed medical therapy, who are in normal sinus rhythm, are not indicated for Cardiac Resynchronization Therapy, and have a left ventricular ejection fraction ranging from 25 percent to 45 percent, Optimizer® System is a substantial clinical improvement over existing treatment options for this population. The provided studies support improvements in functional status, quality of life, and exercise tolerance, all of which are relevant outcomes in this population. While the studies describe improved survival in a subset of patients and substantially reduced hospitalizations, the numbers are small, the observation period is short, and the data on readmissions are not specifically highlighted. However, we accept the manufacturer's note that while mortality benefit cannot be claimed based on currently published data, the Optimizer® System does not appear to have a negative impact on mortality.

Accordingly, we have determined that the Optimizer® System has demonstrated substantial clinical improvement relative to existing treatment options for patients diagnosed with moderate to severe chronic heart failure. As the Optimizer® System received a Breakthrough Device designation from FDA, it meets the substantial clinical improvement criterion under this alternative pathway as well.

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 Optimizer® System would be reported with CPT codes 0408T, 0409T, 0410T, 0411T, 0412T, 0413T, 0414T, 0415T, 0416T,

0417T, and 0418T. The associated APCs are APC 5231 (Level 1 ICD and Similar Procedures) and APC 5222 (Level 2 Pacemaker and Similar 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 5222, which had a CY 2019 payment rate of $7,404.11 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 0410T had a device offset amount of $2,295.27 at the time the application was received. According to the applicant, the cost of the Optimizer® System was $15,700.

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 $15,700 for the Optimizer® System exceeds 212 percent of the applicable APC payment amount for the service related to the category of devices of $7,404.11 ($15,700/$7,404.11 × 100 = 212 percent). Therefore, we believe the Optimizer® 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 $15,700 for the Optimizer® System exceeds the cost of the device-related portion of the APC payment amount for the related service of $2,295.27 by 684 percent ($15,700/$2,295.27) × 100 = 684 percent. Therefore, we believe that the Optimizer® 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 $15,700 for the Optimizer® System and the portion of the APC payment amount for the device of $2,295.27 exceeds the APC payment amount for the related service of $7,404.11 by 181 percent (($15,700 − $2,295.27)/$7,404.11) × 100 = 181 percent). Therefore, we believe that the Optimizer® System meets the third cost significance requirement.

We invited public comments on whether the Optimizer® System meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

Comment: The manufacturer of the Optimizer® System believed that the device meets the cost criterion for device pass-through payment status. The manufacturer noted a point of clarification regarding the average sales price (ASP) of the Optimizer® System used for these calculations. They stated that the $15,700 price in the application was based on discounted clinical trial pricing used during the FDA IDE clinical trials to cover the manufacturing and research costs only. After FDA approval on March 21, 2019, commercial pricing took effect, changing the Optimizer® System to $23,000. The manufacturer contended the Cost Criteria are still met with the current $23,000 ASP for the Optimizer Smart System.

Response: We appreciate the manufacturer's input. After consideration of the public comments we received, we believe that Optimizer® System meets the cost criterion for device pass-through payment status.

After consideration of the public comments we received, we believe that the Optimizer® System qualifies for device pass-through payment status and we are approving the application for device pass-through payment status for the Optimizer® System beginning in CY 2020.

(5) AquaBeam® System

PROCEPT BioRobotics Corporation submitted an application for a new device category for transitional pass-through payment status for the AquaBeam® System as a resubmission of their CY 2019 application. The AquaBeam® System is intended for the resection and removal of prostate tissue in males suffering from lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH). The applicant stated that this is a very common condition typically occurring in elderly men. The clinical symptoms of this condition can include diminished urinary stream and partial urethral obstruction.[26] According to the applicant, the AquaBeam® system resects the prostate to relieve symptoms of urethral compression. The resection is performed robotically using a high velocity, nonheated sterile saline water jet (in a procedure called Aquablation). The applicant stated that the AquaBeam® System utilizes real-time intra-operative ultrasound guidance to allow the surgeon to precisely plan the surgical resection area of the prostate and then the system delivers Aquablation therapy to accurately resect the obstructive prostate tissue without the use of heat. The materials submitted by the applicant state that the AquaBeam® System consists of a disposable, single-use handpiece as well as other components that are considered capital equipment.

With respect to the newness criterion at § 419.66(b)(1), FDA granted a De Novo request classifying the AquaBeam® System as a Class II device under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act on December 21, 2017. The application for a new device category for transitional pass-through payment status for the AquaBeam® System was received on March 1, 2018, which is within 3 years of the date of the initial FDA approval or clearance. We invited public comments on whether the AquaBeam® System meets the newness criterion. We did not receive any comments on the newness of the AquaBeam® System. We believe AquaBeam® System meets the transitional pass-through payment newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the AquaBeam® System 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 the AquaBeam® System meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or items for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. However, in the CY 2019 OPPS/ASC proposed and final rules, we cited the CY 2000 OPPS interim final rule with comment period (65 FR 67804 through 67805), where we explained how we interpreted § 419.43(e)(4)(iv). We stated that we consider a device to be surgically implanted or inserted if is surgically inserted or implanted via a natural or surgically created orifice, or inserted or implanted via a surgically created incision. We also stated that we do not consider an item used to cut or otherwise create a surgical opening to be

[26] Chungtai B. Forde JC. Thomas DDM et al. Benign Prostatic Hyperplasia. Nature Reviews Disease Primers 2 (2016) article 16031.

a device that is surgically implanted or inserted. We consider items used to create incisions, such as scalpels, electrocautery units, biopsy apparatuses, or other commonly used operating room instruments to be supplies or capital equipment not eligible for transitional pass-through payments. We stated that we believe the function of these items is different and distinct from that of devices that are used for surgical implantation or insertion. Finally, we stated that, generally, we would expect that surgical implantation or insertion of a device occurs after the surgeon uses certain primary tools, supplies, or instruments to create the surgical path or site for implanting the device. In the CY 2006 OPPS final rule with comment period (70 FR 68329 and 68630), we adopted as final our interpretation that surgical insertion or implantation criteria include devices that are surgically inserted or implanted via a natural or surgically created orifice, as well as those devices that are inserted or implanted via a surgically created incision. We reiterated that we maintain all of the other criteria in § 419.66 of the regulations, namely, that we do not consider an item used to cut or otherwise create a surgical opening to be a device that is surgically implanted or inserted.

The applicant resubmitted their application with additional information that they believe supports their stance that the device should be considered eligible under the device pass-through payment eligibility criteria. The applicant stated that the AquaBeam® System's handpiece is temporarily surgically inserted into the urethra via the urinary meatus. The applicant indicated that the AquaBeam® System's handpiece does not create an incision or surgical opening or pathway, but instead ablates prostate tissue. The applicant further stated that the device only cuts the prostatic tissue after being inserted into the prostatic urethra and therefore it should be considered eligible. The applicant also stated that the prostatic urethra tissue is cut because it is at the center of the obstruction in the prostate. Additionally, the applicant explained that to relieve the symptoms of BPH, both the prostatic urethra and prostate tissue encircling the prostatic urethra must be ablated, or cut, to relieve the symptoms of BPH and provide some additional clearance for future swelling or growth of the prostate. The applicant stated that the prostatic urethra tissue is not cut or disturbed to access the prostate tissue underneath, but the removal of the prostatic urethra is a key aspect of treating the obstruction that causes BPH symptoms. Finally, the applicant believes that clinically the distinction between the prostatic urethra tissue and the prostate tissue are not meaningful in the context of a BPH surgical intervention. We invited public comments on whether the AquaBeam® System meets the eligibility criteria at § 419.66(b).

Comments: We received several comments in regards to the eligibility of the AquaBeam® System. While other stakeholders commented generally on the eligibility of the AquaBeam® System, the applicant provided additional detail in support of AquaBeam's eligibility. Stakeholders agreed that AquaBeam® System was eligible, and providing the following reasons: AquaBeam® System is not used to cut or otherwise create a surgical opening; the AquaBeam System handpiece is not a commonly used operation room instrument; the AquaBeam System handpiece is integral to the service provided; it is a single use item; it comes into contact with human tissue and finally, it is inserted into the prostatic urethra through a natural orifice.

The applicant restated that the AquaBeam® System does not cut or otherwise create a surgical opening. They reiterated that the AquaBeam® System is inserted into the body through a natural orifice at the meatus of the urethra without any cutting. The applicant again stated that the AquaBeam® System is not used to cut or otherwise create a surgical opening at the meatus, or the prostatic urethra. The applicant further detailed that the purpose of the ablation procedure is to remove the tissue that is obstructing urine flow through the urethra as well as to remove additional tissue that may obstruct the urethra causing LUTS. The applicant claimed that the removal of the obstruction is not the creation of a surgical opening for inserting the device and that the device is already positioned inside the body.

The applicant further argued that ablating both the prostatic urethra and the prostate tissue is central to the treatment of BPH symptoms. Additionally, they argued that clinically, the distinction between the prostatic urethra and the prostate tissue are not meaningful to treat BPH and the procedure does not create an opening at the urethra to access the prostate for tissue removal. The applicant further argued that the plain meaning of the language used to expand eligibility to include devices inserted through natural orifices [27] means that passing the AquaBeam® System through the natural orifice into the body is taking the place of creating a surgical opening.

Response: We appreciate the comments submitted by the stakeholders on the eligibility of the AquaBeam® System. After consideration of submitted comments and after gaining additional clarity on the clinical details of the procedure, we have determined that the AquaBeam® System meets the eligibility criteria at § 419.66(b). Specifically, we believe that the AquaBeam® System is inserted into the urethra, a natural orifice. We recognize that after being inserted into the urethra, the device then ablates both the prostatic urethra and the prostate tissue in order to relieve and treat the symptoms of BPH.

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. In the proposed rule, we had not identified an existing pass-through payment category that describes the AquaBeam® System. The applicant proposed a category descriptor for the AquaBeam® System of ''Probe, image guided, robotic resection of prostate.'' We invited public comments on whether the AquaBeam® System meets this criterion.

We did not receive public comments that identified an existing pass-through payment category that describes the AquaBeam® System. We believe that the AquaBeam® System meets this criterion.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines 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. The applicant stated that the AquaBeam® System provides a substantial clinical improvement as the first autonomous tissue resection robot for the treatment of lower urinary tract symptoms due to BPH. The applicant further provided that the AquaBeam® System is also a substantial clinical improvement because the Aquablation procedure demonstrated superior

[27] 70 FR 68630.

efficacy and safety for larger prostates (prostates sized 50–80 mL) as compared to transurethral resection of the prostate (TURP). The applicant also believes that the Aquablation procedure would provide better outcomes for patients with large prostates (>80 mL) who may undergo open prostatectomy whereas the open prostatectomy procedure would require a hospital inpatient admission. With respect to this criterion, the applicant submitted several articles that examined the use of a current standard treatment for BPH—transurethral prostatectomy TURP, including complications associated with the procedure and the comparison of the effectiveness of TURP to other modalities used to treat BPH, including holmium laser enucleation of the prostate (HoLEP) [28] and photoselective vaporization (PVP).[29]

The most recent clinical study involving the AquaBeam® System was an accepted manuscript describing a double-blind trial that compared men treated with the AquaBeam® System versus men treated with traditional TURP.[30] This was a multicenter study in 4 countries with 17 sites, 6 of which contributed 5 patients or fewer. Patients were randomized to receive treatment with either the AquaBeam® System or TURP in a two-to-one ratio. With exclusions and dropouts, 117 patients were treated with the AquaBeam® System and 67 patients with TURP. The data on efficacy supported the equivalence of the two procedures based upon noninferiority analysis. The safety data were reported as showing superiority of the AquaBeam® System over TURP, although the data were difficult to track because adverse consequences were combined into categories. The applicant claimed that the International Prostate Symptom Scores (IPPS) were significantly improved in AquaBeam® System patients as compared to TURP patients in men whose prostate was greater the 50 mL in size. The applicant also claimed that the proportion of men with a worsening of sexual function (as shown with a decrease in Male Sexual Health Questionnaire for Ejaculatory Dysfunction (MSHQ) score of at least 2 points or a decrease in International Index of Erectile Function (IIEF–5) score of at least 6 points by 6 months) was lower for the Aquablation procedure at 32.9 percent compared to the TURP groups at 52.8 percent.

In the CY 2020 OPPS/ASC proposed rule, we stated that we believed that the comparison of the AquaBeam® System with TURP does not recognize that there are other treatment modalities available that are likely to have a similar safety profile as the AquaBeam® System. No studies comparing other treatment modalities were cited to show that the AquaBeam® System is a significant improvement over other available procedures.

Based on the evidence submitted with the application, we were concerned that there was a lack of sufficient evidence that the AquaBeam® System provides a substantial clinical improvement over other similar products, particularly in the outpatient setting where large prostates are less likely to be treated. We invited public comments on whether the AquaBeam® System meets the substantial clinical improvement criterion.

Comment: We received several comments regarding the substantial clinical improvement that the AquaBeam® System may provide. They were concerned that the comparison of the AquaBeam® System with TURP does not recognize that there are other treatment modalities available that are likely to have a similar safety profile as the AquaBeam® System and that there were no studies provided comparing other treatment modalities to show that the AquaBeam® System is a significant improvement over other available procedures.

The applicant commented that in the FY 2019 IPPS notice of final rulemaking, CMS concluded that the WATER study findings were statistically significant and showed Aquablation superior to TURP in safety, as well as that patients in the WATER study with prostates larger than 50 mL in volume treated with Aquablation had superior improvement in quantifiable symptom outcomes.

Additionally, the applicant provided that TURP is the gold standard and most common treatment for LUTS due to BPH and that through a direct comparison to TURP, the WATER study demonstrates that the AquaBeam® System is a substantial clinical improvement over the gold standard. The applicant also provides that the direct comparison to TURP in the WATER study allows a comparison of Aquablation to other treatment modalities, including transurethral incision of the prostate, photoselective vaporization prostatectomy, transurethral needle ablation of the prostate, transurethral microwave therapy, and prostatic urethral lift. The applicant included several additional pieces of clinical literature to demonstrate that the above-mentioned modalties are inferior in efficacy to TURP in numerous objective and subjective measurers, including peak urine flow, post-void reduction, and BPH symptom reduction.[31] [32] [33]

Additionally, the applicant provided published data on a list of all surgical treatment modalities. The applicant claims that based on this provided data it is evident that larger prostates are a clinical challenge for all other transurethral surgical approaches to BPH due to high rates of sexual dysfunction in TURP, SP, PVP, HoLEP, and ThuLEP; high rates of blood transfusions in TURP and SP; longer operative time due to the size of prostate in PVP, HoLEP, and ThuLEP; transurethral resection (TUR) syndrome due to length of procedure; high rates of re-intervention or secondary procedures in PVP; and, transient incontinence in HoLEP and ThuLEP. The applicant states that these complication have traditionally limited the treatment of larger prostates in the outpatient setting. The applicant further details that the reason for the increase in complications in large prostates is due to the length of the resection time required. In support of their claim of being appropriate for the outpatient study, the applicant restates findings from the WATER II study, which utilized Aquablation therapy to treat large prostates 80 to 150 mL in volume, with greater than 50 percent of the cases involving large prostates in the hospital outpatient setting. The average Aquablation operative time was 37 minutes, including 8 minutes of resection time and 29 minutes used for planning and robotic programming.

Response: We appreciate the submission of public comments.

[28] Montorsi, F. et al.: Holmium Laser Enucleation Versus Transurethral Resection of The Prostate: Results from A 2-Center, Prospective, Randomized Trial In Patients With Obstructive Benign Prostatic Hyperplasia. *J. Urol.* 172, 1926–1929 (2004).

[29] Bachmann A, et al.: 180–W XPS GreenLight laser vaporisation versus transurethral resection of the prostate for the treatment of benign prostatic obstruction: 6-month safety and efficacy results of a European Multicentre Randomised Trial—the GOLIATH study. *Eur Urol,* 2014;65(5):931–42.

[30] Gilling P. Barber M. Anderson P et al.: WATER—A Double-Blind Randomized Controlled Trial of Aquablation vs Transurethal Resection of the Prostate in Benign Prostatic Hyperplasia. *J Urol.* Accepted December 29, 2017 doi 10.1016/j.juro.2017.12.065.

[31] Christidis, D. et al. Minimally Invasive Therapies for Benign Prostatic Hypertrophy: The Rise in Minimally Invasive Surgical Therapies, Prostate International. 5, 41–46 (2017).

[32] Bachmann A, Tubaro A, Barber N et al: 180–W XPS GreenLight laser vaporisation versus transurethral resection of the prostate for the treatment of benign prostatic obstruction: 6-month safety and efficacy results of a European multicenter randomised trial—the GOLIATH study. Eur Urol 2014; 65: 931.

[33] Sonksen J et al. Prospective, Randomized, Multinational Study of Prostatic Urethral Lift Versus Transurethral Resection of the Prostate: 12-month Results from the BPH6 Study. Eur Urol 2015; 68:643–52.

Specifically, we appreciate the additional scientific data provided that demonstrates the AquaBeam® System's superiority to other techniques, specifically for reducing operative time and complications in general, especially for larger prostates. We agree that the results of the WATER study are statistically significant with a 95 percent confidence interval of the difference between AquaBeam® and TURP and show AquaBeam® is superior to TURP in safety as evidenced by a lower proportion of persistent Clavien-Dindo (CD) Grade 1 adverse events (incontinence, ejaculatory dysfunction and erectile dysfunction) at 3 months. We also agree that when considering CD Grade 2 and above events (events requiring pharmacological treatment, blood transfusions, or endoscopic, surgical or radiological interventions) the WATER study demonstrated a superior safety rate to TURP. Additionally, patients enrolled in the WATER study with prostate sizes greater than 50 mL in volume and treated with AquaBeam® had superior BPH symptom reduction (IPSS) than those treated with TURP, as well as better peak urinary flow rates at 6 months (Qmax), improved ejaculatory function, and improved incontinence scores at 3 months.

Additionally, results from the WATER II study for patients with large prostates demonstrate better outcomes of the AquaBeam® System over open prostatectomy, regarding shorter operative time, shorter length of stay, and decreased rates of severe hemorrhage and transfusions. We also agree that the minimally invasive nature of Aquablation offers men with large prostates (>80 mL) an outpatient option. In conclusion, after review of the additional data and literature, we agree that the AquaBeam® System provides a 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 AquaBeam® System would be reported with CPT code 0421T. CPT code 0421T is assigned to APC 5375 (Level 5 Urology and Related Services). 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 5375, which has a CY 2018 payment rate of $3,706.03. 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 0421T had device offset amount of $0.00 at the time the application was received. According to the applicant, the cost of the handpiece for the AquaBeam® System 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 the AquaBeam® System exceeds 25 percent of the applicable APC payment amount for the service related to the category of devices of $3,706.03 ($2,500/$3,706.03 × 100 = 67.5 percent). Therefore, we believe the AquaBeam® 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). Given that there are no device-related costs in the APC payment amount and the AquaBeam® System has an estimated average reasonable cost of $2,500, we believe that the AquaBeam® 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 $2,500 for the AquaBeam® System and the portion of the APC payment amount for the device of $0.00 exceeds the APC payment amount for the related service of $3,706.03 by 68 percent (($2,500 − $0.00)/$3,706.03 × 100 = 67.5 percent). Therefore, we believe that the AquaBeam® System meets the third cost significance requirement.

We invited public comments on whether the AquaBeam® System meets the device pass-through payment criteria discussed in this section, including the cost criterion.

Comment: The manufacturer believed that the AquaBeam® System meets the device pass-through payment criteria, including the cost criterion.

Response: We thank the manufacturer for their input. After consideration of the public comments we received, we believe the AquaBeam® System meets the cost criterion and we are approving it for device pass-through payment status beginning in CY 2020.

(6) Eluvia™ Drug-Eluting Vascular Stent System

Boston Scientific Corporation submitted an application for new technology add-on payments for the Eluvia™ Drug-Eluting Vascular Stent System for FY 2020. According to the applicant, the Eluvia™ system is a sustained-release drug-eluting stent indicated for improving luminal diameter in the treatment of peripheral artery disease (PAD) with symptomatic de novo or restenotic lesions in the native superficial femoral artery (SFA) and/or the proximal popliteal artery (PPA) with reference vessel diameters (RVD) ranging from 4.0 to 6.0 mm and total lesion lengths up to 190 mm.

The applicant stated that PAD is a circulatory condition in which narrowed arteries reduce blood flow to the limbs, usually in the legs. Symptoms of PAD may include lower extremity pain due to varying degrees of ischemia, claudication which is characterized by pain induced by exercise and relieved with rest. According to the applicant, risk factors for PAD include individuals who are age 70 years old and older; individuals who are between the ages of 50 years old and 69 years old with a history of smoking or diabetes; individuals who are between the ages of 40 years old and 49 years old with diabetes and at least one other risk factor for atherosclerosis; leg symptoms suggestive of claudication with exertion, or ischemic pain at rest; abnormal lower extremity pulse examination; known atherosclerosis at other sites (for example, coronary, carotid, renal artery disease); smoking; hypertension, hyperlipidemia, and homocysteinemia.[34] PAD is primarily caused by atherosclerosis—the buildup of fatty plaque in the arteries. PAD can occur in any blood vessel, but it is more common in the legs than the arms. Approximately 8.5 million people in the U.S. have PAD, including 12 to 20

[34] Neschis, David G. & MD, Golden, M., ''Clinical features and diagnosis of lower extremity peripheral artery disease.'' Available at: *https://www.uptodate.com/contents/clinical-features-and-diagnosis-of-lower-extremity-peripheral-artery-disease.*

percent of individuals who are age 60 years old and older.[35]

Management of the disease is aimed at improving symptoms, improving functional capacity, and preventing amputations and death. Management of patients who have been diagnosed with lower extremity PAD may include medical therapies to reduce the risk for future cardiovascular events related to atherosclerosis, such as myocardial infarction, stroke, and peripheral arterial thrombosis. Such therapies may include antiplatelet therapy, smoking cessation, lipid-lowering therapy, and treatment of diabetes and hypertension. For patients with significant or disabling symptoms unresponsive to lifestyle adjustment and pharmacologic therapy, intervention (percutaneous, surgical) may be needed. Surgical intervention includes angioplasty, a procedure in which a balloon-tip catheter is inserted into the artery and inflated to dilate the narrowed artery lumen. The balloon is then deflated and removed with the catheter. For patients with limb-threatening ischemia (for example, pain while at rest and/or ulceration), revascularization is a priority to reestablish arterial blood flow. According to the applicant, treatment of the SFA is problematic due to multiple issues including high rate of restenosis and significant forces of compression.

The applicant describes the Eluvia™ Drug-Eluting Vascular Stent System as a sustained-release drug-eluting self-expanding, nickel titanium alloy (nitinol) mesh stent used to reestablish blood flow to stenotic arteries. According to the applicant, the Eluvia™ stent is coated with the drug paclitaxel, which helps prevent the artery from restenosis. The applicant stated that Eluvia™'s polymer-based drug delivery system is uniquely designed to sustain the release of paclitaxel beyond 1 year to match the restenotic process in the SFA. According to the applicant, the Eluvia™ Drug-Eluting Vascular Stent System is comprised of: (1) The implantable endoprosthesis; and (2) the stent delivery system (SDS). On both the proximal and distal ends of the stent, radiopaque markers made of tantalum increase visibility of the stent to aid in placement. The tri-axial designed delivery system consists of an outer shaft to stabilize the stent delivery system, a middle shaft to protect and constrain the stent, and an inner shaft to provide a guide wire lumen. The delivery system is compatible with 0.035 in (0.89 mm) guide wires. The Eluvia™ stent is available in a variety of diameters and lengths. The delivery system is offered in 2 working lengths (75 cm and 130 cm).

With respect to the newness criterion at § 419.66(b)(1), Eluvia™ received FDA premarket approval (PMA) on September 18, 2018. The application for a new device category for transitional pass-through payment status for Eluvia™ was received on November 15, 2018, which is within 3 years of the date of the initial FDA approval or clearance. We invited public comments on whether the Eluvia™ Drug-Eluting Vascular Stent System meets the newness criterion. We did not receive public comments in regards to Eluvia's newness, however, since the application was received within 3 years of the initial date of FDA approval or clearance, we believe that the Eluvia™ Drug-Eluting Vascular Stent System meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the Eluvia™ Drug-Eluting Vascular Stent System 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 the Eluvia™ Drug-Eluting Vascular Stent System meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or items for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. We invited public comments on whether the Eluvia™ Drug-Eluting Vascular Stent System meets the eligibility criterion at § 419.66(b).

We did not receive any public comments on this issue. We believe that Eluvia™ Drug-Eluting Vascular Stent System meets the eligibility criterion.

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 have not identified an existing pass-through payment category that describes the Eluvia™ Drug-Eluting Vascular Stent System. The applicant proposed a category descriptor for the Eluvia™ Drug-Eluting Vascular Stent System of ''Stent, non-coronary, polymer matrix, minimum 12-month sustained drug release, with delivery system.'' We invited public comments on this issue.

Comment: One commenter stated that the stent platform, the drug coating, and the polymer coating of the Eluvia™ Drug-Eluting Vascular Stent System are not new. The commenter compared Eluvia™ to the Zilver PTX drug-eluting stent, arguing that both are self-expanding nitinol stents coated with paclitaxel. The commenter also compared the underlying stent platform and delivery system of Eluvia™ to Boston Scientific's Innova self-expanding stent.[36] Finally, the commenter believed that the polymers used in the Eluvia™ coating are the same used in the Xience V and Promus Element coronary stents.[37]

Comment: Another commenter, the manufacturer, restated that they are vastly different than the Zilver PTX drug eluting stent, as well as any other device. The commenter provided that Eluvia's polymer matrix layer is different from the paclitaxel-coated Zilver PTX, and allows for targeted, localized, sustained, low-dose amorphous paclitaxel delivery with minimal systemic distribution or particulate loss. The commenter also states that there is a difference in the diffusion gradient: Paclitaxel is delivered to the lesion via a diffusion gradient with poly(vinylidene fluoride)-co-hexafluoropropylene, whereas they state that the Zilver PTX does not have a diffusion gradient. The commenter stated that Eluvia™ releases paclitaxel directly to the target lesion, while Zilver PTX release is non-specific to the target lesion. The commenter also stated that Eluvia releases paclitaxel over approximately 12 to 15 months, while Zilver PTX's release is complete at two months. The commenter stated that these significant differences in the device designs impact drug dose, drug release mechanism, and drug release kinetics.

Response: We appreciate the stakeholders' comments and comparison of the polymer matrix Eluvia™ versus the paclitaxel-coated Zilver PTX and several other devices. After consideration of the comments, we

[35] Centers for Disease Control and Prevention, ''Peripheral Arterial Disease (PAD) Fact Sheet,'' 2018, Available at: *https://www.cdc.gov/DHDSP/data_statistics/fact_sheets/fs_PAD.htm.*

[36] Gray W, et al. A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): a randomised, non-inferiority trial. Lancet; Published Online September 22, 2018; *http://dx.doi.org/10.1016/S0140-6736(18)32262-1.*

[37] Gray W, et al. A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): a randomised, non-inferiority trial. Lancet; Published Online September 22, 2018; *http://dx.doi.org/10.1016/S0140-6736(18)32262-1.*

believe that Eluvia™ device is a new design with a unique mechanism of action, and therefore is not described by any current device category. Therefore, the Eluvia™ device meets the device category eligibility criterion.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines 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. With respect to this criterion, the applicant submitted several articles that examined the use of a current standard treatment for peripheral artery disease (PAD) with symptomatic de novo or restenotic lesions in the native superficial femoral artery (SFA) and/or proximal popliteal artery (PPA), with claims of substantial clinical improvement in achieving superior primary patency; reducing the rate of subsequent therapeutic interventions; decreasing the number of future hospitalizations or physician visits; reducing hospital readmission rates; reducing the rate of device-related complications; and achieving similar functional outcomes and EQ–5D index values while associated with half the rate of target lesion revascularizations (TLRs) procedures.

The applicant submitted the results of the MAJESTIC study, a single-arm, first-in-human study of the Eluvia™ Drug-Eluting Vascular Stent System. The MAJESTICT [38] study is a prospective, multi-center, single-arm, open-label study. According to the applicant, the MAJESTIC study demonstrated long-term treatment durability among patients whose femoropopliteal arteries were treated with the Eluvia™ stent. The applicant asserted that the MAJESTIC study demonstrates the sustained impact of the Eluvia™ stent on primary patency. The MAJESTIC study enrolled 57 patients who had been diagnosed with symptomatic lower limb ischemia and lesions in the SAF or PPA. Efficacy measures at 2 years included primary patency, defined as duplex ultrasound peak systolic velocity ratio of less than 2.5 and the absence of TLR or bypass. Safety monitoring through 3 years included adverse events and TLR. The 24-month clinic visit was completed by 53 patients; 52 had Doppler ultrasound evaluable by the core laboratory, and 48 patients had radiographs taken for stent fracture analysis. The 3-year follow-up was completed by 54 patients. At 2 years, 90.6 percent (48/53) of the patients had improved by 1 or more Rutherford categories as compared with the pre-procedure level without the need for TLR (when those with TLR were included, 96.2 percent sustained improvement); only 1 patient exhibited a worsening in level, 66.0 percent (35/53) of the patients exhibited no symptoms (Category 0) and 24.5 percent (13/53) had mild claudication (Category 1) at the 24-month visit. Mean ABI improved from 0.73 ± 0.22 at baseline to 1.02 ± 0.20 at 12 months and 0.93 ± 0.26 at 24 months. At 24 months, 79.2 percent (38/48) of the patients had an ABI increase of at least 0.1 compared with baseline or had reached an ABI of at least 0.9. The applicant also noted that at 12 months the Kaplan–Meier estimate of primary patency was 96.4 percent.

With regard to the Eluvia™ stent achieving superior primary patency, the applicant submitted the results of the IMPERIAL [39] study in which the Eluvia™ stent is compared, head-to-head, to the Zilver® PTX Drug-Eluting stent. The IMPERIAL study is a global, multi-center, randomized controlled trial consisting of 465 subjects. Eligible patients were aged 18 years old or older and had a diagnosis of symptomatic lower-limb ischaemia, defined as Rutherford Category 2, 3, or 4 and stenotic, restenotic (treated with a drug-coated balloon greater than 12 months before the study or standard percutaneous transluminal angioplasty only), or occlusive lesions in the native SFA or PPA, with at least 1 infrapopliteal vessel patent to the ankle or foot. Patients had to have stenosis of 70 percent or more (via angiographic assessment), vessel diameter between 4 mm and 6 mm, and total lesion length between 30 mm and 140 mm.

Patients who had previously stented target lesion/vessels treated with drug-coated balloon less than 12 months prior to randomization/enrollment and patients who had undergone prior surgery of the SFA/PPA in the target limb to treat atherosclerotic disease were excluded from the study. Two concurrent single-group (Eluvia™ only) substudies were done: A nonblinded, nonrandomized pharmacokinetic sub-study and a nonblinded, nonrandomized study of patients who had been diagnosed with long lesions (greater than 140 mm in diameter).

The IMPERIAL study is a prospective, multi-center, single-blinded randomized, controlled (RCT) noninferiority trial. Patients were randomized (2:1) to implantation of either a paclitaxel-eluting polymer stent (Eluvia™) or a paclitaxel-coated stent (Zilver® PTX) after the treating physician had successfully crossed the target lesion with a guide wire. The primary endpoints of the study are Major Adverse Events defined as all causes of death through 1 month, Target Limb Major Amputation through 12 months and/or Target Lesion Revascularization (TLR) procedure through 12 months and primary vessel patency at 12 months post-procedure. Secondary endpoints included the Rutherford categorization, Walking Impairment Questionnaire, and EQ–5D assessments at 1 month, 6 months, and 12 months post-procedure. Patient demographic and characteristics were balanced between the Eluvia™ stent and Zilver® PTX stent groups.

The applicant noted that lesion characteristics for the patients in the Eluvia™ stent versus the Zilver® PTX stent arms were comparable. Clinical follow-up visits related to the study were scheduled for 1 month, 6 months, and 12 months after the procedure, with follow-up planned to continue through 5 years, including clinical visits at 24 months and 5 years and clinical or telephone follow-up at 3 and 4 years.

The applicant asserted that in the IMPERIAL study the Eluvia™ stent demonstrated superior primary patency over the Zilver® PTX stent, 86.8 percent versus 77.5 percent, respectively (p = 0.0144). The noninferiority primary efficacy endpoint was also met. The applicant provided that the superior primary patency results at the SFA are notable because the SFA presents unique challenges with respect to maintaining long-term patency. There are distinct pathological differences between the SFA and coronary arteries. The SFA tends to have higher levels of calcification and chronic total occlusions when compared to coronary arteries. Following an intervention within the SFA, the SFA produces a healing response which often results in restenosis or re-narrowing of the arterial lumen. This cascade of events leading to restenosis starts with inflammation, followed by smooth muscle cell

[38] Müller-Hülsbeck, S., et al., ''Long-Term Results from the MAJESTIC Trial of the Eluvia Paclitaxel-Eluting Stent for Femoropopliteal Treatment: 3-Year Follow-up,'' *Cardiovasc Intervent Radiol,* December 2017, vol. 40(12), pp. 1832–1838.

[39] Gray, W.A., et al., ''A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): a randomised, non-inferiority trial,'' *Lancet,* September 24, 2018.

proliferation and matrix formation.[40] Because of the unique mechanical forces in the SFA, this restenotic process of the SFA can continue well beyond 300 days from the initial intervention. Results from the IMPERIAL study showed that primary patency at 12 months, by Kaplan-Meier estimate, was significantly greater for Eluvia™ than for Zilver® PTX, 88.5 percent and 79.5 percent, respectively (p = 0.0119). According to the applicant, these results are consistent with the 96.4 percent primary patency rate at 12 months in the MAJESTIC study.

The IMPERIAL study included two concurrent single-group (Eluvia™ only) substudies: A nonblinded, nonrandomized pharmacokinetic substudy and a nonblinded, nonrandomized study of patients with long lesions (greater than 140 mm in diameter). For the pharmacokinetic sub-study, patients had venous blood drawn before stent implantation and at intervals ranging from 10 minutes to 24 hours post implantation, and again at either 48 hours or 72 hours post implantation. The pharmacokinetics sub-study confirmed that plasma paclitaxel concentrations after Eluvia™ stent implantation were well below thresholds associated with toxic effects in studies in patients who had been diagnosed with cancer (0·05 μM or ~43 ng/mL).

The IMPERIAL substudy long lesion subgroup consisted of 50 patients with average lesion length of 162.8 mm that were each treated with two Eluvia™ stents. According to the applicant, 12-month outcomes for the long lesion subgroup are 87 percent primary patency and 6.5 percent TLR. According to the applicant, in a separate subgroup analysis of patients 65 years old and older (Medicare population), the primary patency rate in the Eluvia™ stent group is 92.6 percent, compared to 75.0 percent for the Zilver® PTX stent group (p = 0.0386).

With regard to reducing the rate of subsequent therapeutic interventions, secondary outcomes in the IMPERIAL study included repeat re-intervention on the same lesion, referred to as target lesion revascularization (TLR), over the 12 months following the index procedure. The rate of subsequent interventions, or TLRs, in the Eluvia™ stent group was 4.5 percent compared to 9.0 percent in the Zilver® PTX stent group. The applicant asserted that the TLR rate in the Eluvia™ stent group represents a substantial reduction in reintervention on the target lesion compared to that of the Zilver® PTX stent group (at a p = 0.067 p-value). The Eluvia® stent group clinically driven TLR rates through 12 months following the index procedure were likewise lower for U.S. patients age 65 and older as well as for those with medically treated diabetes (confidential and unpublished as of the date of the device transitional pass-through payment application, data on file with Boston Scientific). In the subgroup of U.S. patients age 65 and older, the rates of TLR were 2.4 percent in the Eluvia™ group compared to 3.1 percent in the Zilver® PTX group, and in the subgroup of medically treated diabetes patients, the rates of TLR were 3.7 percent compared to 13.6 percent in the Zilver® PTX group (p = 0.0269).

With regard to decreasing the number of future hospitalizations or physician visits, the applicant asserted that the substantial reduction in the lesion revascularization rate led to a reduced need to provide additional intensive care, distinguishing the Eluvia™ stent group from the Zilver® PTX stent group. In the IMPERIAL study, the Eluvia™-treated patients required fewer days of re-hospitalization. Patients in the Eluvia™ group averaged 13.9 days of rehospitalization for all adverse events compared to 17.7 days of rehospitalization for patients in the Zilver® PTX stent group. Patients in the Eluvia™ group were rehospitalized for 2.8 days for TLR/Total Vessel Revascularization (TVR) compared to 7.1 days in the Zilver® PTX stent group. Lastly, patients in the Eluvia™ stent group were rehospitalized for 2.7 days for procedure/device-related adverse events compared to 4.5 days from the Zilver® PTX stent group.

Regarding reduction in hospital readmission rates, the applicant asserted that patients treated in the Eluvia™ stent group experienced reduced rates of hospital readmission following the index procedure compared to those in the Zilver® PTX stent group. Hospital readmission rates at 12 months were 3.9 percent for the Eluvia™ stent group compared to 7.1 percent for the Zilver® PTX stent group. Similar results were noted at 1 and 6 months; 1.0 percent versus 2.6 percent and 2.4 percent versus 3.8 percent, respectively.

With regard to reducing the rate of device-related complications, the applicant asserted that while the rates of adverse events were similar in total between treatment arms in the IMPERIAL study, there were measurable differences in device-related complications. Device-related adverse-events were reported in 8 percent of the patients in the Eluvia™ stent group compared to 14 percent of the patients in the Zilver® PTX stent group.

Lastly, the applicant asserted that while functional outcomes appear similar between the Eluvia™ and Zilver® PTX stent groups at 12 months, these improvements for the Zilver® PTX stent group are associated with twice as many TLRs to achieve similar EQ–5D index values.[41] Secondary endpoints improved after stent implantation and were generally similar between the groups. At 12 months, of the patients with complete Rutherford assessment data, 241 (86 percent) of the 281 patients in the Eluvia™ group and 120 (85 percent) of the 142 patients in the Zilver® PTX group had symptoms reported as Rutherford Category 0 or 1 (none to mild claudication). The mean ankle-brachial index was 1·0 (SD 0·2) in both groups at 12 months (baseline mean ankle-brachial index 0·7 [SD 0·2] for Eluvia™; 0·8 [0·2] for Zilver® PTX), with sustained hemodynamic improvement for approximately 80 percent of the patients in both groups. Walking function improved significantly from baseline to 12 months in both groups, as measured with the Walking Impairment Questionnaire and the 6-minute walk test. In both groups, the majority of patients had sustained improvement in the mobility dimension of the EQ–5D, and approximately half had sustained improvement in the pain or discomfort dimension. No significant between-group differences were observed in the Walking Impairment Questionnaire, 6-minute walk test, or EQ–5D. Secondary endpoint results for the Eluvia™ stent and Zilver® PTX stent groups are shown in Table 39 as follows:

[40] Forrester, J.S., Fishbein, M., Helfant, R., Fagin, J., ''A paradigm for restenosis based on cell biology: clues for the development of new preventive therapies,'' *J Am Coll Cardiol,* March 1, 1991, vol. 17(3), pp. 758–69.

[41] Gray, W.A., Keirse, K., Soga, Y., et al., ''A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): A randomized, non-inferiority trial,'' *Lancet,* 2018. Available at: *http://dx.doi.org/10.1016/S0140-6736(18)32262-1.*

Table 39.—Secondary Endpoint Results for the Eluvia™ Stent and Zilver® PTX Stent Groups

Functional Measure	Eluvia	Zilver PTX
Walking Impairment		
12 months	79.1	77.8
Change from baseline	40.8	35.8
Distance Scores		
12 months	64.6	63.4
Change from baseline	33.2	29.5
Speed Scores		
12 months	43.7	43.7
Change from baseline	18.3	18.1
Stair Climbing Scores		
12 months	61	59.8
Change from baseline	19.4	21.1
Total Walk Time (mins), 12 mos	5.7	5.6
Total Distance Walked (m), 12 mos	323.8	323.4
Speed (m/min), 12 mos	55.5	56.1

We noted that the IMPERIAL study, which showed significant differences in primary patency at 12 months, was designed for noninferiority and not superiority. Therefore, we wereconcerned that results showing primary patency at 12 months may not be valid given the study design. We also are concerned that the results of a recently published meta-analysis of randomized controlled trials of the risk of death associated with the use of paclitaxel-coated balloons and stents in the femoropopliteal artery of the leg, which found that there is increased risk of death following application of paclitaxel-coated balloons and stents in the femoropopliteal artery of the lower limbs and that further investigations are urgently warranted,[42] although the Eluvia™ system was not included in the meta-analysis. We were also concerned that the findings from this study indicated that the data suggesting that drug-coated stents are substantially clinically improved are unconfirmed. We invited public comments on whether the Eluvia™ Drug-Eluting Vascular Stent System meets the substantial clinical improvement criterion, including the implications of the meta-analysis results with respect to a finding of substantial clinical improvement for the Eluvia™ system.

We further noted that the applicant for the Eluvia™ Drug Eluting Vascular Stent System also applied for the IPPS new technology add-on payment (FY 2020 IPPS/LTCH PPS proposed rule; 86 FR 19314). In the FY 2020 IPPS/LTCH PPS proposed rule, we discussed several publicly available comments that also raised concerns relating to substantial clinical improvement. We list several of those concerns below. While the Eluvia™ IMPERIAL study does cite a reduced rate of ''Subsequent Therapeutic Interventions'', public comments for the IPPS proposed rule note that ''Subsequent Therapeutic Interventions'' was not further defined in the New Technology Town Hall presentation nor in the IMPERIAL study. The commenters stated that it would appear from the presentation materials, however, that this claim refers specifically to ''target lesion revascularizations (TLR)'', which does not appear statistically significant.

With regard to the applicant's assertion that the use of the Eluvia™ stent reduces hospital readmission rates, a commenter noted that during the New Technology Town Hall presentation, the presenter noted that the Eluvia™ group had a hospital readmission rate at 12 months of 3.9 percent compared to the Zilver® PTX group's rate of 7.1 percent, and that no p-value was included on the slide used for the presentation to offer an assessment of the statistical significance of this difference. The commenter noted that the manufacturer of the Eluvia™ stent did not discuss this particular hospital readmission rate data comparison in the main body of *The Lancet* paper; however, the data could be found in the online appendix and is shown as not statistically significant.

With regards to longer-term data on the Zilver® PTX stent and the Eluvia™ stent, the commenter noted that in the commentary in *The Lancet* paper accompanying the IMPERIAL study, Drs. Salvatore Cassese and Robert Byrne write that a follow-up duration of 12 months is insufficient to assess late failure, which is not infrequently observed. According to Drs. Cassese and Byrne, the preclinical models of restenosis after stenting of peripheral arteries have shown that stents permanently overstretch the arterial wall, thus stimulating persistent neointimal growth, which might cause a catch-up phenomenon and late failure. *The Lancet* paper noted that, in this regard, data on outcomes beyond one year will be important to confirm the durability of the efficacy of the Eluvia™ stent.[43] The commenter stated that, at

[42] Katsanos, K., et al., ''Risk of Death Following Application of Paclitaxel-Coated Balloons and Stents in the Femoropopliteal Artery of the Leg: A Systematic Review and Meta-Analysis of Randomized Controlled Trials,'' *JAHA,* vol. 7(24).

[43] Cassese, S., & Byrne, R.E., ''Endovascular stenting in femoropopliteal arteries,'' *The Lancet,* 2018, vol. 392(10157), pp. 1491–1493.

this point in time, very limited longer-term data are available on the use of the Eluvia™ stent and that the IMPERIAL study offers only 12-month data, although data out to three years have been published from the relatively small 57-patient single-arm MAJESTIC study. The commenter noted that the MAJESTIC study demonstrates a decrease in primary patency from 96.4 percent at one year to 83.5 percent at 2 years; and a doubling in TLR rates from 1 year to 2 years (3.6 percent to 7.2 percent) and again from 2 years to 3 years (7.2 percent to 14.7 percent). The commenter stated that this is not inconsistent with Drs. Cassese and Byrne's commentary regarding late failure, and that the relatively small, single-arm design of the study does not lend itself well to direct comparison to other SFA treatment options such as the Zilver® PTX stent.

The commenter also stated that Eluvia™'s lack of long-term data contrasts with 5-year data that is available from the Zilver® PTX stent's pivotal 479-patient RCT comparing the use of the Zilver® PTX stent to angioplasty (with a sub-randomization comparing provisional use of Zilver® PTX stenting to bare metal Zilver stenting in patients experiencing an acute failure of percutaneous transluminal angioplasty (PTA)). The commenter believed that these 5-year data demonstrate that the superiority of the use of the Zilver® PTX stent demonstrated at 12 and 24 months is maintained through 5 years compared to PTA and provisional bare metal stenting, and actually increases rather than decreases over time. The commenter also believed that, given that these stent devices are permanent implants and they are used to treat a chronic disease, long-term data are important to fully understand an SFA stent's clinical benefits. The commenter stated that with 5-year data available to support the ongoing safety and effectiveness of the use of the Zilver® PTX stent, but no such corresponding data available for the use of the Eluvia™ stent, it seems incongruous to suggest that the use of the Eluvia™ stent results in a substantial clinical improvement compared to the Zilver® PTX stent.

The commenter further stated that, in addition to the limited long-term data available for the Eluvia™ stent, there is also a lack of clinical data for the use of the Eluvia™ stent to confirm the benefit of the device outside of a strictly controlled clinical study population. The commenter stated that, in contrast, the Zilver® PTX stent has demonstrated comparable outcomes across a broad patient population, including a 787 patient study conducted in Europe with 2-year follow-up and a 904-patient study of all-comers (no exclusion criteria) in Japan with 5-year follow-up completed. The commenter believed that, with no corresponding data for the use of the Eluvia™ stent in a broad patient population, it seems unreasonable to suggest that the use of the Eluvia™ stent results in a substantial clinical improvement compared to the Zilver® PTX stent.

Based on the evidence submitted with the application, we were concerned that there was a lack of sufficient evidence that the Eluvia™ Vascular Drug-Eluting Stent System provides a substantial clinical improvement over other similar products. We invited public comments on whether Eluvia™ Vascular Drug-Eluting Stent System meets the substantial clinical improvement criterion.

Comment: One commenter, the manufacturer, stated that the IMPERIAL trial's design as a non-inferiority study is consistent with accepted research methodology and is typical of many head-to-head trials of medical devices. The commenter stated that they defined a pre-specified, post-hoc superiority analysis before evaluation of the clinical trial results, the non-inferiority and subsequent superiority testing methodology and results are not subjected to bias. The commenter argued that the pre-specified success criteria for superiority used the same logic as the pre-specified success criteria for non-inferiority. The commenter stated: ''Eluvia will be concluded to be superior to Zilver PTX for device effectiveness if the one-sided lower 95 percent confidence bound on the difference between treatment groups in 12-month primary patency is greater than zero.'' The commenter believes that the more stringent one-sided lower 97.5 percent confidence bound (shown as two-sided 95 percent confidence interval on the difference between treatment groups) was observed to be greater than zero and the corresponding p-value was 0.0144. The commenter also provided that the aforementioned data were published in *The Lancet* following its rigorous peer-review process, suggesting that the claims are not misleading and are supported by valid scientific evidence. The commenters also claimed that clinical guidelines support performing a pre-specified post-hoc analysis given specific requirements, that they believe they met.

Comment: Two commenters mentioned the meta-analysis of paclitaxel-coated balloons and stents [44] that initiated an FDA panel and analysis. The meta-analysis and systematic review of several randomized controlled trials of the risk of death associated with the use of paclitaxel-coated balloons and stents in the femoropopliteal artery of the leg and found that there is an increased risk of death following the application of paclitaxel-coated devices.

Commenters stated that Eluvia™ is different from the devices that were studied in the meta-analysis of paclitaxel-coated balloons and stents. Specifically, the commenters claim that Eluvia™ delivers paclitaxel in lower doses than the devices in the meta-analysis and is the only peripheral device to deliver paclitaxel through a sustained-release mechanism of action where delivery of paclitaxel is controlled and focused on the target lesion. The commenters, including the applicant, believe that the suggestion in the meta-analysis of a late-term mortality risk associated with paclitaxel-coated devices is not directly applicable to the Eluvia™ device.

Additionally, the applicant stated that given the differences between Eluvia™'s paclitaxel delivery mechanisms and other peripheral paclitaxel-coated devices, it would be more appropriate to examine safety considerations and data for Eluvia relative to products with similar mechanisms of action and dose levels. The applicant provides the TAXUS coronary stent as such an appropriate comparator, stating that Eluvia and TAXUS are similar in design intent and mechanism of action. In support, the applicant provided additional data showing a 5-year all-cause mortality observed between paclitaxel-eluting and bare metal stents. The applicant also stated that coronary and peripheral atherosclerotic lesions have similar disease presentation and the same antiproliferative impact of paclitaxel on the lesions regardless of vessel bed. The applicant recommends that signals for any potential long-term systemic effects of targeted paclitaxel eluted from a stent polymer matrix would be apparent in patients treated with TAXUS. As opposed to the meta-analysis and the resulting FDA panel analysis, the applicant believes that data on TAXUS can be used to gauge potential system

[44] Katsanos, K., Spiliopoulos, S., Kitrou, P., Krokidis, M., & Karnabatidis, D. (2018). Risk of Death Following Application of Paclitaxel-Coated Balloons and Stents in the Femoropopliteal Artery of the Leg: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. Journal of the American Heart Association, 7(24). *https://doi.org/10.1161/jaha.118.011245.*

effects of paclitaxel eluted from Eluvia. The applicant argues that the TAXUS stent's safety and effects has been extensively studied with more than 14 years of commercial experience and clinical trial data out to 10 years [45 46 47 48] in patients with coronary implants and 5 years for those with infrapopliteal implants. The applicant then recognizes that mortality rates for patients treated for peripheral artery disease (PAD) are not directly comparable to rates for patients with coronary artery or infrapopliteal disease due to appreciable differences in baseline risk. The applicant states that an additive effect due to low dose paclitaxel elution over time, if it exists, would have been observed in patients receiving treatment in these vessel beds. In regards to the meta-analysis and the risk of late mortality, the applicant further argues that understanding possible effects of paclitaxel exposure is not possible without complete analysis of uniformly re-adjudicated patient level data, particularly with treatment arm crossover and previous interventions or subsequent reinterventions with paclitaxel-coated devices, which occurred in the analyzed studies.

The applicant also provided responses to several comments that CMS noted in the CY 2020 OPPS/ASC proposed rule that were originally mentioned during and following the NTAP Town Hall meeting (84 FR 39479). In the CY 2020 OPPS/ASC proposed rule, CMS noted a comment that showed concern over the Eluvia™ IMPERIAL study's citation of a reduced rate of ''Subsequent Therapeutic Interventions''. The applicant states that the use of the term ''Subsequent Therapeutic Interventions'' was used as a lay explanation for target lesion revascularization. The applicant then states that it has recently obtained and analyzed IMPERIAL trial 2-year TLR results, which they also released at the FDA panel meeting on June 19, 2019. The applicant states that 1-year trial results, published in *The Lancet,* demonstrated a 50 percent reduction in TLRs and 2-year data demonstrated a statistically significantly (p-value not provided) lower rate of repeat re-interventions at 2 years compared to Zilver PTX. The applicant states that the clinical impact of fewer TLR procedures is significant and therefore demonstrates substantial clinical improvement.

The applicant also addressed concerns regarding hospital readmissions. Specifically, the applicant stated that in the NTAP Town Hall Eluvia Meeting, they presented 12-month readmission rates for Eluvia (3.9 percent) and Zilver PTX (7.1 percent), with a self-reported p-value of 0.1369. The applicant argues that statistical significance of the 12-month readmission rates should not be expected to be statistically significant due to the small number of patients. They conclude their response by stating that the data suggests a lower patient and health system burden for rehospitalization of patients for Eluvia™ versus patients for Zilver PTX.

Additionally, the applicant responded to concerns regarding long-term data and real-world evidence, stating that due to the nature of the transitional pass-through status requirements for medical devices, Eluvia™ is new to the market and would no longer meet the newness criterion if the applicant were to wait until 5-year data are available. The applicant further stated that Medicare NTAP precedent suggests that one-year peer reviewed published results are sufficient to prove substantial clinical improvement, given that at the time of Zilver PTX's NTAP approval they only provided 12-month data published in peer-reviewed literature.[49] The applicant further argues that waiting for a substantial amount of real-world evidence for the use of the Eluvia™ drug-eluting stent would disqualify the technology for the transitional pass-through consideration, as the technology would no longer be considered new by the time the data are available.

Response: We appreciate the comments. We are aware of FDA's actions in regards to the meta-analysis of paclitaxel devices and the late mortality signal in patients treated for PAD with paclitaxel-coated balloons and paclitaxel-eluting stents. We agree with the applicant that mortality rates for patients treated for peripheral artery disease are not directly comparable to rates for patients with coronary artery or infrapopliteal. We have continued to closely follow FDA's guidance and recommendations for the use of paclitaxel-coated balloons and paclitaxel-eluting stents for PAD, with details provided below.

On June 19–20, 2019, FDA convened a public meeting of the Circulatory System Devices Panel of the Medical Devices Advisory Committee to discuss, analyze, and make recommendations on the topic of a potential late mortality signal after treatment of PAD in the femoropopliteal artery with paclitaxel-coated balloons and paclitaxel-eluting stents. The Panel concluded that a late mortality signal associated with the use of paclitaxel-coated devices to treat femoropopliteal PAD was present. With that, the Panel and FDA cautiously interpreted the magnitude of the signal due to multiple limitations in the available data including: Wide confidence intervals due to a small sample size, pooling of studies of different paclitaxel-coated devices that were not intended to be combined, substantial amounts of missing study data, no clear evidence of a paclitaxel dose effect on mortality, and no identified pathophysiologic mechanism for the late deaths. The Panel and FDA further concluded that additional clinical study data are needed to fully evaluate the late mortality signal.

As of August 7, 2019,[50] FDA continues to actively work with the manufacturers and investigators on developing additional clinical evidence to better assess the long-term safety of paclitaxel-coated devices. They continue to assert that data could potentially suggest that paclitaxel-coated balloons and stents may improve blood flow to the legs and decrease the likelihood of repeat procedures to reopen blocked blood vessels compared to uncoated devices. However, they also continue to stress the importance of clinicians weighing potential benefits of the paclitaxel-coated devices with the potential risks, including late mortality.

After consideration of public comments and the latest available information from FDA advisory panel, we note that FDA's panel's has continued to review data that has identified a potentially concerning signal of increased long-term mortality in study subjects treated with paclitaxel-coated products compared to patients treated with uncoated devices. We also note that FDA determined that the analysis revealed no clear evidence of a

[45] Yamaji K, Raber L, Zanchin T, et al. Ten-year clinical outcomes of first-generation drug-eluting stents: The Sirolimus-Eluting vs. Paclitaxel-Eluting Stents for Coronary Revascularization (SIRTAX) VERY LATE trial. Eur Heart J. 2016;37(45):3386–3395.

[46] Ormiston JA, Charles O, Mann T, et al. Final 5-year results of the TAXUS ATLAS, TAXUS ATLAS Small Vessel, and TAXUS ATLAS Long Lesion clinical trials of the TAXUS Liberte paclitaxel-eluting stent in de-novo coronary artery lesions. Coron Artery Dis. 2013;24(1):61–68.

[47] Kereiakes DJ, Cannon LA, Dauber I, et al. Long-term follow-up of the platinum chromium TAXUS Element (ION) stent: The PERSEUS Workhorse and Small Vessel trial five-year results. Catheter Cardiovasc Interv. 2015;86(6):994–1001.

[48] Stone GW, Ellis SG, Colombo A, et al. Long-term safety and efficacy of paclitaxel-eluting stents final 5-year analysis from the TAXUS Clinical Trial Program. JACC Cardiovasc Interv. 2011;4(5):530–542.

[49] 84 FR 39479.

[50] *https://www.fda.gov/medical-devices/letters-health-care-providers/august-7-2019-update-treatment-peripheral-arterial-disease-paclitaxel-coated-balloons-and-paclitaxel.*

paclitaxel dose effect on mortality. While FDA continues to further evaluate the increased long-term mortality signal and its impact on the overall benefit-risk profile of these devices, we remain concerned that we do not have enough information to determine that the Eluvia™ device represents a substantial clinical improvement over existing devices. Therefore, we are not approving the Eluvia™ device for CY 2020 device transitional payment. We will continue to monitor any new information and/or recommendations as they become available.

(7) AUGMENT® Bone Graft

Wright Medical submitted an application for a new device category for transitional pass-through payment status for the AUGMENT® Bone Graft. The applicant describes AUGMENT® Bone Graft as a device/drug indicated for use as an alternative to autograft in arthrodesis of the ankle and/or hindfoot where the need for supplemental graft material is required. The applicant stated that the product has two components: Recombinant human platelet-derived growth factor-BB (rhPDGF–BB) solution (0.3 mg/mL) and Beta-tricalcium phosphate (β-TCP) granules (1000–2000 μm). The two components are combined at the point of use and applied to the surgical site. The beta-TCP provides a porous osteoconductive scaffold for new bone growth and the rhPDGF–BB, which act as an osteoinductive chemo-attractant and mitogen for cells involved in wound healing and through promotion of angiogenesis.

According to the applicant, the AUGMENT® Bone Graft is indicated for use in arthrodesis of the ankle and/or hindfoot due to osteoarthritis, post-traumatic arthritis (PTA), rheumatoid arthritis, psoriatic arthritis, avascular necrosis, joint instability, joint deformity, congenital defect or joint arthropathy as an alternative to autograft in patients needing graft material. Osteoarthritis is the most common joint disease among middle aged and older individuals and has been shown to also have health related mental and physical disabilities, which can be compared to the severity as patients with end-stage hip arthritis.[51] Additionally, post-traumatic arthritis develops after an acute direct trauma to the joint and can cause 12 percent of all osteoarthritis cases.[52] Common causes leading to PTOA include intra-articular fractures and meniscal, ligamentous and chondral injuries.[53] The ankle is cited as the most affected joint, reportedly accounting for 54 to 78 percent of over 300,000 injuries occurring in the USA annually. The applicant stated that autologous bone graft has often been used in ankle arthrodesis. Autologous bone is retrieved from a donor site, which may require an incision separate from the arthrodesis.[54] The applicant stated that, in these procedures, harvested autologous bone graft is implanted to stimulate healing between the bones across a diseased joint. The applicant further stated that the procedures may require the use of synthetic bone substitutes to fill the bony voids or gaps or to serve as an alternative to the autograft where autograft is not feasible. The applicant stated that the AUGMENT® Bone Graft removes the need for autologous retrieval. The applicant noted that during the procedure, the surgeon prepares the joint for the graft application and locates any potential bony defect, then applying and packing the AUGMENT® Bone Graft into the joint defects intended for arthrodesis.

With respect to the newness criterion at § 419.66(b)(1), FDA granted the AUGMENT® Bone Graft premarket approval on September 1, 2015. The application for a new device category for transitional pass-through payment status for the AUGMENT® Bone Graft was received May 31, 2018, which is within 3 years of the date of the initial FDA approval or clearance. We invited public comments on whether the AUGMENT® Bone Graft meets the newness criterion.

Comment: We received one comment from the manufacturer restating the date of their application and their initial FDA approval or clearance.

Response: As the application was received within 3 years of the date of the initial FDA approval or clearance, we believe that AUGMENT® Bone Graft meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the use of the AUGMENT® Bone Graft 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 the AUGMENT® Bone Graft meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or items 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. We have not identified an existing pass-through payment category that describes the AUGMENT® Bone Graft. The applicant proposed a category descriptor for the AUGMENT® of ''rhPDGF–BB and β-TCP as an alternative to autograft in arthrodesis of the ankle and/or hindfoot.''

We did not receive any public comments on these issue. We continue to believe that there is no existing pass-through category that describes AUGMENT® Bone Graft and have determined that AUGMENT® Bone Graft meets this eligibility criterion.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines 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. The applicant claims that the AUGMENT® Bone Graft provides a substantial clinical improvement over autograft procedures by reducing pain at the autograft donor site. With respect to this criterion, the applicant submitted data that examined the use of autograft arthrodesis of the ankle and/or hind foot and arthrodesis with the use of the AUGMENT® Bone Graft.

In a randomized, nonblinded, placebo controlled, noninferiority trial of the AUGMENT® Bone Graft versus autologous bone graft, the AUGMENT® arm showed equivalence bone bridging as demonstrated by CT, pain on weight bearing, The American Orthopaedic Foot & Ankle Society Ankle-Hindfoot (AOFAS—AHS) score, and the Foot Function Index to autologous bone graft. The study noted that patients experienced significantly decreased (in fact no) pain due to elimination of the donor site procedure. In the autograft group, at 6 months, 18/142 patients (13 percent) experienced pain >20 mm (of

[51] Greaser M, Ellington JK. 2014. ''Ankle arthritis.'' *Journal of Arthritis,* 3:129. doi:10.4172/2167-7921.1000129.

[52] Punzi, Leonardo et al. 2016. ''Post-traumatic arthritis: overview on pathogenic mechanisms and role of inflammation.'' Rheumatic & Musculoskeletal Diseases. *RMD open, 2*(2), e000279. doi:10.1136/rmdopen–2016–000279.

[53] Ibid.

[54] Lareau, Craig R. et al. 2015.''Does autogenous bone graft work? A logistic regression analysis of data from 159 papers in the foot and ankle literature.'' *Foot and Ankle Surgery.* 21 (3):150–59.

100 mm) on the Visual Analog Scale (VAS) at the autograft donor site as compared to 0/272 in the AUGMENT® Bone Graft group. At 12 months, 13/142 autograft patients (9 percent) had pain defined as >20 mm VAS as compared to 0/272 AUGMENT® patients.[55] The VAS has patients mark a visual representation of pain on a ruler based scale from 1 to 100. The measured distance (in mm) on the 10-cm line between the ''no pain'' anchor and the patient's mark represents the level of pain. We were concerned that we are unable to sufficiently determine substantial clinical improvement using the provided data, given that a comparison to alternatives to autologous bone graft, such as the reamer-irrigator-aspirator (RIA) technique were not evaluated. Specifically, the RIA technique has been suggested in a number of studies to be a viable alternative to bone autograft, because autogenous bone graft can be readily obtained without the need for additional incisions, therefore eliminating pain from an incisional site.[56] Another concern was the time period of the study because certain ankle arthrodesis complications such as ankle replacement and repeat arthrodesis can happen more than two years after the initial surgery.[57] A long-term study of at least 60 months is currently underway in order to assess long-term safety and efficacy, looking at the following 4 primary outcomes: bone bridging as demonstrated by CT, pain on weight bearing, The American Orthopaedic Foot & Ankle Society Ankle-Hindfoot (AOFAS—AHS) score, and the Foot Function Index. We believe that this long-term study is necessary for meaningful information about long-term efficacy of the Augment® Bone Graft. Further, there was a notable difference in the infection rate, musculoskeletal and tissue disorders, and pain in extremity for those in the AUGMENT® Bone Graft group. These findings were unfortunately not tested for significance and also were not necessarily focused on relevance to the procedure. Should these be significant and related to the device, these findings would suggest that the adverse outcomes due to the Augment® Bone Graft may outweigh its potential benefits.

We invited public comments on whether the AUGMENT® Bone Graft meets the substantial clinical improvement criterion.

Comment: We received several comments in regards to our inquiry of whether or not RIA is an appropriate comparator to AUGMENT® Bone Graft. Specifically, the applicant asserted that the standard of care has been autograft, as evidenced by peer-review literature, a review of claims, and randomized controlled trials. The commenters further asserted that the RIA technique is another way to harvest autograft, requires a separate incision, and is not appropriate given the volume of graft needed for ankle and hindfoot arthrodesis. The applicant further argued that given that the RIA technique still requires a separate incision, the concerns surrounding the second procedure, including pain and potential complications, would still apply. Finally, the applicant asserted that the RIA technique has additional risks and complications, including: A steep learning curve for surgeons with the potential for technical errors creating risk of potential complications;[58] select populations for whom the technique is not appropriate, including patients with osteoporosis and osteopenia, as well as elderly patients;[59] and, risk for fractures, penetration of the anterior cortex, violation of the knee joint, blood loss, and pressure emboli. [60] [61] [62]

The applicant also commented on concerns regarding long-term outcomes. In the CY 2020 OPPS/ASC proposed rule, we noted a potential lack of data on AUGMENT® beyond 2 years after the initial procedure. In response, the applicant submitted information on ongoing longer-term post-market surveillance data for AUGMENT®. Specifically, the applicant describes FDA post-market approval studies as a post-market requirement for the FDA PMA approval order to be submitted in Q4 2019.

In response to our concern about potential safety and adverse event rates, the applicant stated that available data demonstrates that the benefits of AUGMENT® outweigh the risks. Specifically, the applicant stated that although the reported percentage of infection rates outlined in the FDA's Summary of Safety and Effectiveness Data were higher for the AUGMENT® versus autograft, this is due to various infections unrelated to ankle and hindfoot arthrodesis. The applicant focused on infections related to the surgical support and commented that there was a dramatically lower infection rate, not significantly different between AUGMENT® versus autograft (p = 0.447). The applicant reported that surgical site infections occurred in 7 percent of AUGMENT® subjects and 9.2 percent in traditional autograft procedure subjects. The applicant also stated that it is common when studying a novel therapy against an active comparator that is known to be safe and effective to use a non-inferiority study. The applicant also stated that they conducted an additional analysis of the IDE trial data to determine the impact of graft type (AUGMENT® Bone Graft versus autograft) and subject age (over 65 vs those 65 and younger) on fusion outcomes.[63] The applicant believed that the data confirm results of prior studies that have found that autograft tissue quality is affected by age. The applicant suggested that while AUGMENT® was non-inferior to autograft overall, the elderly population data shows better odds of fusion success with AUGMENT® compared with autograft.

Response: We appreciate the additional information and analysis provided by the applicant and other stakeholders. After reviewing the additional information provided by the applicant and other stakeholders addressing our concerns raised in the CY 2020 OPPS/ASC proposed rule, we agree with the applicant that AUGMENT® provides a substantial clinical improvement by significantly reducing, or eliminating, chronic pain (measured at > 20mm on VAS) associated with the autograft donor site with the elimination of the donor site procedure, at 6 months and 12 months. We also note that in subjects 65+, AUGMENT® was more than twice as

[55] DiGiovanni CW, Lin SS, Baumbauer JF, et al. 2013. ''Recombinant Human Platelet-Derived Growth Factor-BB and Beta-Tricalcium Phosphate (rhPDGF–BB/b-TCP): An Alternative to Autogenous Bone Graft.'' *J Bone Joint Surg Am.,* 95: 1184–92.

[56] Herscovici, D., Scaduto, J.M. 2012. ''Use of the reamer–irrigator–aspirator technique to obtain autograft for ankle and hindfoot arthrodesis.'' *The Journal of Bone & Joint Surgery.* 94–B:75–9.

[57] Stavrakis, AL., SooHoo, NF. 2016. ''Trends in complication rates following ankle arthrodesis and total ankle replacement.'' *The Journal of Bone & Joint Surgery.* JBJS 1453–1458.

[58] Haubruck P, Ober J, Heller R, Miska M, Schmidmaier G, Tanner MC (2018) Complications and risk management in the use of the reaming-irrigator-aspirator (RIA) system: RIA is a safe and reliable method in harvesting autologous bone graft. PLoS ONE 13(4): e0196051.

[59] Ibid.

[60] Dimitriou R, Mataliotakis GI, Angoules AG, et al. Complications following autologous bone graft harvesting from the iliac crest and using the RIA: a systematic review. Injury. 2011 Sep;42 Suppl 2:S3–15.

[61] *See* Complications and risk management in the use of the reaming-irrigator-aspirator (RIA) system: RIA is a safe and reliable method in harvesting autologous bone graft, *supra.*

[62] *See* Use of the reamer–irrigator–aspirator technique to obtain autograft for ankle and hindfoot arthrodesis, *supra.*

[63] Haddad SL, Berlet GC, Baumhauer JF, et al. Impact of patient age and graft type on fusion following ankle and hindfoot arthrodesis. Combined Australia & New Zealand Orthopaedic Foot & Ankle Societies Conference, Surfers Paradise, Queensland, Australia, 2019

likely as autograft to result in fusion.[64] Finally, after analyzing the additional data provided through public comment, we believe that AUGMENT® will provide a substantial clinical improvement by reducing chronic pain and also reducing complications.

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 use of the AUGMENT® Bone Graft would be reported with CPT code 27870 (Arthrodesis, ankle, open), which is assigned to APC 5115 (Level 5 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 5115, which has a CY 2019 payment rate of $10,122.92. 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 27870 had a device offset amount of $4,553.29. According to the applicant, the cost of the AUGMENT® Bone Graft is $3,077 per device/drug combination. The applicant further provided a weighted average cost of the graft, accounting for how many procedures required one, two, or three AUGMENT® Bone Graft device/drug kits, equaling a weighted average cost of $6,020.22.

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 the AUGMENT® Bone Graft is more than 25 percent of the applicable APC payment amount[65] for the service related to the category of devices of $10,122.92 (($6,020.22/$10,122.92) × 100 = 59 percent)). Therefore, we believe that the AUGMENT® Bone Graft 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 $6,020.22 for AUGMENT® Bone Graft exceeds the cost of the device-related portion of the APC payment amount for the related service of $4,553.29 by at least 25 percent (($6,020.22/$4,553.29) × 100 = 132 percent). Therefore, we believe AUGMENT® Bone Graft 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 $6,020.22 for the AUGMENT® Bone Graft and the portion of the APC payment amount for the device of $4,553.29 exceeds the APC payment amount for the related service of $10,122.92 by more than 10 percent (($6,020.22 − $4,553.29)/$10,122.92 × 100 = 15 percent). Therefore, we believe that AUGMENT® Bone Graft meets the third cost significance test. We invited public comments on whether the AUGMENT® Bone Graft meets the device pass-through payment criteria discussed in this section, including the cost criterion.

Comment: The applicant submitted a comment in support of our cost analysis of AUGMENT® Bone Graft.

Response: We thank the applicant for their comment in support, and continue to believe AUGMENT® Bone Graft meets the cost criteria.

After consideration of the public comments we received, we are approving the AUGMENT® Bone Graft for device pass-through payment status beginning in CY 2020.

3. Request for Information and Potential Revisions to the OPPS Device Pass-Through Substantial Clinical Improvement Criterion in the FY 2020 IPPS/LTCH PPS Proposed Rule

As mentioned earlier, 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. Separately, the criteria as set forth under § 419.66(c) are used to determine whether a new category of pass-through payment devices should be established. One of these criteria, at § 419.66(c)(2), states that CMS determines 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. CMS considers the totality of the substantial clinical improvement claims and supporting data, as well as public comments, when evaluating this aspect of each application. CMS summarizes each applicant's claim of substantial clinical improvement as part of its discussion of the entire application in the relevant proposed rule, as well as any concerns regarding those claims. In the relevant final rule for the OPPS, CMS responds to public comments and discusses its decision to approve or deny the application for separate transitional pass-through payments.

Over the years, applicants and commenters have indicated that it would be helpful for CMS to provide greater guidance on what constitutes ''substantial clinical improvement.'' In the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19368 through 19371), we requested information on the substantial clinical improvement criterion for OPPS transitional pass-through payments for devices and stated that we were considering potential revisions to that criterion. In particular, we sought public comments in the FY 2020 IPPS/LTCH PPS proposed rule on the type of additional detail and guidance that the public and applicants for device pass-through transitional payment would find useful (84 FR 19367 to 19369). This request for public comments was intended to be broad in scope and provide a foundation for potential rulemaking in future years. We refer readers to the FY 2020 IPPS/LTCH proposed rule for the full text of this request for information.

In addition to the broad request for public comments for potential rulemaking in future years, in order to respond to stakeholder feedback requesting greater understanding of CMS' approach to evaluating substantial clinical improvement, we also solicited comments from the public in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19369 through 19371) on specific changes or clarifications to the IPPS and OPPS substantial clinical improvement criterion that CMS might consider making in the FY 2020 IPPS/LTCH PPS final rule to provide greater clarity and predictability. We refer readers to the FY 2020 IPPS/LTCH PPS proposed rule

[64] *Ibid.*

[65] Due to the timing of the application, the AUGMENT® Bone Graft cost values were calculated using the 2018 proposed rule data.

for complete details on those potential revisions. We noted that any responses to public comments we received on potential revisions to the OPPS substantial clinical improvement criterion in response to the FY 2020 IPPS/LTCH PPS proposed rule, as well as any revisions that might be adopted, would be included in this final rule with comment period and would inform future OPPS rulemaking.

Comment: We received one comment addressing this RFI, which recommended that CMS demonstrate greater flexibility in considering what constitutes substantial clinical improvement, including evidence developed through data registries and evidence from markets outside the U.S.

Response: We thank the commenter for their response. We note that we accept a wide range of data and other evidence to help determine whether a device meets the substantial clinical improvement criterion.

4. Proposed Alternative Pathway to the OPPS Device Pass-Through Substantial Clinical Improvement Criterion for Transformative New Devices

Since 2001 when we first established the substantial clinical improvement criterion, FDA programs for helping to expedite the development and review of transformative new devices that are intended to treat or diagnose serious diseases or conditions and address unmet medical needs (referred to, for purposes of this rule) as FDA's expedited programs) have continued to evolve in tandem with advances in medical innovations and technology. There is currently one FDA expedited program for devices, the Breakthrough Devices Program. The 21st Century Cures Act (Cures Act) (Pub. L. 144–255) established the Breakthrough Devices Program to expedite the development of, and provide for priority review of, medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions and which meet one of the following four criteria: (1) That represent breakthrough technologies; (2) for which no approved or cleared alternatives exist; (3) that offer significant advantages over existing approved or cleared alternatives, including the potential, compared to existing approved alternatives, to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients' ability to manage their own care (such as through self-directed personal assistance), or establish long-term clinical efficiencies; or (4) the availability of which is in the best interest of patients.

Some stakeholders over the years have requested that devices that receive marketing authorization and are part of an FDA expedited program be deemed as representing a substantial clinical improvement for purposes of OPPS device pass-through status. We understand this request would arguably create administrative efficiency because the commenters currently view the two sets of criteria as the same, overlapping, similar, or otherwise duplicative or unnecessary.

The Administration is committed to addressing barriers to health care innovation and ensuring Medicare beneficiaries have access to critical and life-saving new cures and technologies that improve beneficiary health outcomes. As detailed in the President's FY 2020 Budget (we refer readers to HHS FY 2020 Budget in Brief, Improve Medicare Beneficiary Access to Breakthrough Devices, pp. 84–85), HHS is pursuing several policies that will instill greater transparency and consistency around how Medicare covers and pays for innovative technology.

Therefore, given the existence of the current and past FDA programs for helping to expedite the development and review of certain devices intended to treat or diagnose serious or life-threatening or irreversibly debilitating diseases or conditions for which there is an unmet medical need), we considered whether it would also be appropriate to similarly facilitate access to these transformative new technologies for Medicare beneficiaries taking into consideration that, at the time of marketing authorization (that is, Premarket Approval (PMA); 510(k) clearance; or the granting of a De Novo classification request) for a product that is the subject of a FDA expedited program, the evidence base for demonstrating substantial clinical improvement in accordance with CMS' current standard may not be fully developed. We also considered whether FDA marketing authorization of a product that is part of an FDA expedited program is evidence that the product is sufficiently different from existing products for purposes of newness.

After consideration of these issues, and consistent with the Administration's commitment to addressing barriers to health care innovation and ensuring Medicare beneficiaries have access to critical and life-saving new cures and technologies that improve beneficiary health outcomes, we concluded that it would be appropriate to develop an alternative pathway for transformative medical devices. In situations where a new medical device is part of the Breakthrough Devices Program and has received FDA marketing authorization (that is, the device has received PMA; 510(k) clearance; or the granting of a De Novo classification request), we proposed an alternative outpatient pass-through pathway to facilitate access to this technology for Medicare beneficiaries beginning with applications received for pass-through payment on or after January 1, 2020.

We continue to believe that hospitals should receive pass-through payments for devices that offer clear clinical improvement and that cost considerations should not interfere with patient access. In light of the criteria designation as a Breakthrough Device, and because we recognize that such devices may not have a sufficient evidence base to demonstrate substantial clinical improvement at the time of FDA marketing authorization, we proposed to amend the OPPS device transitional pass-through payment regulations to create an alternative pathway to demonstrating substantial clinical improvement that would enable devices that receive FDA marketing authorization and are part of the FDA Breakthrough Devices Program to qualify for our quarterly approval process for device pass-through payment under the OPPS for pass-through payment applications received on or after January 1, 2020. With this proposal, OPPS device pass-through payment applicants for devices that have received FDA marketing authorization and are part of the FDA Breakthrough Devices Program would not be 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 would continue to need to meet the other requirements for pass-through payment status in our regulation at § 419.66. Devices that have received FDA marketing authorization and are part of the Breakthrough Devices Program can be approved through the quarterly process and would be announced through that process (81 FR 79655). Finally, we would include proposals regarding these devices and whether pass-through payment status should continue to apply in the next applicable OPPS rulemaking cycle.

As such, we proposed to revise paragraph (c)(2) under § 419.66. Under proposed revised paragraph (c)(2), we proposed to establish an alternative pathway where applications for device pass-through payment status for new

medical devices received on or after January 1, 2020 that are a part of FDA's Breakthrough Devices Program and have received FDA marketing authorization (that is, the device has received PMA, 510(k) clearance, or the granting of a De Novo classification request) will not be evaluated for substantial clinical improvement for the purposes of determining device pass-through payment status. Under this proposed alternative pathway, a medical device that has received FDA marketing authorization (that is, has been approved or cleared by, or had a De Novo classification request granted by, FDA) and that is part of FDA's Breakthrough Devices Program would still need to meet the eligibility criteria under § 419.66(b), the other criteria for establishing device categories under § 419.66(c), and the cost criterion under § 419.66(d). We noted that this proposal aligns with a proposal in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19371 through 19373) and final rule (84 FR 42292 through 42297) and will help achieve the goals of expedited access to innovative devices to further reduce administrative burden.

Comment: MedPAC opposed our proposal and stated that participation in the FDA Breakthrough Device Program does not necessarily reflect improvements in outcomes or justify increased payment for Medicare beneficiaries. MedPAC expressed concern that such a policy would provide inappropriate incentives for providers to use new technology without proven safety or efficacy by allowing increased payment for the new technology.

Most commenters supported the proposal for an alternative pathway and offered suggestions that they thought would enhance the proposal. Specifically, commenters requested that CMS expand the alternative pathway to include other FDA designations, namely the Expedited Access Pathway and the Regenerative Medicine Advanced Therapy (RMAT) Designation. A commenter requested that similar to the IPPS policy, we also waive the newness criterion under the alternative pathway. Commenters also requested that we expand the alternative pathway to New Technology APCs, drug pass-through payment, and non-opioid alternatives.

Finally, a number of commenters encouraged us to ensure coverage for devices that are approved under the alternative pathway.

Response: We appreciate the commenters' support for the alternative pathway proposal. After reviewing the public comments, we continue to believe that the benefits of providing earlier access to Breakthrough Devices can improve beneficiary health outcomes support establishing this alternative pathway. While we appreciate the commenter's concern regarding potential negative incentives, we continue to believe that it is appropriate to facilitate beneficiary access to transformative new medical devices by establishing an alternative pathway for devices that receive FDA marketing authorization through FDA's Breakthrough Devices Program, and not to require substantial clinical improvement as a requirement for pass-through status for these devices because the evidence base to demonstrate substantial clinical improvement may not be completely developed at the time of FDA marketing authorization for such devices, which would delay their eligibility for pass-through status.

In regards to expanding the alternative pathway to include pass-through drugs and New Technology APCs, we continue to believe that it is appropriate to distinguish between drugs and devices, while we continue to work on other initiatives for drug affordability; a priority for this Administration. Importantly, substantial clinical improvement is not a requirement to be assigned to a New Technology APC or for drug pass-through status, so it is not necessary to waive such a criterion under either of these policies. Finally, we appreciate the commenters' suggestion that we should apply the alternative pathway to other types of FDA designations and will continue to take those comments into consideration for future rulemaking, where appropriate.

Comment: Several commenters suggested that we revise the effective date of the policy, and specifically requested that the policy be effective on or after January 1, 2020 for applications submitted prior to the September 2019 quarterly application submission deadline.

Response: We thank the commenters for their input. We agree with commenters and do not believe applicants with devices that would qualify for the alternative pathway should be required to re-submit their pass-through applications after January 1, 2020 in order to be considered for the alternative pathway. Therefore, after considering the public comments we received, we are finalizing a policy that the alternative pathway will apply for devices that will receive pass-through payments effective on or after January 1, 2020 and we are revising paragraph (c)(2) under § 419.66 consistent with this final policy.

Where we received a device pass-through application by the September 2019 quarterly application deadline for a device that qualifies for the alternative pathway and the device meets the other criteria for device pass-through status, the device can be approved for pass-through status beginning on January 1, 2020. Similarly, devices for which we received a device pass-through application prior to the December 2019 quarterly deadline can receive pass-through status beginning April 1, 2020, assuming they qualify for the alternative pathway and meet the other criteria for device pass-through status.

In summary, we are finalizing our proposal with the change to the effective date suggested by commenters to establish an alternative pathway to the substantial clinical improvement criterion for devices that have FDA Breakthrough Devices Program designation and have received FDA marketing authorization (that is, the device has received PMA, 510(k) clearance, or the granting of a De Novo classification request) for devices approved for transitional pass-through status effective on or after January 1, 2020.

Devices Approved for Pass-Through Status Under the Breakthrough Device Alternative Pathway

We received two device pass-through applications by the September 2, 2019 quarterly application deadline that have received FDA marketing authorization and a Breakthrough Devices designation from FDA and that qualify for consideration under the alternative pathway to the OPPS device pass-through substantial clinical improvement criterion. These devices meet the other criteria for device pass-through including the eligibility criteria under § 419.66(b), the criteria for establishing device categories under § 419.66(c), and the cost criterion under § 419.66(d) and are approved for pass-through status beginning on January 1, 2020.

The devices include: (1) Optimizer® System which is discussed earlier in this section and approved under the standard pathway, and (2) ARTIFICIAL*Iris*® which is an iris prosthesis for the treatment of iris defects. The ARTIFICIAL*Iris*® application was received in June 2019 after the March 2019 quarterly deadline for applications to be received in time to be included in CY 2020 rulemaking. We are approving ARTIFICIAL*Iris*® for transitional pass-through payment under the alternative pathway for CY 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 a discussion of this application will be included in CY 2021 rulemaking.

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 2020 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 below in section IV.B.1.b. of the CY 2020 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 2020 OPP/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 above—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 above 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 CMS' 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 its 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 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

(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 medical 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 medical 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 medical 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 above 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 medical 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 of a medical 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 medical 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 and 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.

For CY 2020, we did not propose any changes to our device-intensive policy.

Comment: Some commenters noted that CPT codes 22612 and 64912 had a device-offset percentage greater than 30 percent and should have been proposed to have device-intensive status for CY 2020.

Response: We agree with commenters that CPT codes 22612 and 64912 were inadvertently omitted from Addendum P and were not assigned device-intensive status in the CY 2020 OPPS/ASC proposed rule. For the CY 2020 OPPS/ASC final rule with comment period, the device offset for both procedures exceeds the 30 percent threshold and these procedures are assigned device-intensive status for CY 2020.

Comment: One commenter requested that we assign HCPCS code C9752 a higher device offset percentage. Additionally, one commenter requested that we assign HCPCS code C9754 a higher device offset percentage.

Response: We thank the commenters for their recommendations and 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 2020.

Comment: One commenter requested we assign device-intensive status for CPT codes 36904, 36905, 50590, and HCPCS code 0275T for CY 2020.

Response: Using the most currently available data for this CY 2020 OPPS/ASC final rule with comment period, we have determined that the device offset percentages for CPT codes 36905, 50590, and HCPCS code 0275T are not above the 30-percent threshold and, therefore, these procedures are not eligible to be assigned device-intensive status. Additionally, based on the most currently available data for this CY 2020 OPPS/ASC final rule with comment period, we have determined that the device offset percentage for CPT code 36904 exceeds the 30-percent threshold and therefore, this procedure is assigned device-intensive status for CY 2020.

Comment: One commenter stated that the device offset for CPT code 53854 should be based on the predecessor code of HCPCS code 0275T and that CPT code 53854 should be assigned device-intensive status for CY 2020.

Response: We agree with the commenter that, in the absence of device cost statistics for a particular procedure, we may use the predecessor code (in this case HCPCS code 0275T) to make a device-intensive determination. However, we note that the device-intensive percentage for HCPCS code 0275T is below the 30 percent threshold and, therefore, we are not assigning CPT code 53854 device-intensive status for CY 2020.

The full listing of the proposed CY 2020 device-intensive procedures can be found in Addendum P to this CY 2020 OPPS/ASC proposed rule (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 2020.

Comment: Several commenters requested that CMS restore the device-to-procedure and procedure-to-device edits. Additionally, some commenters requested specific device edits for total hip arthroplasty procedures and total knee arthroplasty procedures as well as device-intensive ''C'' HCPCS codes.

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 will 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. Further, we also note that our current device edit policy requires hospitals to report a device for certain device-intensive procedures, which include total knee arthroplasty, device-intensive ''C'' HCPCS codes, as well as total hip arthroplasty beginning in CY 2020.

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 Medical 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 our 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.

We did not propose any changes to our no cost/full credit and partial credit device policies in the CY 2020 OPPS/ASC proposed rule.

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 above 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 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 2020, this policy would apply to CPT code 0308T, which we proposed to assign to APC 5495 (Level 5 Intraocular Procedures) in the CY 2020 OPPS/ASC proposed rule. The CY 2020 OPPS/ASC proposed rule geometric mean cost for the procedure described by CPT code 0308T (based on 7 claims containing the device HCPCS C-code, in accordance with the device-intensive edit policy) was $28,237, and the median cost was $19,270. The proposed CY 2020 payment rate (calculated using the median cost) was $19,740 and can be found in Addendum B to the CY 2020 OPPS/ASC proposed rule (which is available via the internet on the CMS website).

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 the proposed rule, the term ''biological'' is used because this is the term that appears in section 1861(t) of the Act. A ''biological'' as used in the proposed rule 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 disease 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 2020 pass-through drugs and biologicals and their designated APCs are 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 the CMS 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 the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html.*

2. Three-Year Transitional Pass-Through Payment Period for All 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.

3. Drugs and Biologicals With Expiring Pass-Through Payment Status in CY 2019

We proposed that the pass-through payment status of six drugs and biologicals would expire on December 31, 2019 as listed in Table 14. These drugs and biologicals will have received OPPS pass-through payment for 3 years during the period of January 1, 2017 until December 31, 2019.

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 is proposed to be $130 for CY 2020), as discussed further in section V.B.2. of the 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 is proposed at ASP+6 percent for CY 2020, as discussed further in section V.B.3. of the proposed rule).

The proposed packaged or separately payable status of each of these drugs or biologicals is listed in Addendum B to the proposed rule (which is available via the internet on the CMS website).

Comment: One commenter suggested that CMS should establish a new policy to require equal payment for all drugs, biologicals, and radiopharmaceuticals included in the same CED trial to avoid affecting the trial by implicitly favoring one product over another through a higher payment rate. The commenter referenced a current CED trial for amyloid positron emission tomography (PET) that will be active into CY 2020. (Information on this CED trial can be found on the CMS website at *https://www.cms.gov/Medicare/Coverage/Coverage-withEvidence-Development/AmyloidPET.html*). In the CED trial, Neuraceq™ (florbetaben F18, HCPCS code Q9982) and Vizamyl™ (flutemetamol F18, HCPCS code Q9983) have not had pass-through status since December 31, 2018, while a third drug, Amyvid™ (florbetapir F18, HCPCS code A9586) continues to have pass-through status until September 30, 2020.

Response: We do not agree with the commenter's request that we establish a policy to require the equal payment of all drugs, biologicals, and radiopharmaceuticals in the same CED trial. The payment rate for each product is consistent with current OPPS statutory requirements. In the case of the particular products mentioned above, one product has drug pass-through status through September 30, 2020, as required by section 1833(t)(6)(G), while the pass-through period for the other products has already expired, meaning payment for these products is packaged into the payment for the primary procedure. Further, section 1833(t)(6) establishes the statutory authority for CMS to provide pass-through payment to cover the additional costs of innovative drugs including radiopharmaceuticals. All of these products receive payment that is consistent with statutory and regulatory requirements and payment will be packaged for all three products once the statutory pass-through period for Amyvid expires. We note that the payment rate for each product does not affect the protocol established under the CED trial because the protocol does not consider the cost of the radiopharmaceutical used for treatment. Therefore, we expect providers to make their own decision about which radiopharmaceutical to use to provide the treatment independent of the payment received for an individual drug.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to expire the pass-through payment status of the 6 drugs and biologicals listed in Table 40 below on December 31, 2019.

TABLE 40.—DRUGS AND BIOLOGICALS FOR WHICH PASS-THROUGH PAYMENT STATUS WOULD EXPIRE DECEMBER 31, 2019

CY 2019 HCPCS Code	CY 2019 Long Descriptor	CY 2019 Status Indicator	CY 2019 APC	Pass-Through Payment Effective Date
A9587	Gallium ga-68, dotatate, diagnostic, 0.1 millicurie	G	9056	01/01/2017
A9588	Fluciclovine f-18, diagnostic, 1 millicurie	G	9052	01/01/2017
J0570	Buprenorphine implant, 74.2 mg	G	9058	01/01/2017
J7179	Injection, von willebrand factor (recombinant), (Vonvendi), 1 i.u. vwf:rco	G	9059	01/01/2017
J7210	Injection, factor viii, (antihemophilic factor, recombinant), (afstyla), 1 i.u.	G	9043	01/01/2017
J9034	Injection, bendamustine hcl (Bendeka), 1 mg	G	1861	01/01/2017

4. Drugs, Biologicals, and Radiopharmaceuticals With New or Continuing Pass-Through Payment Status in CY 2020

We proposed to continue pass-through payment status in CY 2020 for 61 drugs and biologicals. These drugs and biologicals, which were approved for pass-through payment status between April 1, 2017 and April 1, 2019 are listed in Table 15. The APCs and HCPCS codes for these drugs and biologicals approved for pass-through payment status on or after January 1, 2020 are assigned status indicator ''G'' in Addenda A and B to the proposed rule (which are available via the internet on the CMS website). In addition, there are four drugs and biologicals that have already had 3 years of pass-through payment status but for which pass-through payment status is required to be extended for an additional 2 years, effective October 1, 2018 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). That means the last 9 months of pass-through status for these drugs will occur in CY 2020. Because of this requirement, these drugs and biologicals are also included in Table 15, which brings the total number of drugs and biologicals with proposed pass-through payment status in CY 2020 to 65.

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 2020, 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 2020. We proposed that a $0 pass-through payment amount would be paid for pass-through drugs and biologicals under the CY 2020 OPPS because the difference between the amount authorized under section 1842(o) of the Act, which is proposed at ASP+6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, which is 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 2020 minus a payment offset for any predecessor drug products contributing to the pass-through payment as described in section V.A.6. of the proposed rule. We are making this proposal 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 2020 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 2020, consistent with our CY 2019 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 2020, 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 is 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 and comments 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 these proposals. Therefore, we are finalizing these proposals for CY 2020 without modification. We note that public comments pertaining to our proposal to continue to pay WAC+3 percent for drugs and biologicals without ASP information are addressed elsewhere in this final rule with comment period. The drugs and biologicals that continue to have pass-through payment status for CY 2020 or have been granted pass-through payment status as of January 2020 are shown in Table 41 below.

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TABLE 41.—DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS DURING CY 2020

CY 2019 HCPCS Code	CY 2020 HCPCS Code	Long Descriptor	CY 2020 Status Indicator	CY 2020 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
A9586	A9586	Florbetapir f18, diagnostic, per study dose, up to 10 millicuries	G	9084	10/01/2018	09/30/2020
C9035	J1943	Injection, aripiprazole lauroxil (aristada initio), 1 mg	G	9179	01/01/2019	12/31/2021
C9036	J0222	Injection, patisiran, 0.1 mg	G	9180	01/01/2019	12/31/2021
C9037	J2798	Injection, risperidone (perseris), 0.5 mg	G	9181	01/01/2019	12/31/2021
C9038	J9204	Injection, mogamulizumab-kpkc, 1 mg	G	9182	01/01/2019	12/31/2021
C9039	J0291	Injection, plazomicin, 5 mg	G	9183	01/01/2019	12/31/2021
C9040	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
C9041	C9041	Injection, coagulation factor Xa (recombinant), inactivated (andexxa), 10mg	G	9198	04/01/2019	03/31/2022
C9043	J0642*	Injection, levoleucovorin (khapzory), 0.5 mg	G	9334	04/01/2019	03/31/2022
C9044	J9119	Injection, cemiplimab-rwlc, 1 mg	G	9304	04/01/2019	03/31/2022
C9045	J9313	Injection, moxetumomab pasudotox-tdfk, 0.01 mg	G	9305	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
C9047	C9047	Injection, caplacizumab-yhdp, 1 mg	G	9199	07/01/2019	06/30/2022

CY 2019 HCPCS Code	CY 2020 HCPCS Code	Long Descriptor	CY 2020 Status Indicator	CY 2020 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
C9141	J7208	Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl (jivi) 1 i.u.	G	9299	04/01/2019	03/31/2022
C9407	C9407	Iodine i-131 iobenguane, diagnostic, 1 millicurie	G	9184	01/01/2019	12/31/2021
C9408	C9408	Iodine i-131 iobenguane, therapeutic, 1 millicurie	G	9185	01/01/2019	12/31/2021
C9447	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
C9462	C9462	Injection, delafloxacin, 1 mg	G	9462	04/01/2018	03/31/2021
C9488	C9488	Injection, conivaptan hydrochloride, 1 mg	G	9488	04/01/2017	03/31/2020
J0121	J0121	Injection, omadacycline, 1 mg	G	9311	07/01/2019	06/30/2022
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
J0565	J0565	Injection, bezlotoxumab, 10 mg	G	9490	07/01/2017	06/30/2020
J0567	J0567	Injection, cerliponase alfa, 1 mg	G	9014	01/01/2018	12/31/2020
J0599	J0599	Injection, c-1 esterase inhibitor (human), (haegarda), 10 units	G	9015	01/01/2018	12/31/2020
J1095	J1095	Injection, dexamethasone 9%, intraocular, 1 microgram	G	9172	10/01/2018	09/30/2021
J1096	J1096	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg	G	9308	07/01/2019	06/30/2022
J1301	J1301	Injection, edaravone, 1 mg	G	9493	10/01/2017	09/30/2020
J1303	J1303	Injection, ravulizumab-cwvz, 10 mg	G	9312	07/01/2019	06/30/2022
J1428	J1428	Injection, eteplirsen, 10 mg	G	9484	04/01/2017	03/31/2020
J1454	J1454	Injection, fosnetupitant 235 mg and palonosetron 0.25 mg	G	9099	10/01/2018	09/30/2021
J1627	J1627	Injection, granisetron extended release, 0.1 mg	G	9486	04/01/2017	03/31/2020

CY 2019 HCPCS Code	CY 2020 HCPCS Code	Long Descriptor	CY 2020 Status Indicator	CY 2020 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J1628	J1628	Injection, guselkumab, 1 mg	G	9029	01/01/2018	12/31/2020
J2326	J2326	Injection, nusinersen, 0.1 mg	G	9489	07/01/2017	06/30/2020
J2350	J2350	Injection, ocrelizumab, 1 mg	G	9494	10/01/2017	09/30/2020
J2797	J2797	Injection, rolapitant, 0.5 mg	G	9464	04/01/2018	03/31/2021
J3111	J3111	Injection, romosozumab-aqqg, 1 mg	G	9327	10/01/2019	09/30/2022
J3245	J3245	Injection, tildrakizumab, 1 mg	G	9306	04/01/2019	03/31/2022
J3304	J3304	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg	G	9469	04/01/2018	03/31/2021
J3316	J3316	Injection, triptorelin, extended-release, 3.75 mg	G	9016	01/01/2018	12/31/2020
J3358	J3358	Ustekinumab, for intravenous Injection, 1 mg	G	9487	04/01/2017	03/31/2020
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
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
J7328	J7328	Hyaluronan or derivative, gelsyn-3, for intra-articular injection, 0.1 mg	G	1862	04/01/2017	03/31/2020
J7345	J7345	Aminolevulinic acid hcl for topical administration, 10% gel, 10 mg	G	9301	01/01/2018	12/31/2020
J9023	J9023	Injection, avelumab, 10 mg	G	9491	10/01/2017	09/30/2020

CY 2019 HCPCS Code	CY 2020 HCPCS Code	Long Descriptor	CY 2020 Status Indicator	CY 2020 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J9036	J9036	Injection, bendamustine hcl (belrapzo), 1 mg	G	9313	04/01/2019	06/30/2022
J9057	J9057	Injection, copanlisib, 1 mg	G	9030	07/01/2018	06/30/2021
J9153	J9153	Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine	G	9302	01/01/2018	12/31/2020
J9173	J9173	Injection, durvalumab, 10 mg	G	9492	10/01/2017	09/30/2020
J9203	J9203	Injection, gemtuzumab ozogamicin, 0.1 mg	G	9495	01/01/2018	12/31/2020
J9210	J9210	Injection, emapalumab-lzsg, 1 mg	G	9310	07/01/2019	06/30/2022
J9229	J9229	Injection, inotuzumab ozogamicin, 0.1 mg	G	9028	01/01/2018	12/31/2020
J9269	J9269	Injection, tagraxofusp-erzs, 10 micrograms	G	9309	07/01/2019	06/30/2022
J9285	J9285	Injection, olaratumab, 10 mg	G	9485	04/01/2017	03/31/2020
J9311	J9311	lnjection, rituximab 10 mg and hyaluronidase	G	9467	04/01/2018	03/31/2021
J9313	J9313	Injection, moxetumomab pasudotox-tdfk, 0.01 mg	G	9305	04/01/2019	03/31/2022
J9356	J9356	Injection, trastuzumab, 10 mg and Hyaluronidase-oysk	G	9314	07/01/2019	09/30/2022
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
Q4195	Q4195	Puraply, per square centimeter	G	9175	10/01/2018	09/30/2020
Q4196	Q4196	Puraply am, per square centimeter	G	9176	10/01/2018	09/30/2020

CY 2019 HCPCS Code	CY 2020 HCPCS Code	Long Descriptor	CY 2020 Status Indicator	CY 2020 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
Q5103	Q5103	Injection, infliximab-dyyb, biosimilar, (inflectra), 10 mg	G	1847	04/01/2017	03/31/2020
Q5104	Q5104	Injection, infliximab-abda, biosimilar, (renflexis), 10 mg	G	9036	04/01/2018	03/31/2021
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
Q5107	Q5107	Injection, bevacizumab-awwb, biosimilar, (mvasi), 10 mg	G	9329	01/01/2020	12/31/2022
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
Q5117	Q5117	Injection, trastuzumab-anns, biosimilar, (kanjinti), 10 mg	G	9330	01/01/2020	12/31/2022
Q9950	Q9950	Injection, sulfur hexafluoride lipid microsphere, per ml	G	9085	10/01/2018	09/30/2020
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
N/A	C9054	Injection, lefamulin (Xenleta), 1 mg	G	9331	01/01/2020	12/31/2022
N/A	C9055	Injection, brexanolone, 1mg	G	9332	01/01/2020	12/31/2022

CY 2019 HCPCS Code	CY 2020 HCPCS Code	Long Descriptor	CY 2020 Status Indicator	CY 2020 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
N/A	J9309	Injection, polatuzumab vedotin-piiq (Polivy), 1 mg	G	9330	01/01/2020	12/31/2022

*HCPCS Code C9043 (Injection, levoleucovorin, 1 mg) will be deleted on December 31, 2019, and will be replaced by HCPCS code J0642 (Injection, levoleucovorin (khapzory), 0.5 mg) on January 1, 2020.

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5. Drugs, Biologicals, and Radiopharmaceuticals With Pass-Through Status as a Result of Section 1301 of the Consolidated Appropriations Act of 2018 (Pub. L. 115–141)

As mentioned earlier, section 1301(a)(1) of the Consolidated Appropriations Act of 2018 (Pub. L. 115–141) amended section 1833(t)(6) of the Act and added a new section 1833(t)(6)(G), which provides that for drugs or biologicals whose period of pass-through payment status ended on December 31, 2017 and for which payment was packaged into a covered hospital outpatient service furnished beginning January 1, 2018, such pass-through payment status shall be extended for a 2-year period beginning on October 1, 2018 through September 30, 2020. There are four products whose period of drug and biological pass-through payment status ended on December 31, 2017 and for which payment would have been packaged beginning January 1, 2018. These products were listed in Table 39 of the CY 2019 OPPS/ASC final rule with comment period (83 FR 58962).

Starting in CY 2019, the HCPCS code Q4172 (PuraPly, and PuraPly Antimicrobial, any type, per square centimeter) was discontinued. In its place, two new HCPCS codes were established—Q4195 (Puraply, per square centimeter) and Q4196 (Puraply am, per square centimeter). Because these HCPCS codes are direct successors to HCPCS code Q4172, the provisions of section 1833(t)(6)(G) of the Act apply to HCPCS codes Q4195 and Q4196, and these codes were listed in Table 16 of the proposed rule (84 FR 39495). For CY 2020, we proposed to continue pass-through payment status for the drugs and biologicals listed in Table 16 of the proposed rule (we note that these drugs and biologicals are also listed in Table 15 of the proposed rule) through September 30, 2020 as required in section 1833(t)(6)(G) of the Act, as added by section 1301(a)(1)(C) of the Consolidated Appropriations Act of 2018. The APCs and HCPCS codes for these drugs and biologicals approved for pass-through payment status are assigned status indicator ''G'' in Addenda A and B to the proposed rule (which are available via the internet on the CMS website).

We proposed to continue to update pass-through payment rates for HCPCS codes Q4195 and Q4196 along with the other three drugs and biologicals covered by section 1833(t)(6)(G) of the Act on a quarterly basis on the CMS website during CY 2020 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 drugs or biologicals are necessary. The replacement of HCPCS code Q4172 by HCPCS codes Q4195 and Q4196 means there are five HCPCS codes for drugs and biologicals covered by section 1833(t)(6)(G) of the Act. For a full description of this policy, we refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 58960 through 58962).

The five HCPCS codes for drugs and biologicals that we proposed would have pass-through payment status for CY 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, are shown in Table 16 of the CY 2020 OPPS/ASC proposed rule. Included as two of the five HCPCS codes for drugs and biologicals with pass-through payment status for CY 2020 are HCPCS codes Q4195 (Puraply, per square centimeter) and Q4196 (Puraply am, per square centimeter). PuraPly and PuraPly AM are skin substitute products that were approved for pass-through payment status on January 1, 2015 through the drug and biological pass-through payment process. Beginning on April 1, 2015, skin substitute products are evaluated for pass-through payment status through the device pass-through payment process. However, we stated in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66887) that skin substitutes that are approved for pass-through payment status as biologicals effective on or before January 1, 2015 would continue to be paid as pass-through biologicals for the duration of their pass-through payment period. Because PuraPly and PuraPly AM were approved for pass-through payment status through the drug and biological pass-through payment pathway, we finalized a policy to consider both PuraPly and PuraPly AM to be drugs or biologicals as described by section 1833(t)(6)(G) of the Act, as added by section 1301(a)(1)(C) of the Consolidated Appropriations Act of 2018, and to be eligible for extended pass-through payment under our proposal for CY 2020 (83 FR 58961 through 58962).

We did not receive any comments on this policy. Therefore, we are finalizing this proposal without modification. Starting on October 1, 2020, the drugs and biologicals listed in Table 42 will no longer receive pass-through status, and will be assigned to status indicator ''N'', which means these drugs will once again be packaged in the OPPS.

TABLE 42.— DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS IN CY 2020 IN ACCORDANCE WITH PUB. L. 115-141

CY 2019 HCPCS Code	CY 2020 HCPCS Code	Long Descriptor	CY 2020 Status Indicator	CY 2020 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
A9586	A9586	Florbetapir f18, diagnostic, per study dose, up to 10 millicuries	G	9084	10/01/2018	09/30/2020
C9447	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
Q4195	Q4195	Puraply, per square centimeter	G	9175	10/01/2018	09/30/2020
Q4196	Q4196	Puraply AM, per square centimeter	G	9176	10/01/2018	09/30/2020
Q9950	Q9950	Injection, sulfur hexafluoride lipid microsphere, per ml	G	9085	10/01/2018	09/30/2020

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 2020, as we did in CY 2019, 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 43 below.

We did not receive any comments on this proposal. Therefore, we are finalizing this proposal without modification.

TABLE 43.—APCS TO WHICH A POLICY-PACKAGED DRUG OR RADIOPHARMACEUTICAL OFFSET MAY BE APPLICABLE IN CY 2020

CY 2020 APC	CY 2020 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

We proposed to continue to post annually on the CMS 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.

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 $125 for CY 2019 (83 FR 58963 through 58964).

Following the CY 2007 methodology, for this CY 2020 OPPS/ASC final 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 2020 and rounded the resulting dollar amount ($128.11) 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 2019 OPPS/ASC final rule with comment period, based on these calculations using the CY 2007 OPPS methodology, we are finalizing a packaging threshold for CY 2020 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 2020 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 2018 and were paid (via packaged or separate payment) under the OPPS. We used data from CY 2018 claims processed before January 1, 2019 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 2020: 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 2020, we used 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 for CY 2020, as discussed in more detail in section V.B.2.b. of the proposed rule) to calculate the CY 2020 proposed rule per day costs. We used the manufacturer-submitted ASP data from the fourth quarter of CY 2018 (data that were used for payment purposes in the physician's office setting, effective April 1, 2019) to determine the proposed rule per day cost.

As is our standard methodology, for CY 2020, we proposed to use payment rates based on the ASP data from the first 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 are 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, 2019. 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 2018 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 2018 HCPCS codes that were reported to the CY 2019 HCPCS codes that we display in Addendum B to the proposed rule (which is available via the internet on the CMS website) for proposed payment in CY 2020.

Comment: Two commenters suggested that CMS create an exception to the drug cost threshold packaging policy in situations where a shortage of a drug that is packaged under the drug cost threshold packaging policy requires providers to use a higher-cost substitute drug that presumably is still packaged because of the drug cost packaging threshold. The commenters suggested that the substitute drug be separately paid even though the per day cost of the substitute drug is still below the drug cost packaging threshold amount.

Response: We thank the commenter for its suggestion but disagree that such a policy is necessary at this time. We note that the purpose of the drug cost threshold is to require the packaging of relatively small per day drug costs into the associated outpatient hospital procedure. This suggestion runs contrary to our policy goal of bundling more services to encourage provider efficiency. However, we are cognizant of issues surrounding drug shortages and will consider this suggestion for the future.

Comment: One commenter requested that we no longer package HCPCS code J2274 (Injection, Morphine Sulfate, Preservative-Free For Epidural Or Intrathecal Use, 10 mg) because the drug is used in an implantable infusion pump for intrathecal management of pain and/or spasticity, and another drug, HCPCS code J0475 (injection, baclofen, 10 mg) which can be used with the same infusion pump, currently receives separate payment in the OPPS.

Response: We disagree with the commenter. Neither HCPCS code J2274 nor HCPCS code J0475 are classified as drugs that are policy packaged. We refer readers to section V.B.1.c. for a description of drugs that are policy packaged. Also, neither of these drugs is assigned to drug pass-through status. Therefore, we use our drug cost threshold methodology as described in this section of the rule to determine whether the drugs are packaged into an associated procedure or if the drugs are separately paid. The per day cost of HCPCS code J2274 is below the $130 drug packaging threshold, and therefore, the drug is packaged in the OPPS. The per day cost of HCPCS code J0475 is above the drug packaging threshold, and therefore, the drug is paid separately in the OPPS. The drug packaging threshold is based on the per day cost of the specific drug administered, and the threshold is not affected by the means by which the drug is administered to the beneficiary (in this case, through a pump). In the case brought up by the commenter, the per day cost of HCPCS code J2274 is below the $130 drug packaging threshold, and is therefore packaged into the payment for its associated procedure.

After consideration of the public comments we received, and consistent with our methodology for establishing the packaging threshold using the most recent PPI forecast data, we are adopting a CY 2019 packaging threshold of $130.

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 2020 OPPS/ASC proposed rule, we proposed to use ASP data from the fourth quarter of CY 2018, 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, 2019, along with updated hospital claims data from CY 2018. We note that we also proposed to use these data for budget neutrality estimates and impact analyses for this CY 2020 OPPS/ASC proposed rule.

Payment rates for HCPCS codes for separately payable drugs and biologicals included in Addenda A and B for the final rule with comment period will be based on ASP data from the third quarter of CY 2019. 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, 2019. These payment rates would then be updated in the January 2020 OPPS update, based on the most recent ASP data to be used for physicians' office and OPPS payment as of January 1, 2020. 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 2018 claims data and update cost report information available for the CY 2020 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 2020 OPPS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2019. 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 2020,

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 2019 and that are proposed for separate payment in CY 2020, and that then have per day costs equal to or less than the CY 2020 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2020 final rule, would continue to receive separate payment in CY 2020.
- HCPCS codes for drugs and biologicals that were packaged in CY 2019 and that are proposed for separate payment in CY 2020, and that then have per day costs equal to or less than the CY 2020 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2020 final rule, would remain packaged in CY 2020.
- HCPCS codes for drugs and biologicals for which we proposed packaged payment in CY 2020 but that then have per-day costs greater than the CY 2020 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2020 final rule, would receive separate payment in CY 2020.

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 2018 claims data and updated cost report information available for this CY 2020 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 2020, we are finalizing these two proposals without modification.

c. Policy Packaged Drugs, Biologicals, and Radiopharmaceuticals

As mentioned earlier in this section, in the OPPS, we package several categories of 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).

We did not make any proposals to revise our policy-packaged drug policy.

Comment: CMS received several comments from stakeholders regarding the policy-packaged status of diagnostic radiopharmaceuticals. Several commenters recommended that CMS continue to apply the nuclear medicine procedure to radiolabeled product edits to ensure that all packaged costs are included on nuclear medicine claims in order to establish appropriate payment rates in the future. There was concern that many providers performing nuclear medicine procedures are not including the cost of diagnostic radiopharmaceuticals used for the procedures in their claims submissions. Commenters believe this lack of drug cost reporting could be causing the cost of nuclear medicine procedures to be underreported and therefore requests that the radiolabeled product edits be reinstated.

Response: We appreciated the commenter's feedback; however, we do not agree with the commenter that we should reinstate the nuclear medicine procedure to radiolabeled product edits, which required a diagnostic radiopharmaceutical to be present on the same claim as a nuclear medicine procedure for payment under the OPPS to be made. As previously discussed in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58965), 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: Several commenters requested that diagnostic radiopharmaceuticals be paid separately in all cases, not just when the drugs have pass-through payment status. Some commenters 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 the inadequate payment after pass-through expires. Several commenters recommended treating diagnostic radiopharmaceuticals similarly to therapeutic radiopharmaceuticals. Commenters opposed incorporating the cost of the drug into the associated APC, and provided limited evidence showing procedures in which diagnostic radiopharmaceuticals are considered to be a surgical supply that the commenter believed are often paid at a lower rate than the payment rate for the diagnostic radiopharmaceutical itself when the drug was paid separately because it 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. Conversely, other commenters disagreed with the idea to pay separately for diagnostic radiopharmaceuticals that cost more than $500 because they claimed that this would incentivize radiopharmaceutical companies to raise their prices to exceed the threshold. Additionally, commenters stated that nearly 95 percent of radiopharmaceuticals are priced less than $500, so creating a diagnostic radiopharmaceutical packaging threshold of $500 would not be appropriate.

Response: We thank commenters for their responses. 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 2020 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 the rates are established in a manner that uses the average, more specifically 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 items and services because the billing patterns of hospitals may not reflect that a particular item or service is always billed with the primary procedure. 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 that does not align with our overall packaging policy and limited data has been submitted 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, which 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.

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 2020.

For CY 2020, 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 2018 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 2020 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 2018 claims data to make the proposed packaging determinations for these drugs: 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 2020 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 2020 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 2020 was displayed in Table 18 of the proposed rule (84 FR 39499).

We did not receive any public comments on this proposal. Therefore, for CY 2020, we are finalizing our CY 2020 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. Table 44 below displays the final packaging status of each drug and biological HCPCS code to which the finalized methodology applies for CY 2020.

TABLE 44.— HCPCS CODES TO WHICH THE CY 2020 DRUG-SPECIFIC PACKAGING DETERMINATION METHODOLOGY WOULD APPLY

CY 2020 HCPCS Code	CY 2020 Long Descriptor	CY 2020 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
J1840	Injection, kanamycin sulfate, up to 500 mg	N
J1850	Injection, kanamycin sulfate, up to 75 mg	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
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

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.[66]

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 this CY 2020 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 2019.

b. CY 2020 Payment Policy

For CY 2020, we proposed to continue our payment policy that has been in effect since CY 2013 to pay for separately payable drugs and biologicals at ASP+6 percent in accordance with section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default). We proposed to continue to pay for separately payable nonpass-through drugs acquired with a 340B discount at a rate of ASP minus 22.5 percent, but we also solicited comments on alternative policies as well as the appropriate remedy for CYs 2018 and 2019 in the event that we do not prevail on appeal in the pending litigation, as discussed in greater detail later in this section. We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59353 through 59371) and the CY 2019 OPPS/ASC final rule with comment period (83 FR 58979 through 58981) for more information about how the payment rate for drugs acquired with a 340B discount was established.

In the case of a drug or biological during an initial sales period in which data on the prices for sales for 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), 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), 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). For the CY 2020 OPPS, 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. For drugs and biologicals that would otherwise be subject to a payment reduction because they were acquired under the 340B Program, the 340B Program rate (in this case, WAC minus 22.5 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 proposal.

Comment: Several commenters opposed our proposal 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. Commenters were concerned that paying less for new drugs may discourage the use of new innovative drugs and inhibit access to patients. Commenters also noted that the sequestration cuts further decreased payment for drugs, which leaves a smaller margin for providers. Additionally, some commenters believe that this proposal would only negatively impact providers, and would not address increasing drug costs. Additionally, commenters suggested excluding certain drugs and biologicals

[66] 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.*

from this policy, such as biosimilar biological products or radiopharmaceuticals. These commenters felt as though the policy was appropriate for drugs in general, but not for the previously mentioned products, which could potentially offer savings to the Medicare program if utilized in the case of biosimilars or which have a higher associated overhead in the case of radiopharmaceuticals. Commenters also discussed value-based payments as a more meaningful change than this proposal.

Response: We appreciate the commenter's feedback. We continue to believe our policy will improve Medicare payment rates by better aligning payments with drug acquisition costs, which is of the utmost importance to CMS as Part B drug spending has grown significantly. WAC plus a 3 percent add-on is more comparable to an ASP plus a 6 percent add-on, since the WAC pricing does not reflect many of the discounts associated with ASP, such as rebates. This proposal to continue 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 is consistent with MedPAC's previous analysis and recommendations in its June 2017 Report to the Congress. This policy is not meant to provide preferential treatment to any specific drug or biological, but to address WAC based payment under 1847A of the Act. We remind commenters that this proposal still results in a net payment greater than the WAC. In addition, this policy decreases the beneficiary cost-sharing for these drugs. This could help Medicare beneficiaries afford to pay for new drugs by reducing their out-of-pocket expenses.

After consideration of the public comments we received, we are finalizing our proposal, without modification, 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) of the Act.

We proposed that payments for separately payable drugs and biologicals are included in the budget neutrality adjustments, under the requirements in section 1833(t)(9)(B) of the Act. We also proposed that the budget neutral weight scalar not be applied in determining payments for these separately paid drugs and biologicals.

We note that separately payable drug and biological payment rates listed in Addenda A and B to the proposed rule (available via the internet on the CMS website), which illustrate the proposed CY 2020 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, 2019, or WAC, AWP, or mean unit cost from CY 2018 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 2020 payment rates. This is because payment rates for drugs and biologicals with ASP information for January 2020 will be determined through the standard quarterly process where ASP data submitted by manufacturers for the third quarter of CY 2019 (July 1, 2019 through September 30, 2019) will be used to set the payment rates that are released for the quarter beginning in January 2020 near the end of December 2019. 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 2019 are based on mean unit cost in the available CY 2018 claims data. If ASP information becomes available for payment for the quarter beginning in January 2020, 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 2019 ASP data) that do not have ASP information available for the quarter beginning in January 2020. These drugs and biologicals would then be paid based on mean unit cost data derived from CY 2018 hospital claims. Therefore, the proposed payment rates listed in Addenda A and B to the proposed rule are not for January 2020 payment purposes and are only illustrative of the CY 2020 OPPS payment methodology using the most recently available information at the time of issuance of the proposed rule.

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+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 current 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 believe that these changes would better reflect the resources and production costs that biosimilar manufacturers incur. We also 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 believe 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), for CY 2019, 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 2020, 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 policy to pay nonpass-through biosimilars acquired under the 340B Program at the biosimilar's 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, in accordance with section 1833(t)(14)(A)(iii)(II) of the Act. In addition, as discussed further below, we solicited comments on the appropriate remedy in the event of an adverse decision on appeal in the litigation related to our policy for payment of 340B-acquired drugs and biologicals, including on whether paying for 340B-acquired biosimilars at ASP+3 percent of the reference product's ASP would be an appropriate policy in line with that discussion. Our policy for 340B-acquired drugs and biologicals is discussed in V.B.6. of this final rule with comment period.

Comment: Many commenters supported our biosimilar 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. Commenters believe this would continue to improve access to these treatments and lower costs, and they stressed the importance of consistency with biosimilar payment. Commenters stated that there is a large disparity between payment for biosimilars and their reference products and that this proposal helps to mitigate that concern. Commenters also advocated for additional proposals to increase the utilization of biosimilars, such as extended pass-through payment.

Response: We appreciate the commenters' support. We believe this proposal will continue to encourage competition, lower costs for the Medicare program and beneficiaries, and eliminate any financial incentive to utilize one product over another. We will continue to assess biosimilar utilization under the OPPS.

Comment: Several commenters supported our proposal to pay nonpass-through biosimilars acquired under the 340B Program at ASP minus 22.5 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 for a discussion of payment for biosimilars aquired under 340B.

Comment: Some commenters 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. Commenters believe biosimilars are not new or innovative drugs or biologicals, because they believe the originator product is the only new and innovative product. Therefore, they stated biosimilars should not be considered for pass-through payment status. Additionally, commenters stated there should be a level playing field between biosimilars and their originator reference products in order to increase competition and reduce costs for beneficiaries. Commenters believe that this proposal could potentially lead to increased Medicare spending on biosimilars, and commenters articulated concerns that therapies will be interrupted by providers switching from innovator products to biosimilars.

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. Additionally, we are not convinced that making all biosimilar biological products eligible for pass-through payment status will lead to inappropriate treatment changes from a reference product without pass-through payment to a biosimilar product with pass-through payment. Under current policy, both originator products and their associated biosimilars receive the same percentage add-on amount, regardless of the ASP of the product; therefore, we do not believe that therapies will be interrupted by providers switching from innovator products to biosimilars. We note that Section 351(i) of the Public Health Service Act defines biosimilarity to mean ''that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components'' and that ''there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.'' Therefore, concerns that therapy would be interrupted by a switch from an innovator product to a biosimilar are unfounded as the biosimilar has been determined to have no clinically meaningful difference from the reference product. In regards to the increased payment of biosimilars under this policy, overall increased competition due to 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.

For CY 2020, 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 also are finalizing our proposal to pay nonpass-through biosimilars acquired under the 340B Program at the biosimilar's ASP minus 22.5 percent of the reference product's ASP, in accordance with section 1833(t)(14)(A)(iii)(II) of the Act.

3. Payment Policy for Therapeutic Radiopharmaceuticals

In the CY 2020 OPPS/ASC proposed rule (84 FR 39502), for CY 2020, 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 2020. Therefore, we proposed for CY 2020 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 2018 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 2020 payment rates for nonpass-through, separately payable therapeutic radiopharmaceuticals were included in Addenda A and B to the proposed rule (which are available via the internet on the CMS website).

Comment: Commenters supported the continuation of the policy to pay ASP+6 percent for radiopharmaceuticals, if available, and to base payment on the mean unit cost derived from hospital claims data when not available. Commenters also stressed the high overhead, handling, compounding and storage costs associated with delivering therapeutic radiopharmaceuticals and asked CMS to look into higher payment rates for radiopharmaceuticals or ways to compensate hospitals for the higher overhead and handling costs.

Response: We appreciate the commenters' support. As previously stated, we continue to believe a single payment is appropriate for therapeutic radiopharmaceuticals and that the payment rate of ASP+6 percent is appropriate because it provides payment for both the therapeutic radiopharmaceutical's acquisition cost and the associated costs such as storage and handling of the radiopharmaceuticals. Payment for the radiopharmaceutical and radiopharmaceutical processing services is made through the single ASP-based payment.

For CY 2020, after consideration of the public comments we received, 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 2018 mean unit cost data derived from hospital claims data for payment rates for therapeutic radiopharmaceuticals for which ASP data are unavailable. The CY 2020 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 2019, 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 2019, 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 2019 updated furnishing fee was $0.220 per unit.

For CY 2020, 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 were 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 the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html.*

Comment: Commenters supported CMS' proposal to continue to pay for blood clotting factors at ASP+6 percent plus a blood clotting factor furnishing fee in the hospital outpatient department.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, 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 2020, we proposed to continue to use the same payment policy as in CY 2019 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 2020 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 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 2020 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 2020 if pricing information becomes available. The CY 2020 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 2020 OPPS Payment Methodology for 340B Purchased Drugs

In the CY 2018 OPPS/ASC proposed rule (82 FR 33558 through 33724), we proposed changes to the Medicare Part B drug payment methodology for 340B hospitals. We proposed these changes to better, and more accurately, reflect the resources and acquisition costs that these hospitals incur. We believe 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 on 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 included in this 340B policy change because they are paid under section 1834(g) of the Act. 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 on 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 nonexcepted off-campus PBDs paid under the PFS. We adopted this payment policy effective for CY 2019 and for subsequent years.

As discussed in the CY 2019 OPPS/ASC proposed rule (83 FR 37125), another topic that was brought to our attention since we finalized the payment adjustment for 340B-acquired drugs in the CY 2018 OPPS/ASC final rule with comment period was whether drugs that do not have ASP pricing but instead receive WAC or AWP pricing are subject to the 340B payment adjustment. We did not receive public comments on this topic in response to the CY 2018 OPPS/ASC proposed rule. However, we later heard from stakeholders that there had been some confusion about this issue. We clarified in the CY 2019 proposed rule that 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. The 340B payment adjustment for WAC-priced drugs is WAC minus 22.5 percent and AWP-priced drugs have a payment rate of 69.46 percent of AWP when the 340B payment adjustment is applied. 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. The number of separately payable drugs receiving WAC or AWP pricing that are affected by the 340B payment adjustment is small—consisting of less than 10 percent of all separately payable Medicare Part B drugs in April 2018.

Furthermore, data limitations previously inhibited our ability to identify which drugs were acquired under the 340B Program in the Medicare OPPS claims data. This lack of information within the claims data has limited researchers' and our ability to precisely analyze differences in acquisition cost of 340B and non-340B acquired drugs with Medicare claims data. Accordingly, in the CY 2018 OPPS/ASC proposed rule (82 FR 33633), we stated our intent to establish a modifier, to be effective January 1, 2018, for hospitals to report with separately payable drugs that were not acquired under the 340B Program. Because a significant portion of hospitals paid under the OPPS participate in the 340B Program, we stated our belief that it is appropriate to presume that a separately payable drug reported on an OPPS claim was purchased under the 340B Program, unless the hospital identifies that the drug was not purchased under the 340B Program. We stated in the CY 2018 proposed rule that we intended to provide further details about this modifier in the CY 2018 OPPS/ASC final rule with comment period and/or through subregulatory guidance, including guidance related to billing for dually eligible beneficiaries (that is, beneficiaries covered under Medicare and Medicaid) for whom covered

entities do not receive a discount under the 340B Program. 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, CMS 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 those hospitals paid under the Maryland waiver), or excepted from the 340B drug payment policy for CY 2018, are 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 are excepted from the 340B payment adjustment. These hospitals are 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 modifier ''JG''.

In the CY 2019 OPPS/ASC proposed rule (83 FR 37125), for CY 2019, we proposed to continue the 340B Program policies that were implemented in CY 2018 with the exception of the way we calculate payment for 340B-acquired biosimilars (that is, we proposed 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). More information on our revised policy for the payment of biosimilars acquired through the 340B Program is available in section V.B.2.c. of the CY 2019 OPPS/ASC final rule with comment period. For CY 2019, we proposed, in accordance with section 1833(t)(14)(A)(iii)(II) of the Act, to pay for separately payable Medicare Part B drugs (assigned status indicator ''K''), other than vaccines and drugs on pass-through payment status, that meet the definition of ''covered outpatient drug'' as defined in section 1927(k) of the Act, that are acquired through the 340B Program at ASP minus 22.5 percent when billed by a hospital paid under the OPPS that is not excepted from the payment adjustment. Medicare Part B drugs or biologicals excluded from the 340B payment adjustment include vaccines (assigned status indicator ''F'', ''L'' or ''M'') and drugs with OPPS transitional pass-through payment status (assigned status indicator ''G''). 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. We also proposed for CY 2019 that Medicare would continue to pay for drugs or biologicals that were not purchased with a 340B discount at ASP+6 percent.

As stated earlier, to effectuate the payment adjustment for 340B-acquired drugs, CMS implemented modifier ''JG'', effective January 1, 2018. For CY 2019, we proposed that hospitals paid under the OPPS, other than a type of hospital excluded from the OPPS, or excepted from the 340B drug payment policy for CY 2018, continue to be required to report modifier ''JG'' on the same claim line as the drug HCPCS code to identify a 340B-acquired drug. We also proposed for CY 2019 that rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals would continue to be excepted from the 340B payment adjustment. We proposed for CY 2019 that these hospitals be required to report informational modifier ''TB'' for 340B-acquired drugs, and continue to be paid ASP+6 percent. In the CY 2019 OPPS/ASC final rule with comment period (83 FR 58981), after consideration of the public comments we received, we finalized our proposals without modification.

Our CY 2018 and 2019 OPPS payment policies for 340B-acquired drugs are the subject of ongoing litigation. On December 27, 2018, in the case of *American Hospital Association et al.* v. *Azar et al.,* the United States District Court for the District of Columbia (hereinafter referred to as ''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.[67] 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.[68] 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.[69] 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,''[70] 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.''[71] *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.''[72]

CMS respectfully disagreed with the district court's understanding of the scope of its adjustment authority. On July 10, 2019, the district court entered final judgment, and the agency has filed its appeal. Nonetheless, CMS is taking the steps necessary to craft an appropriate remedy in the event of an unfavorable decision on appeal. Notably, after the proposed rule was issued, CMS announced in the **Federal Register** (84 FR 51590) its intent to conduct a 340B hospital survey to collect drug acquisition cost data for CY 2018 and 2019. 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. *See* 348 F. Supp. 3d at 82. 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—a significant omission because 340B hospitals have their own data regarding their drug acquisition costs. We thus anticipate that survey data collected for CY 2018 and 2019 will confirm that the ASP minus 22.5 percent rate is a conservative measure that overcompensates 340B hospitals. A

[67] *American Hosp. Ass'n, et al.* v. *Azar, et al.,* No. 1:18–cv–2084 (D.D.C. Dec. 27, 2018).

[68] *Id.* at 35 (quoting *Amgen, Inc.* v. *Smith,* 357 F.3d 103, 112 (D.C. Cir. 2004) (citations omitted)).

[69] *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.

[70] *Id.* at 13.

[71] *Id.* at 19.

[72] *Id.* (citing Declaration of Elizabeth Richter).

remedy that relies on such survey data could avoid the remedial complexities discussed below and in the proposed rule.

Recognizing Medicare's complexity in formulating an appropriate remedy, any changes to the OPPS must be budget neutral, and reversal of the policy change, 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 approximate 3,900 facilities that are paid for outpatient items and services covered under the OPPS. Second, any remedy that increases payments to 340B hospitals is likely to 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 statute, are required to pay cost-sharing for such items and services, which is usually 20 percent of the total Medicare payment rate.

CMS solicited initial public comments on how to formulate a solution that would account for all of the complexities the district court recognized in the event of an unfavorable decision on appeal. A summary of the public comments received on a potential remedy is included later in this section. In the event 340B hospital survey data are not used to devise a remedy, we intend to consider this public input to further inform the steps that are required under the Administrative Procedure Act to provide adequate notice and an opportunity for meaningful comment on our proposed policies, which would entail devising the specific remedy itself, presenting the specific budget neutrality implications of that remedy in the proposed rule, and potentially calculating all the different payment rates under the OPPS for 340B-acquired drugs, as well as all other items and services under the OPPS. (In essence, we would need to provide hospitals with sufficient notice of the impact of the remedy on their rates to enable them to comment meaningfully on the proposed rule.) Our own best practices for preparing notices of proposed rulemaking dictate that we begin policy development in the year before the proposed rule is issued, and that we begin the rule drafting process in the first quarter of each year.

In the event of an unfavorable decision on appeal, if 340B hospital survey data are not used to devise a remedy, as we stated in the CY 2020 OPPS/ASC proposed rule, we anticipate proposing the specific remedy for CYs 2018 and 2019 in the CY 2021 OPPS/ASC proposed rule in the event of an unfavorable decision on appeal. Those potential proposals for CY 2021 would be informed by the comments that CMS solicited in the CY 2020 proposed rule.

Thus, for CY 2020, we proposed 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. We proposed to continue the 340B 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, as well as 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.

In the CY 2020 OPPS/ASC proposed rule (84 FR 39504), we also solicited public comment on the appropriate OPPS payment rate for 340B-acquired drugs, including whether a rate of ASP+3 percent could be an appropriate remedial payment amount for these drugs, both for CY 2020 and for purposes of determining the remedy for CYs 2018 and 2019. This amount would result in payment rates that are well above the actual costs hospitals incur in purchasing 340B drugs, and we proposed it solely because of the court decision. However, to the extent the courts are limiting the size of the payment reduction the agency can permissibly apply, the agency believes it could be appropriate to apply a payment reduction that is at the upper end of that limit, to the extent it has been or could be clearly defined, given the substantial discounts that hospitals receive through the 340B program. For example, absent further guidance from the Court of Appeals on what it believes is an appropriate ''adjustment'' amount, CMS could look to the district court's December 27, 2018 opinion, which cites to payment reductions of 0.2 percent and 2.9 percent as ''not significant enough'' to fall outside of the Secretary's authority to ''adjust'' ASP.[73] This payment rate would apply to 340B-acquired drugs and biologicals billed by a hospital paid under the OPPS that are not excepted from the payment adjustment and to 340B-acquired drugs and biologicals furnished in nonexcepted off-campus PBDs paid under the PFS. We welcomed public comments on payment rates other than ASP+3 percent that commenters believe would be appropriate for purposes of addressing CY 2020 payment as an alternative to our proposal above, as well as for potential future rulemaking related to CY 2018 and 2019.

Comments on the Appropriate Payment Rate for 340B-Acquired Drugs in CY 2020

Comment: Several commenters supported the continuation of the 340B Program policy of ASP minus 22.5 percent for CY 2020. One commenter believed the 340B program's recent growth may be contributing to the consolidation of community oncology practices. This commenter and others asserted that the growth of the 340B program has resulted in a shift in the site of service for chemotherapy administration from the physician-office setting to the more costly hospital outpatient setting, since hospitals are able to acquire drugs, including oncologic drugs, at a significant discount under the 340B program. Another commenter believed that the 340B program is no longer serving its intended purpose to help America's most vulnerable patients access the drugs they need. They further asserted that instead, 340B profits are being used for hospitals to make larger profits.

Response: We appreciate the commenters' support. We note that comments related to the 340B program itself are outside the scope of this rule, however, we note that we adopted the 340B payment policy so that our payment policy would be more in line with the acquisition costs hospitals incur, and thereby lower drug expenditures for Medicare beneficiaries and the Medicare Trust Fund.

Comment: Many commenters, the majority of which represented hospitals or hospital associations, opposed CMS' proposal to continue to pay ASP minus 22.5 percent for 340B-acquired drugs in CY 2020. Many of these commenters believe the proposal undermines the intent and goals of the 340B program and will have negative impacts on patients and 340B hospitals. One commenter asserted that CMS should pay hospitals participating in the 340B program the statutory default payment of ASP+6 percent. Another commenter opposed the proposal on the belief that it undermines the Public Health Service Act (PHSA), which authorized the 340B program and exceeds CMS' statutory authority. Furthermore, a hospital organization commented that the application of the reduced payment for the 340B policy has resulted in negative consequences for patients and providers and does not save any money for

[73] 348 F. Supp. 3d 62, 81 (D.D.C. 2018) (citing to payment reductions of 0.2 percent and 2.9 percent that other decisions have recognized as being within the agency's adjustment authority for Medicare rates under the inpatient prospective payment system).

Medicare because the policy is implemented in a budget-neutral manner.

Several commenters who opposed the continuation of the 340B program payment policy stated that the district court's ruling showed that the payment reduction is illegal and exceeded the Administration's authority. These commenters recommended CMS refrain from ''doing more damage'' to impacted hospitals by continuing the ASP minus 22.5 percent policy and return to the payment rate of ASP+6 percent for CY 2020.

Response: 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 and better represents acquisition costs.

We disagree with commenters that the 340B payment policy has had a negative impact on Medicare patients; we 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.

In regards to the commenters' belief that CMS lacks the legal authority to continue paying a reduced amount for drugs and biologicals obtained through the 340B Program and that we should pay the statutory default amount of ASP+6 percent, we refer commenters to our detailed response regarding our statutory authority to require payment reductions for drugs and biologicals obtained through the 340B Program in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59359 through 59364), as well as our statements in the proposed rule regarding our appeal of the district court's decision.

After considering these public comments and the comments summarized below, and in light of the fact that we are awaiting a decision on our appeal in the litigation, for CY 2020, we are finalizing our proposal, without modification, to pay ASP minus 22.5 percent for 340B-acquired drugs including when furnished in nonexcepted off-campus PBDs paid under the PFS. Our finalized proposal continues the 340B 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.

As noted in the proposed rule (84 FR 39504), we are appealing the district court's decision and are awaiting a decision from the Court of Appeals for the District of Columbia Circuit. Because we hope to prevail on appeal and have our 340B policy upheld, we believe it is appropriate to finalize our proposal of ASP minus 22.5 percent rather than an alternative payment amount of either ASP+3 percent or ASP+6 percent, and to maintain the other payment policies we adopted for 340B-acquired drugs in the CY 2018 and 2019 OPPS final rules with comment period. In the event of an adverse decision on appeal, we solicited public comments on the appropriate remedy for use in the CY 2021 rulemaking. Those comments are summarized below. We note that in the event 340B hospital survey data are not used to devise a remedy, we intend to consider the following comments to develop an appropriate remedy to propose in next year's rulemaking.

Comments on the CY 2020 Payment Policy for 340B-Aquired Drugs to Non-Excepted Off-Campus Provider Based Departments (PBDs)

Comment: Many commenters disagreed with CMS' assertion that 340B hospitals will move drug administration services for 340B-acquired drugs to non-excepted off-campus PBDs if CMS does not continue to pay for drugs furnished in these settings at the adjusted amount, and recommended CMS study hospital's drug administration behavior pre- and post-implementation of the CY 2018 final rule to confirm this presumption before finalizing the proposal to continue paying ASP minus 22.5 percent for 340B drugs furnished by non-excepted PBDs. Several commenters asserted that CMS should not continue with this policy for CY 2020 for non-excepted PBDs and stated that continuing to do so would be unlawful.

Response: We appreciate the commenters' input on the proposal to continue to pay at ASP minus 22.5 percent under the PFS for 340B drugs furnished in non-excepted off-campus PBDs. As we stated in the CY 2019 OPPS/ASC final rule with comment (83 FR 59017), because hospitals can, in some cases, acquire drugs and biologicals under the 340B Program for use in nonexcepted off-campus PBDs, we believe that not adjusting payment exclusively for these departments would present a significant incongruity between the payment amounts for these drugs depending on where they are furnished. This incongruity would distort the relative accuracy of the resource-based payment amounts under the site-specific PFS rates and could result in significant perverse incentives for hospitals to acquire drugs and biologicals under the 340B Program and avoid Medicare payment adjustments that account for the discount by providing these drugs to patients predominantly in nonexcepted off-campus PBDs. In light of the significant payment differences between excepted and nonexcepted off-campus PBDs, in combination with the potential eligibility for discounts, which result in reduced costs under the 340B Program for both kinds of departments, a different payment policy for 340B drugs in the two settings could undermine the use of the OPPS payment structure in nonexcepted off-campus PBDs. In order to avoid such perverse incentives and the potential resulting distortions in drug payment, pursuant to our authority at section 1833(t)(21)(c) of the Act we adopted a policy to identify the PFS as the ''applicable payment system for 340B-acquired drugs and biologicals and, accordingly, to pay under the PFS instead of under section 1847A/1842(o) of the Act an amount equal to ASP minus 22.5 percent for drugs and biologicals acquired under the 340B Program that are furnished by nonexcepted off-campus PBDs. We continue to believe this payment policy is necessary to avoid the significant incongruity between the payment amounts that would exist for these drugs depending upon whether they are furnished by excepted off-campus PBDs or nonexcepted off-campus PBDs. We believe we have discretion under section 1833(t)(21)(c) of the Act to continue to adjust payments for nonexcepted off-campus PBDs.

Comments on Use of ASP Plus 3 Percent for CY 2020

Comment: Many commenters opposed a payment amount of ASP+3 percent as a potential remedial payment for 340B-acquired drugs furnished in CY 2018 and CY 2019 as well as for CY 2020 payments. These commenters believe CMS did not provide a rationale to support the proposed ASP+3 percent adjustment and stated that CMS does not have statutory authority to pay one group of hospitals at ASP+3 percent and all other hospitals at ASP+6 percent.

Some commenters stated that section 1833(t)(14)(A)(iii)(II) requires CMS to pay hospitals for covered outpatient drugs at ASP+6 percent and that CMS does not have the legal authority to change that payment amount to ASP+3 percent. Furthermore, some commenters stated that although CMS has some authority to make adjustments, the agency's stated rationale of imposing a payment reduction at the upper end of the court's ''limit [on] the size of the payment reduction the agency can permissibly apply . . . given the substantial discounts that hospitals receive under the 340B program'' would be inconsistent with the law itself and therefore, reducing payment for 340B-acquired drugs to ASP+3 percent would be unlawful.

However, a few commenters supported the proposal to pay ASP+3 percent for 340B-acquired drugs in CY 2020, rather than to continue to pay ASP minus 22.5 percent. One commenter supported the approach of paying ASP+3 percent for 340B-acquired drugs if CMS receives an adverse decision on appeal.

Response: We appreciate commenters' support of CMS' suggestion to pay at ASP+3 percent if we are unsuccessful in the Appeals Court. As explained above, we are finalizing our proposal to continue to pay for 340B-acquired drugs at ASP minus 22.5 percent. In the event of an adverse decision on appeal, we will take these comments into consideration in crafting an appropriate remedy.

Comment: One commenter believed a rate closer to ASP+6 percent, such as ASP+3 percent, would mitigate remediation efforts should the Agency not ultimately prevail on appeal and have to return the difference in payments between ASP minus 22.5 percent and ASP+6 percent based on a negative court decision.

Response: We thank the commenter for its feedback. As explained above, we are finalizing our proposal to continue to pay for 340B-acquired drugs at ASP minus 22.5 percent. In the event of an adverse decision on appeal, we will take these comments into consideration in crafting an appropriate remedy.

Comments on Use of Hospital Acquisition Costs

Comment: Several commenters, including a large medical association, suggested that CMS gather hospitals' acquisition costs for drugs. One commenter stated that ''since CMS has the authority to base reimbursement rates on the hospitals' acquisition cost (340B price) if the Agency considers hospital acquisition cost survey data, we urge CMS to collect such data.'' Another commenter urged CMS to gather additional data to better understand 340B acquisition costs and the impact of payment reductions on 340B providers prior to making payment changes that the commenter believes jeopardizes access and 340B program participation.

Response: We appreciate the commenters' suggestion and note that we announced in the **Federal Register** (84 FR 51590) our intent to conduct a 340B hospital survey to collect drug acquisition cost data for CY 2018 and 2019. We have no evidence that the current 340B policy has limited patient access to 340B drugs or program participation. For the reasons explained above, we believe it is appropriate to continue our 340B payment policies for CY 2020.

Thus, for CY 2020, we are finalizing our proposal, without modification, to pay ASP minus 22.5 percent for 340B-acquired drugs including when furnished in nonexcepted off-campus PBDs paid under the PFS. Our finalized proposal 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.

Comments on a Potential Remedy for CYs 2018 and 2019

In addition to comments on the appropriate payment amount for calculating the remedy for CYs 2018 and 2019 and for use for CY 2020, we sought public comment on how to structure the remedy for CYs 2018 and 2019. This request for public comment included whether such a remedy should be retrospective in nature (for example, made on a claim-by-claim basis), whether such a remedy could be prospective in nature (for example, an upward adjustment to 340B claims in the future to account for any underpayments in the past), and whether there is some other mechanism that could produce a result equitable to hospitals that do not acquire drugs through the 340B program while respecting the budget neutrality mandate.

We stated in the CY 2020 OPPS/ASC proposed rule that one potential remedy for alleged underpayments in 2018 and 2019 would involve making additional payments to the parties who have demonstrated harm from the alleged underpayments (which could be defined as hospitals that submitted a claim for drug payment with the ''JG'' modifier in CYs 2018 and 2019) outside the normal claims process. Under this approach, we would calculate the amount that such hospitals should have been paid and would utilize our Medicare contractors to make one payment to each affected hospital. This approach—one additional payment made to each affected hospital by our contractors—is a different approach than reprocessing each and every claim submitted by plaintiff hospitals for 2018 and 2019. Then, depending on when a final decision is rendered, the Secretary would propose to budget-neutralize those additional expenditures for each of CYs 2018 and 2019. For example, if the Court of Appeals were to render a decision in February of 2020, we might propose those additional payments and an appropriate budget neutrality adjustment for each of CYs 2018, 2019, and, if necessary, 2020, in time for the CY 2021 rule. We noted that we would need to receive a final decision from the Court of Appeals sufficiently early in CY 2020 (likely no later than March 1, 2020) to make it potentially possible for us to propose and finalize an appropriate remedy and budget neutrality adjustments in the CY 2021 rulemaking. We solicited public comment on this approach as well as other suggested approaches from commenters.

In considering these potential future proposals, we noted that we would rely on our statutory authority under section 1833(t)(14) for determining the OPPS payment rates for drugs and biologicals as well as section 1833(t)(9)(A) of the Act to review certain components of the OPPS not less often than annually and to revise the groups, relative payment weights, and other adjustments. In addition, we noted that under section 1833(t)(14)(H) of the Act, any adjustments made by the Secretary to payment rates using the statutory formula outlined in section 1833(t)(14)(A)(iii)(II) of the Act are required to be taken into account under the budget neutrality requirements outlined in section 1833(t)(9)(B) of the Act. In the CY 2020 OPPS/ASC proposed rule (84 FR 39505), we solicited public comments on the best, most appropriate way to maintain budget neutrality, either under a retrospective claim-by-claim approach, with a prospective approach, or any other proposed remedy. We also solicited comments on whether, depending on the amount of those additional expenditures, we should

consider spreading out the relevant budget neutrality adjustment across multiple years. We appreciated all the public comments that we received on the advantages and disadvantages of such an approach.

We also sought public comments on the best, most appropriate treatment of Medicare beneficiary cost-sharing responsibilities under any proposed remedy. We stated that the statutory budget neutrality requirement and beneficiary cost-sharing are extremely difficult to balance, and we sought stakeholder comments as we continue to review the viability of alternative remedies in the event of an adverse decision from the Court of Appeals.

We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59369 through 59370) and the CY 2019 OPPS/ASC final rule with comment period (83 FR 58976 through 58977 and 59015 through 59022) for more detail on the policies implemented in CY 2018 and CY 2019 for drugs acquired through the 340B Program.

We also note that since the CY 2020 OPPS/ASC proposed rule was published, we announced in the **Federal Register** (84 FR 51590) our intent to conduct a 340B hospital survey to collect drug acquisition cost data for CY 2018 and 2019. As noted above, we may use this survey data to devise a remedy for prior years if the district court's ruling is upheld on appeal. A remedy that relies on such survey data could avoid the remedial complexities discussed below and in the proposed rule. If, however, 340B hospital survey data are not used to devise a remedy, we intend to consider the comments summarized below to inform a remedy we would propose in the CY 2021 OPPS/ASC proposed rule in the event of an adverse decision upon appeal.

Comments on Potential Remedy Structure

Comment: On the issue of a remedy structure, many commenters supported a retrospective remedy on a claim-by-claim basis over a prospective adjustment of prior 340B claims. Several commenters believe it is CMS' responsibility to remedy the policy by requiring as little effort as possible on the part of affected hospitals, thus avoiding any additional injuries to the parties. Many commenters believe that CMS should repay the difference between ASP+6 percent and ASP minus 22.5 percent plus interest for all claims for 340B-acquired drugs for CYs 2018 and 2019. They asserted that CMS can calculate the amount owed to the affected 340B hospitals by using the JG modifier that identifies the claims for 340B drugs. One commenter suggested identifying the total amount paid to a hospital for drugs with the status indicator ''K'' and multiplying by 1.3677 (that is ASP+6 percent/ASP minus 22.5 percent = 1.06/0.775). Another commenter stated that the percentage of claims that each hospital was underpaid is the same in each case and that we can calculate the total payment for each hospital and multiply that number by a factor, in order to determine how much each hospital should have been paid. Some commenters supported a lump-sum payment. One commenter supported either a lump-sum payment or a prospective payment segmented out over multiple years. One commenter compared this case to those remedies that the courts and agency have adopted to handle past cases. This commenter believed the affected parties should receive a supplemental payment for those affected claims in an amount equal to the difference between ASP minus 22.5 percent and ASP+6 percent. Another commenter believed that the remedy should be decided by a federal judge.

Additionally, some commenters supported a prospective remedy, pointing out that a retrospective process would be too complex and administratively burdensome. Several commenters supported an aggregate payment for each affected 340B entity outside the normal claims process rather than a retrospective adjustment. One commenter suggested applying an increase factor of 26.89 percent that would pay the affected entities at an amount that would approximate ASP+6 percent. Another commenter supported an upward adjustment to future claims, which they believed would reduce administrative burden.

Another commenter believed that CMS should publish a proposed methodology for conducting the look-back and issuing the payment. Further, they believed that providers should have opportunity for public comment, and that CMS should revise and issue a final methodology in CY 2020 outside of the normal OPPS rulemaking cycle, with the applicable data set and calculation instructions posted on the CMS web page. Other commenters believed the remedy does not necessitate rulemaking.

One commenter offered three remedy suggestions. Two suggestions involved staggered methods of payment. Under the first suggested remedy, this commenter believed that CMS could pay for 340B drugs at the following amounts over three years, which the commenter believed would make affected providers whole: Beginning January 1, 2021, CMS would pay ASP+14.25 percent plus an additional 2 percent; beginning January 1, 2022 would pay ASP+14.25 percent plus an additional 1 percent; and finally, beginning January 1, 2023, CMS would pay ASP+6 percent going forward.

The same commenter suggested a second approach under which CMS would pay affected hospitals set amounts plus interest as follows:

The first payment would be for claims submitted between January 1, 2018 and June 30, 2018 and would be paid out by July 1, 2020. The second payment would be for claims submitted between July 1, 2018 and December 31, 2018 and would be paid out January 1, 2021. The third payment would be for claims submitted between January 1, 2019 and June 30, 2019 and would be paid out July 1, 2021. The final payment would be for claims submitted between July 1, 2019 and December, 31, 2019 and would be paid out January 1, 2022.

Alternatively, the same commenter suggested a third method of making remedy payments under which CMS could recalculate the payments for all claims paid for CYs 2018 and 2019 and pay affected 340B hospitals the difference (between ASP+6 and ASP minus 22.5 percent) in one lump-sum payment plus interest by January 1, 2021. The commenter suggested that CMS would provide affected 340B hospitals notice on or before July 1, 2021 of the calculated payment amount owed to the hospital. The commenter suggested that the repayment amounts should be placed in a 340B-specified account to be redistributed to eligible hospitals and distributed in equal payments over a two-year period beginning January 2021 for covered entities that demonstrate ''responsible program integrity'' as determined in collaboration with HRSA. The commenters suggested that funds not able to be distributed will be used to provide funding to CMS and HRSA to collaborate with industry stakeholders to identify and implement solutions for duplicate discount prevention.

Comments on Budget Neutrality

On the issue of budget neutrality, many commenters asserted that budget neutrality is not necessary given prior court precedents involving underpayments: *Cape Cod Hospital* v. *Sebelius* (DC Cir. 2011), *H. Lee Moffitt Cancer Center & Research Institute, Inc. vs. Azar,* (D.D.C. 2018), *Shands Jacksonville Medical Center* v. *Burwell,* (D.D.C. 2015). Other commenters asserted that neither (t)(9)(B) nor any other provision of the OPPS statue

authorizes the agency to revisit budget neutrality if its estimates of money owed for a prior year turn out to be incorrect. They view the statute as directing CMS to make estimates for the purposes of setting prospective payment rates only, and not authorizing the agency to recalibrate those estimates after the fact if its predictions turn out to be incorrect. These commenters believe that the Congress drafted the OPPS statute to prohibit the agency from revisiting its budget-neutrality determinations after it first makes them on a prospective basis for a given year. They further asserted that CMS should exercise discretion in using its budget neutrality authority in seeking payments back from providers.

Some commenters supported a prospective payment rate reduction on OPPS non-drug items and services to maintain budget neutrality from any remedy. Other commenters supported a gradual rate reduction of the payment amounts for OPPS non-drug items and services ranging from a minimum of two to six years to lessen the impact of rate reduction to the affected entities. Several commenters supported a modest reduction in future OPPS payment by reducing the conversion factor.

Comments on Beneficiary Coinsurance

Additionally, many commenters asserted that there is no law that requires hospitals to adjust beneficiaries' coinsurance for 340B-acquired drugs. They stated that neither the False Claims nor the anti-kickback statutes would apply because beneficiaries did not receive any inducements to seek services. These commenters believe that beneficiaries already fully paid for the hospital care months or years ago and should not have to pay any additional payments. They requested that CMS clearly state in this final rule that there is no requirement for any beneficiary copay adjustments. One commenter offered estimates on what they believe are the percentage of patients who are impacted by any adjustment on the patient's copay citing 29 percent with Medigap, 22 percent enrolled in Medicaid (dually eligible), and 19 percent without a supplemental plan, with the remaining 30 percent enrolled in a Medicare Advantage plan. Thus, this commenter believed that only 19 percent of patients would be impacted directly by cost-sharing implications and CMS would need to calculate payment owed to Medicare for these beneficiaries.

Response: We thank the commenters for their comments on the appropriate remedy for CYs 2018 and 2019. As noted above, we may use the survey data for 2018 and 2019 that we plan to collect from 340B hospitals to devise a remedy for prior years if the district court's ruling is upheld on appeal. A remedy that relies on such survey data could avoid the remedial complexities discussed above and in the proposed rule. If, however, 340B hospital survey data are not used to devise a remedy in the event of an adverse decision from the Court of Appeals, we intend to consider all of these suggestions in determining the appropriate remedy to propose in the CY 2021 OPPS rulemaking. To the extent commenters made legal arguments relating to the False Claims Act or anti-kickback statutes, CMS offers no opinion.

7. High Cost/Low Cost Threshold for Packaged Skin Substitutes

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 finalize the packaging of 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 above 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 2019, the payment rate for APC 5053 (Level 3 Skin Procedures) was $482.89, the payment rate for APC 5054 (Level 4 Skin Procedures) was $1,548.96, 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 2019 OPPS/ASC final rule with comment period (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 2020. 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). For CY 2020, 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. For CY 2020, as we did for CY 2019, we proposed to assign each skin substitute that exceeds either the MUC threshold or the PDC threshold to the high cost group. In addition, as described in more detail later in this section, for CY 2020, as we did for CY 2019, 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 2020, we proposed that any skin substitute product that was assigned to the high cost group in CY 2019 would be assigned to the high cost group for CY 2020, regardless of whether it exceeds or falls below the CY 2020 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 this CY 2020 OPPS/ASC final rule, consistent with the methodology as established in the CY 2014 through CY

2018 final rules with comment period, we analyzed CY 2018 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 2020 MUC threshold is $48 per cm ^{2} (rounded to the nearest $1) (proposed at $49 per cm ^{2}) and the final CY 2020 PDC threshold is $790 (rounded to the nearest $1) (proposed at $789).

For CY 2020, 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 would 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 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 2020 MUC threshold. 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).

Some skin substitute manufacturers have raised concerns about significant fluctuation in both the MUC threshold and the PDC threshold from year to year. 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 refinement 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. We also specified in the CY 2019 OPPS/ASC final rule with comment period that we were interested in any new ideas that are not represented below along with an analysis of how different skin substitute products would fare under such ideas. Finally, we stated that we intend to explore the full array of public comments on these ideas for the CY 2020 rulemaking, and we indicated that we will consider the feedback received in response to our requests for comments in developing proposals for CY 2020.

a. Discussion of CY 2019 Comment Solicitation for Episode-Based Payment and Solicitation of Additional Comments for CY 2020

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 for 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 burdens on providers. Finally, these commenters had concerns about the impacts 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 make us reluctant to present a proposal for this CY 2020 proposed rule without more review of the issues involved 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.

Comment: 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. A few 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 co-morbidities.

Some commenters opposed the idea of a complexity adjustment for skin substitute application procedures. The commenters believe 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.

Regarding the topic of episodic payment, commenters brought up some of the same issues they had mentioned in response to last year's comment solicitation. Supporters of episodic payments believe the policy idea would give providers more flexibility with the treatments they administer to their patients, and will help encourage innovation by encouraging the development of graft skin substitute products that require fewer applications.

Some commenters supported developing an episodic payment model first in the CMS Innovation Center before adopting episodic payment in the OPPS. One commenter wrote about the need for quality measures as a part of episodic payment to ensure providers render appropriate care during a treatment episode. However, another commenter wanted to ensure that quality measures would not prevent providers from using a medically necessary product. Commenters also discussed episode length with a couple of commenters supporting a 12-week payment episode as mentioned in the comment solicitation, and another commenter suggesting that an episode be based not only on the length of time but the number of allowed skin substitute applications during that time period. Commenters also favored establishing a separate payment episode for each wound receiving treatment.

Commenters who oppose episodic payment expressed similar concerns as they did in response to last year's comment solicitation. Many commenters believe that wound care is too complex and variable to be covered through episodic payment even with an option for a complexity adjustment. For example, one commenter noted that the care regimen for diabetic foot ulcers is very different than the care regimen for pressure wounds. A few commenters expressed concerns about the complexities associated with episodic payment, claiming that CMS will have to established several new HCPCS codes and clinical APCs to be able to have

payment rates for all of the care scenarios covered by episodic payment. Commenters also believe it would take several years to implement an episode-based payment system and such system would be operationally and administratively burdensome for providers. Other commenters were concerned about financial incentives created by episodic payment that may discourage providers from rendering the best quality of care and encourage providers to use skin substitute products that may not be the most clinically appropriate for their patients. Finally, commenters had concerns about establishing the length of a payment episode, stating there was no clear evidence on what the appropriate episode length should be. These commenters believe it also would be difficult to establish separate payment episodes when a patient was being treated for multiple wounds at the same time.

Commenters also discussed which services should be included with an episodic payment. Commenters were divided over whether an episode should be limited to application of skin substitute products or encompass other related wound care treatments including hyperbaric oxygen and negative-pressure treatment. Some commenters were concerned that episodic payment may discourage the treatment of large or complicated wounds. There also was one commenter who wanted episodic payment to cover tissue repair products used in surgical procedures.

Response: We appreciate all of the feedback we received from commenters, and we will use the feedback as we consider potential refinements to how we pay for skin substitute products and procedures under the OPPS.

b. Potential Revisions to the OPPS Payment Policy for Skin Substitutes: Comment Solicitation for CY 2020

In addition to possible future rulemaking based on the responses to the comment solicitations in the preceding section, we noted that we were considering adopting for CY 2020 another payment methodology that generated significant public comments in response to the CY 2019 comment solicitation. That option 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. Under this option, the only available procedure codes to bill for skin substitute graft 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 (Skn sub grft f/n/hf/g child). The payment rate would be the geometric mean of all graft skin substitutes procedures for a given CPT code that are covered 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*''. The geometric mean cost for CPT code 15271 was $1,572.17 in the CY 2020 OPPS/ASC proposed rule and the geometric mean cost for HCPCS code C5271 was $728.28 in the proposed rule. We stated in the proposed rule that if this policy option was implemented, only CPT code 15271 would be available in the OPPS, and the geometric mean cost using data from the CY 2020 proposed rule for the procedure code would be $1,465.18.

Commenters that supported this option believe 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 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. Finally, supporters of a single payment category believe it would simplify coding for providers and reduce administrative burden.

There were also commenters that raised concerns that a single payment category would not offer providers incentives to furnish high quality care and would reduce the use of higher-cost skin substitute products (which they seemed to imply are of higher quality than lower cost products). They argued that eliminating the high cost and low cost payment categories also does not maintain homogeneity among APC assignments for services using skin substitutes according to opponents of the single payment category. Commenters stated that instead of having categories grouped by the relative cost of products, there would be only one category to cover the payment of products with a mean unit cost ranging from less than $1 to over $750. Commenters believe a single payment category would favor inexpensive products, which could limit innovation, and could eliminate all but the most inexpensive products from the market. Finally, opponents of a single payment category believe a single payment category would discourage the treatment of wounds that are difficult and costly to treat.

The responses to the comment solicitation show the potential of a single payment category to reduce the cost of wound care services for graft skin substitute procedures for both beneficiaries and Medicare in general. In addition, a single payment category may help to lower 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 a more equitable payment rate for graft skin substitute procedures could substantially reduce the amount Medicare pays for these procedures. We welcomed suggestions or other information regarding the possibility of utilizing a single payment category to pay for skin substitute products under the OPPS, and, depending on the information we received in response to this request, we noted we may consider modifying our skin substitute payment policy in the CY 2020 OPPS/ASC final rule with comment period.

We believe some of the concerns 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, 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 could include, but are not limited to—

- 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.

We sought commenters' feedback on these ideas, or other approaches, to mitigate challenges that could impact providers, manufacturers, and other stakeholders if we establish a single payment category, which we indicated we might include as part of a final skin substitute payment policy that we would adopt in the CY 2020 OPPS/ASC final rule with comment period.

Comment: A few commenters expressed support for a single payment category for the application of skin substitute products. These commenters supported the payment methodology because they believe it would remove incentives for manufacturers to develop and providers to use high-cost products. These commenters maintained that a single payment category would encourage product innovations that maintain the quality of care for beneficiaries while bringing down the cost of skin substitute products, which will help to reduce the co-payments beneficiaries pay for skin substitute application services. Commenters supported more payment homogeneity because they believe most skin substitute products perform in a similar manner and no product or group of products is clinically superior over other skin substitute products. One commenter noted that the device pass-through payment pathway continues to be available for manufacturers to receive additional payment if a superior skin substitute product is developed.

Several commenters in favor of a single payment category believe it would simplify coding for providers and reduce administrative burden. They also believe a single payment category provides adequate payment for providers based on the case mix of smaller, easier to treat wounds and larger, more complex wounds. Also, a single payment category would promote cost stability by eliminating the large payment fluctuation for skin substitutes who are close to the cost-group thresholds in the current high-cost/low-cost payment methodology for skin substitutes.

The vast majority of commenters were opposed to a single payment category for skin substitute products. Commenters stated that the large difference in resource costs between higher cost and lower cost skin substitute products would mean only the most inexpensive products would be used to provide care, which would hurt both product innovation and the quality of care beneficiaries receive. Commenters 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 also stated that a single payment category would increase incentives for providers to use cheaper products that require more applications to generate more revenue. A couple of commenters believe 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 go up according to the commenters is the 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 stated that a single payment rate would lead to too much heterogeneity in the products receiving payment through the skin substitute application procedures. 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 would prefer to have multiple payment categories where the payment rate is more reflective of the cost of the product. Commenters believe that a single payment category would discourage providers from treating more complicated wounds.

Some commenters stated that CMS should not implement a single payment category methodology in CY 2020 because it only sought comments and did not propose it and that CMS should formally propose the methodology to allow commenters a meaningful opportunity to comment on the precise proposal before implementing it.

There also were comments about the idea of having a transition period of 1 to 2 years before the full implementation of a single category payment methodology. 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 who did mention the idea of a transition period wanted it to last multiple years with one commenter suggesting a transition period of four years.

Response: We appreciate the comments we received for this comment solicitation, and we will use the feedback to help inform our development of our payment methodology for skin substitute application procedures in future rulemaking.

c. Proposals for Packaged Skin Substitutes for CY 2020

To allow stakeholders time to analyze and comment on the issues discussed above, we proposed for CY 2020 to continue our policy established in CY 2018 to assign skin substitutes to the low cost or high cost group. Specifically, we proposed 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 2019, in which case we would assign the product to the high cost group for CY 2020, regardless of whether it exceeds the CY 2020 MUC or PDC threshold. We also proposed to assign to the high cost group any skin substitute product that exceeds the CY 2020 MUC or PDC thresholds and assign to the low cost group any skin substitute product that does not exceed the CY 2020 MUC or PDC thresholds and was not assigned to the high cost group in CY 2019. We proposed 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 2020 MUC. In addition, we proposed to use WAC+3 percent for skin substitute products that do not have ASP pricing information or have claims data to determine if those products' costs exceed the CY 2020 MUC. We proposed to continue our established policy to assign new skin substitute products without pricing information to the low cost group.

Table 19 of the proposed rule displayed the proposed CY 2020 cost category assignment for each skin substitute product.

Comment: Most commenters supported our proposal to continue our policy to assign skin substitutes to the low cost or high cost group, mainly

because they still want more information on both episode-based payment for skin substitutes and the possibility of creating a single payment category for skin substitutes. These commenters do not currently support either potential payment methodology and prefer to keep the current high-cost and low-cost payment methodology until an alternative methodology for skin substitutes is better developed.

Response: We appreciate the support of the commenters of our CY 2020 proposal for the payment of skin substitute application services.

Comment: One commenter was opposed to our proposal. This commenter requested that we no longer assign to the high-cost group skin substitute products that do not meet either the MUC or PDC thresholds in CY 2020 because the skin substitute product had previous been assigned to the high-cost group in CY 2019. The commenter believes skin substitute products should be assigned to the cost group that for which they qualify based on current MUC and PDC thresholds because the commenter believes that Medicare payment should reflect to some extent the relative cost of a skin substitute product compared to all other skin substitute products.

Response: We disagree with commenter. Requiring products to potentially switch annually between the high-cost and low-cost group leads to payment instability for skin substitute products (82 FR 59346–59347). The payment rate for a skin substitute application procedure may change by several hundred dollars depending on if a skin substitute product is assigned to the high-cost or low-cost group, which can make it challenging for manufacturers to estimate the payment their products will generate when used by providers. The policy to continue to assign skin substitute products to the high-cost group once they qualify for the group promotes payment stability and allows manufacturers and providers to know over a long period of time the payment rate of the procedures used with each skin substitute product.

Comment: For the CY 2019 OPPS/ASC final rule with comment period, a commenter, the manufacturer, requested that HCPCS code Q4184 (Cellesta, per square centimeter) be assigned to the high-cost skin substitute group because the ASP+6 percent price of HCPCS code Q4184 for Quarter 1 of 2019 was $110.02 per cm^2 which was substantially higher than the MUC threshold for CY 2019 of $49 per cm^2.

Response: HCPCS code Q4184 (Cellesta, per square centimeter) has been assigned to the high-cost group since April 1, 2019 and we proposed assigning the skin substitute product again to the high-cost group in CY 2020.

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 (Dermacell, per square centimeter) and Q4150 (Allowrap ds or dry, per square centimeter) were both assigned to the high-cost group in CY 2019 and also were proposed to the high-cost group for CY 2020. 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 2019 will continue to be assigned to the high-cost group in CY 2020 even if 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 2020.

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 2019, in which case we would assign the product to the high cost group for CY 2020, regardless of whether it exceeds the CY 2020 MUC or PDC threshold. We also are finalizing our proposal to assign to the high cost group any skin substitute product that exceeds the CY 2020 MUC or PDC thresholds and assign to the low cost group any skin substitute product that does not exceed the CY 2020 MUC or PDC thresholds and was not assigned to the high cost group in CY 2019. 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 2020 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 2020 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 45 below displays the final CY 2020 cost category assignment for each skin substitute product.

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TABLE 45.—SKIN SUBSTITUTE ASSIGNMENTS TO HIGH COST AND LOW COST GROUPS FOR CY 2020

CY 2020 HCPCS Code	CY 2020 Short Descriptor	CY 2019 High/Low Cost Assignment	CY 2020 High/Low Cost Assignment
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	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
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, 1cm	High	High
Q4148	Neox 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 1 square cm	High	High

CY 2020 HCPCS Code	CY 2020 Short Descriptor	CY 2019 High/Low Cost Assignment	CY 2020 High/Low Cost Assignment
Q4154	Biovance 1 square cm	High	High
Q4156	Neox 100 or clarix 100	High	High
Q4157	Revitalon 1 square cm	High	High*
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 cm	Low	Low
Q4167	Truskin, per square cm	Low	Low
Q4169	Artacent wound, per sq cm	High	High
Q4170	Cygnus, per square cm	Low	Low
Q4173	Palingen or palingen xplus	High	High
Q4175	Miroderm, per square cm	High	High
Q4176	Neopatch, per square 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	Low
Q4183	Surgigraft, 1 sq cm	High	High*
Q4184	Cellesta, 1 sq cm	High	High*
Q4186	Epifix 1 sq cm	High	High
Q4187	Epicord 1 sq cm	High	High
Q4188	Amnioarmor 1 sq cm	Low	Low
Q4190	Artacent ac 1 sq cm	Low	Low
Q4191	Restorigin 1 sq cm	Low	Low
Q4193	Coll-e-derm 1 sq cm	Low	Low
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	Low
Q4200	Skin te 1 sq cm	Low	Low
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	Low	Low
Q4208	Novafix per sq cm	Low	High
Q4209	Surgraft per sq cm	Low	Low

CY 2020 HCPCS Code	CY 2020 Short Descriptor	CY 2019 High/Low Cost Assignment	CY 2020 High/Low Cost Assignment
Q4210	Axolotl graf dualgraf sq cm	Low	Low
Q4211	Amnion bio or axobio sq cm	Low	Low
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	Low
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	Low	Low

* These products do not exceed either the proposed MUC or PDC threshold for CY 2020, but are assigned to the high cost group because they were assigned to the high cost group in CY 2019.
+ Pass-through payment status in CY 2020. Pass-through payment status expires September 30, 2020.

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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 prorata 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 2020 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 2020. 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 2019 or beginning in CY 2020. The sum of the proposed CY 2020 pass-through spending estimates for these two groups of device categories equaled the proposed total CY 2020 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 2020, 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 2020 for this group of items is $224.1

million, as discussed below, because we proposed to pay for most nonpass-through separately payable drugs and biologicals under the CY 2020 OPPS at ASP+6 percent with the exception of 340B-acquired separately payable drugs that are paid at ASP minus 22.5 percent, and because we proposed to pay for CY 2020 pass-through payment drugs and biologicals at ASP+6 percent, as we discuss in section V.A. of the CY 2020 OPPS/ASC proposed rule. We refer readers to section V.B.6 of the CY 2020 OPPS/ASC proposed rule where we discuss the comments we solicited on an appropriate remedy in litigation involving our OPPS payment policy for 340B purchased drugs, which would inform CY 2021 rulemaking in the event of an adverse decision on appeal in that litigation.

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 nonpass-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 II.A.3. of the CY 2020 OPPS/ASC proposed rule and this final rule with comment period. In the CY 2020 OPPS/ASC proposed rule (84 FR 39511), 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 2020 was not $0, as discussed below. In section V.A.5. of the CY 2020 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 2020. 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 2019 or beginning in CY 2020. The sum of the CY 2020 pass-through spending estimates for these two groups of drugs and biologicals equals the total CY 2020 pass-through spending estimate for drugs and biologicals with pass-through payment status.

B. Estimate of Pass-Through Spending

In the CY 2020 OPPS/ASC proposed rule (84 FR 39511 through 39512), we proposed to set the applicable pass-through payment percentage limit at 2.0 percent of the total projected OPPS payments for CY 2020, consistent with section 1833(t)(6)(E)(ii)(II) of the Act and our OPPS policy from CY 2004 through CY 2019 (82 FR 59371 through 59373).

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 2020, there is one active category for CY 2020. The active category is described by HCPCS code C1823 (Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads). Based on the information from the device manufacturer, we estimated that 100 devices will receive payment in the OPPS in CY 2020 at an estimated cost of $5,655 per device. Therefore, we proposed an estimate for the first group of devices of $565,500. We did not receive any public comments on the proposal. Therefore, we are finalizing the proposed estimate for the first group of devices of $565,500 for CY 2020.

In estimating our proposed CY 2020 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 2020; additional device categories that we estimated could be approved for pass-through status after the development of the proposed rule and before January 1, 2020; and contingent projections for new device categories established in the second through fourth quarters of CY 2020. For CY 2020, 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. For the proposed rule, the proposed estimate of CY 2020 pass-through spending for this second group of device categories was $10 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: Surefire® Spark™ Infusion System; Optimizer® System; AquaBeam® System; AUGMENT® Bone Graft and ARTIFICIAL*Iris*® . The manufacturers of these systems provided utilization and cost data that indicate the spending for the devices would be approximately $116.25 million for Surefire® Spark™ Infusion System, $46 million for Optimizer® System, $11.25 million for AquaBeam® System, $ 72.2 million for AUGMENT® Bone Graft, and $500,500 for ARTIFICIAL*Iris*®. Therefore, we are finalizing an estimate of $246.2 million for this second group of devices for CY 2020.

To estimate proposed CY 2020 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 2020, 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 2020 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 2020, we estimated the pass-through payment amount as the difference between ASP+6 percent and the payment rate for nonpass-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 that are paid at ASP minus 22.5 percent. Therefore, the payment rate difference between the pass-through payment amount and the nonpass-through payment amount is $224.1 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 2020 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 2020 to be $17.0 million. For the proposed rule, using the proposed methodology described above, we calculated a CY 2020 proposed spending estimate for this first group of drugs and biologicals that includes drugs currently on pass-through payment status that would otherwise be separately payable or policy-packaged of approximately $241.1 million. We did not receive any public comments on our proposal. Using our methodology for this final rule with comment period, we calculated a CY 2020 spending estimate for this first group of drugs and biologicals of approximately $399.6 million.

To estimate proposed CY 2020 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 proposed rule were newly eligible for pass-through payment in CY 2020, additional drugs and biologicals that we estimated could be approved for pass-through status subsequent to the development of the proposed rule and before January 1, 2020 and projections for new drugs and biologicals that could be initially eligible for pass-through payment in the second through fourth quarters of CY 2020), 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 2020 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 2020 pass-through payments for this second group of drugs, we calculated a proposed spending estimate for this second group of drugs and biologicals of approximately $17.1 million.

We did not receive any public comments on our proposal. Therefore, for CY 2020, we are continuing to use the general methodology described above. For this final rule with comment period, we calculated a CY 2020 spending estimate for this second group of drugs and biologicals of approximately $26 million.

In summary, in accordance with the methodology described earlier in this section, for this final rule with comment period, 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 2020 and those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2020 is approximately $698.4 million (approximately $246.8 million for device categories and approximately $451.6 million for drugs and biologicals) which represents 0.88 percent of total projected OPPS payments for CY 2020 (approximately $79 billion). Therefore, we estimate that pass-through spending in CY 2020 will not amount to 2.0 percent of total projected OPPS CY 2020 program spending.

VII. OPPS Payment for Hospital Outpatient Visits and Critical Care Services

For CY 2020, 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 proposed rule, we sought public comments on any changes to these codes that we should consider for future rulemaking cycles. We continue to encourage commenters to provide the data and analysis necessary to justify any suggested changes.

Comment: We received two public comments, one from a health system and another from a health information management association, in response to our CY 2020 proposal. Commenters suggested that CMS should adopt the recommendation of the Medicare Payment Advisory Commission (MedPAC) for the development and implementation of a set of national guidelines for coding hospital emergency department (ED) visits under the OPPS. They argued that national guidelines would provide hospitals with a clear set of rules for coding ED visits.

Response: We thank the commenters for their responses. We will consider these comments for future rulemaking.

After consideration of the public comments received, we are finalizing our CY 2020 proposal to continue our current clinic and ED hospital outpatient visits and critical care services payment policies without modifications.

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 the proposed rule and the CY 2019 final rule (FR 58818 through 59179), CY 2020 will be the second year of the 2-year transition of this policy, and in CY 2020, these departments will be paid the site-specific PFS rate for the clinic visit service. For a full discussion of this policy, we refer readers to the CY 2020 final rule with comment period and section X.C of this final rule with comment period.

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.

Section 1833(t)(1)(B)(i) of the Act provides the Secretary with the authority to designate the outpatient department (OPD) services to be covered under the OPPS. The Medicare regulations that implement this provision specify, at 42 CFR 419.21, that payments under the OPPS will be made for partial hospitalization services furnished by CMHCs as well as Medicare Part B services furnished to hospital outpatients designated by the Secretary, which include partial hospitalization services (65 FR 18444 through 18445).

Section 1833(t)(2)(C) of the Act requires the Secretary, in part, to establish relative payment weights for covered OPD services (and any groups of such services described in section 1833(t)(2)(B) of the Act) based on median (or, at the election of the Secretary, mean) hospital costs using data on claims from 1996 and data from the most recent available cost reports. In pertinent part, 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 accordance with these provisions, we have developed the PHP APCs. Since a day of care is the unit that defines the structure and scheduling of partial hospitalization services, we established a per diem payment methodology for the PHP APCs, effective for services furnished on or after July 1, 2000 (65 FR 18452 through 18455). Under this methodology, the median per diem costs were used to calculate the relative payment weights for the PHP APCs. Section 1833(t)(9)(A) of the Act requires the Secretary 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 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.

We began efforts to strengthen the PHP benefit through extensive data analysis, along with policy and payment changes finalized in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66670 through 66676). In that final rule with comment period, we made two refinements to the methodology for computing the PHP median: The first remapped 10 revenue codes that are common among hospital-based PHP claims to the most appropriate cost centers; and the second refined our methodology for computing the PHP median per diem cost by computing a separate per diem cost for each day rather than for each bill.

In CY 2009, we implemented several regulatory, policy, and payment changes, including a two-tier payment approach for partial hospitalization services under which we paid one amount for days with 3 services under PHP APC 0172 (Level 1 Partial Hospitalization) and a higher amount for days with 4 or more services under PHP APC 0173 (Level 2 Partial Hospitalization) (73 FR 68688 through 68693). We also finalized our policy to deny payment for any PHP claims submitted for days when fewer than 3 units of therapeutic services are provided (73 FR 68694). Additionally, for CY 2009, we revised the regulations at 42 CFR 410.43 to codify existing basic PHP patient eligibility criteria and to add a reference to current physician certification requirements under 42 CFR 424.24 to conform our regulations to our longstanding policy (73 FR 68694 through 68695). We also revised the partial hospitalization benefit to include several coding updates (73 FR 68695 through 68697).

For 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. We used only hospital-based PHP data because we were concerned about further reducing both PHP APC per diem payment rates without knowing the impact of the policy and payment changes we made in CY 2009. Because of the 2-year lag between data collection and rulemaking, the changes we made in CY 2009 were reflected for the first time in the claims data that we used to determine payment rates for the CY 2011 rulemaking (74 FR 60556 through 60559).

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 71994), we established four separate PHP APC per diem payment rates: Two for CMHCs (APC 0172 (for Level 1 services) and APC 0173 (for Level 2 services)) and two for hospital-based PHPs (APC 0175 (for Level 1 services) and APC 0176 (for Level 2 services)), based on each provider type's own unique data. For CY 2011, we also instituted a 2-year transition period for CMHCs to the CMHC APC per diem payment rates based solely on CMHC data. Under the transition methodology, CMHC APCs Level 1 and Level 2 per diem costs were calculated by taking 50 percent of the difference between the CY 2010 final hospital-based PHP median costs and the CY 2011 final CMHC median costs and then adding that number to the CY 2011 final CMHC median costs. A 2-year transition under this methodology moved us in the direction of our goal, which is to pay appropriately for partial hospitalization services based on each provider type's data, while at the same time allowing providers time to adjust their business operations and protect access to care for Medicare beneficiaries. We also stated that we would review and analyze the data during the CY 2012 rulemaking cycle and, based on these analyses, we might further refine the payment mechanism. We refer readers to section X.B. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71991 through 71994) for a full discussion.

In addition, in accordance with section 1301(b) of the Health Care and Education Reconciliation Act of 2010 (HCERA 2010), we amended the description of a PHP in our regulations to specify that a PHP must be a distinct and organized intensive ambulatory treatment program offering less than 24-hour daily care other than in an individual's home or in an inpatient or residential setting. In accordance with section 1301(a) of HCERA 2010, we revised the definition of a CMHC in the regulations to conform to the revised definition now set forth under section 1861(ff)(3)(B) of the Act (75 FR 71990).

For CY 2012, as discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74348 through 74352), 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.

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. We established these four PHP APC per diem payment rates based on geometric mean cost levels calculated using the most recent claims and cost data for each provider type. 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), we solicited comments on possible future initiatives that may help to ensure the long-term stability of PHPs and further improve the accuracy of payment for PHP services, but proposed no changes. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75050 through 75053), we summarized the comments received on those possible future initiatives. We also 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 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 PHP APC geometric mean per diem costs, using the most recent claims and cost data for each provider type.

In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70455 through 70465), we described our extensive analysis of the claims and cost data and ratesetting methodology. We found aberrant data from some hospital-based PHP providers that were not captured using the existing OPPS ±3 standard deviation trims for extreme cost-to-charge ratios (CCRs) and excessive CMHC charges resulting in CMHC geometric mean costs per day that were approximately the same as or more than the daily payment for inpatient psychiatric facility services. Consequently, we implemented a trim to remove hospital-based PHP service days that use a CCR that was greater than five to calculate costs for at least one of their component services, and a trim on CMHCs with a geometric mean cost per day that is above or below 2 (±2) standard deviations from the mean. We stated in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70456) that, without using a trimming process, the data from these providers would inappropriately skew the geometric mean per diem cost for Level 2 CMHC services.

In addition, in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70459 through 70460), we corrected a cost inversion that occurred in the final rule data with respect to hospital-based PHP providers. We corrected the cost inversion with an equitable adjustment to the actual geometric mean per diem costs by increasing the Level 2 hospital-based PHP APC geometric mean per diem costs and decreasing the Level 1 hospital-based PHP APC geometric mean per diem costs by the same factor, to result in a percentage difference equal to the average percent difference between the hospital-based Level 1 PHP APC and the Level 2 PHP APC for partial hospitalization services from CY 2013 through CY 2015.

Finally, we renumbered the PHP APCs, which were previously APCs 0172 and 0173 for CMHCs' partial hospitalization Level 1 and Level 2 services, and APCs 0175 and 0176 for hospital-based partial hospitalization Level 1 and Level 2 services to APCs 5851 and 5852 for CMHCs' partial hospitalization Level 1 and Level 2 services, and APCs 5861 and 5862 for hospital-based partial hospitalization Level 1 and Level 2 services, respectively. For a detailed discussion of the PHP ratesetting process, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70462 through 70467).

In the 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 using the most recent claims and cost data for each provider type. However, we finalized a policy to combine the Level 1 and Level 2 PHP APCs for CMHCs and to combine the Level 1 and Level 2 APCs for hospital-based PHPs because we believed this would best reflect actual geometric mean per diem costs going forward, provide more predictable per diem costs, particularly given the small number of CMHCs, and generate more appropriate payments for these services, for example by avoiding the cost inversions for hospital-based PHPs addressed in the CY 2016 and CY 2017 OPPS/ASC final rules with comment period (80 FR 70459 and 81 FR 79682). We also implemented an eight-percent outlier cap for CMHCs to mitigate potential outlier billing vulnerabilities by limiting the impact of inflated CMHC charges on outlier payments. We stated that we will continue to monitor the trends in outlier payments and consider policy adjustments as necessary.

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 using the most recent claims and cost data for each provider type. We also 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 CY 2019 OPPS/ASC final rule with comment period (83 FR 58997 through 58998), we also included proposed updates to the PHP allowable HCPCS codes. Specifically, we proposed to delete six psychological and neuropsychological testing CPT codes, which affect PHPs, and to add nine new codes as replacements. We refer readers to section VIII.D. of the proposed rule for a discussion of those proposed updates and the applicability for CY 2020.

B. Final PHP APC Update for CY 2020

1. Final PHP APC Geometric Mean Per Diem Costs

In summary, for CY 2020, we are finalizing our proposal as proposed to use the CY 2020 CMHC geometric mean per diem cost calculated in accordance with our existing methodology, but with a cost floor equal to the CY 2019 final geometric mean per diem cost for CMHCs of $121.62 (83 FR 58991), as the basis for developing the CY 2020 CMHC APC per diem rate. We are also finalizing our proposal to use the CY 2020 hospital-based PHP geometric mean per diem cost of $233.52, calculated in accordance with our existing methodology for hospital-based

PHPs, as the basis for developing the CY 2020 hospital-based APC per diem rate. We are finalizing our proposal to use the most recent updated claims and cost data to calculate CY 2020 geometric mean per diem costs in this final rule with comment period.

Also, we are finalizing our proposal to continue to use CMHC APC 5853 (Partial Hospitalization (3 or More Services Per Day)) and hospital-based PHP APC 5863 (Partial Hospitalization (3 or More Services Per Day)). These proposals, which we are finalizing as proposed in this final rule with comment period, are discussed in more detail.

2. Development of the Final PHP APC Geometric Mean Per Diem Costs

In preparation for CY 2020 and subsequent years, 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 3 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 II.A.4. of this final rule with comment period.

As previously stated, in the CY 2020 OPPS/ASC proposed rule, we proposed to apply our established methodologies in calculating the CY 2020 geometric mean per diem costs and payment rates, including the application of a ±2 standard deviation trim on costs per day for CMHCs and a CCR greater than 5 hospital service day trim for hospital-based PHP providers. These two trims were finalized in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70455 through 70462) for CY 2016 and subsequent years.

a. CMHC Data Preparation: Data Trims, Exclusions, and CCR Adjustments

For this CY 2020 final rule with comment period, prior to calculating the final 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 is not skewed by providers with extreme data. Before any trims or exclusions were applied, there were 44 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 2020 ratesetting, no CMHCs had geometric mean costs per day below the trim's lower limit of $20.58 or had geometric mean costs per day above the trim's upper limit of $520.48. Therefore, we did not exclude any CMHCs because of the ±2 standard deviation trim.

In accordance with our PHP ratesetting methodology, we also remove service days with no wage index values, because we use the wage index data to remove the effects of geographic variation in costs prior to APC geometric mean per diem cost calculation (80 FR 70465). For this CY 2020 final rule with comment period ratesetting, no CMHC was missing wage index data for all of its service days and, therefore, no CMHC was excluded. However, one CMHC had no days with Medicare payment, and it was excluded from ratesetting.

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 2020 OPPS/ASC final rule with comment period 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 also did not exclude any CMHCs for other missing data or for failing the ±2 standard deviation trim, but excluded one CMHC for having no Medicare payment data, resulting in the inclusion of 43 CMHCs. There were 319 CMHC claims removed during data preparation steps because they either had no PHP-allowable codes or had zero payment days, leaving 12,265 CMHC claims in our CY 2020 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.[74] The calculated CY 2020 geometric mean per diem cost for all CMHCs for providing 3 or more services per day (CMHC APC 5853) is $103.50, a decrease from $121.62 calculated last year for CY 2019 ratesetting (83 FR 58986 through 58989). This final calculated per diem cost for CMHCs is almost the same as the $103.42 geometric mean per diem cost calculated for the CY 2020 OPPS/ASC proposed rule (84 FR 39515 to 39516).

Due to this fluctuation from the CY 2019 final CMHC geometric mean per diem cost, we investigated why the CY 2020 final calculated CMHC APC geometric mean per diem cost had decreased from the prior year, and found that two large providers reported lower costs per day than those reported for the CY 2019 final rule ratesetting; those two providers heavily influenced the calculated geometric mean per diem cost. Because these providers had a high number of paid PHP days, and because the CMHC data set is so small (n=43), these providers had a significant influence on the calculated CY 2020 CMHC APC geometric mean per diem

[74] 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 3 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 3 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 3 or more services were provided.

cost. In the case of PHPs provided by CMHCs, we have a low number of PHP providers in our ratesetting dataset (43 CMHCs compared to 374 hospital-based PHPs) that provide a small volume of services and, therefore, account for a limited amount of payments, relative to the rest of OPPS payments (total CY 2018 CMHC payments are estimated to be approximately 0.02 percent of all OPPS payments).

As noted in the CY 2020 OPPS/ASC proposed rule (84 FR 39516), we are concerned that a final calculated CMHC APC geometric mean per diem cost of $103.50 would not support ongoing access to PHPs in CMHCs. This cost is nearly a 15 percent decrease from the final CY 2019 CMHC geometric mean per diem cost. We believe access to partial hospitalization services and PHPs is better supported when the geometric mean per diem cost does not fluctuate greatly. In addition, while the CMHC APC 5853 is described as providing 3 or more partial hospitalization services per day (81 FR 79680), 95 percent of CMHC paid days in CY 2018 were for providing 4 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 4 or more services per day (we refer readers to Table 22.—Percentage of PHP Days by Service Unit Frequency of the proposed rule). Therefore, the CMHC APC 5853 is actually heavily weighted to the cost of providing 4 or more services. 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. We do not believe it is likely that the actual cost of providing partial hospitalization services through a PHP by CMHCs has suddenly declined when costs generally increase over time. We are concerned by this fluctuation, which we believe is influenced by data from two large providers.

Therefore, rather than simply finalizing the calculated CY 2020 CMHC APC geometric mean per diem cost of $103.50 for CY 2020 ratesetting, we are instead finalizing our proposal as proposed, to use the CY 2020 CMHC APC geometric mean per diem cost, calculated in accordance with our existing methodology, but with a cost floor equal to the CY 2019 final geometric mean per diem cost for CMHCs of $121.62 (83 FR 58991), as the basis for developing the final CY 2020 CMHC APC per diem rate. We believe using the CY 2019 CMHC geometric mean per diem cost as the floor is appropriate because it is based on very recent CMHC PHP claims and cost data and would help to protect provider access by preventing wide fluctuation in the per diem costs for CMHC APC 5853. As we proposed, in this final rule with comment period, we used the most recent updated claims and cost data to calculate CY 2020 CMHC geometric mean per diem cost, which was $103.50. Because the final CY 2020 CMHC calculated geometric mean per diem cost of $103.50 is less than the proposed cost floor (which equals the final CY 2019 CMHC APC geometric mean per diem cost of $121.62), the final CY 2020 CMHC geometric mean per diem cost is $121.62. Implementing the cost floor for CY 2020 will protect CMHCs since the final CY 2020 calculated per diem cost of $103.50 still results in an amount that is less than $121.62. We believe finalizing the CMHC cost floor amount of $121.62 as the final CY 2020 CMHC APC geometric mean per diem cost allows us to use the most recent or very recent CMHC claims and cost reporting data while still protecting provider access. To be clear, this policy would only apply for the CY 2020 ratesetting.

As we noted in the CY 2020 OPPS/ASC proposed rule (84 FR 39516), we also considered proposing a 3-year rolling average calculated using the final PHP geometric mean per diem costs, by provider type, from CY 2018 (82 FR 59378), CY 2019 (83 FR 58991), and the calculated CY 2020 geometric mean per diem cost from that proposed rule of $103.42 for CMHCs, and the calculated CY 2020 geometric mean per diem costs for hospital-based PHPs discussed in section VIII.B.2.b. of the CY 2020 OPPS/ASC proposed rule. The 3-year rolling averages discussed in that proposed rule resulted in geometric mean per diem costs that would have been $122.75 for CMHCs, and $209.79 for hospital-based PHPs. While we believe this option would have avoided the fluctuation in the geometric mean per diem cost and, therefore, supported access to PHPs provided by CMHCs, it would have maintained the fluctuation in the geometric mean per diem costs used to derive the hospital-based PHP APC per diem payment rates. This is further discussed in the hospital-based PHP section VIII.B.2.b. of the CY 2020 OPPS/ASC proposed rule and section VIII.B.2.b. of this final rule. In addition, we believe that it is necessary to recalculate the CMHC geometric mean per diem cost for this final rule with comment period using updated claims and cost data, and simply proposing to use a 3-year rolling average for the CMHC geometric mean per diem cost for CY 2020 would not have allowed us to do so. Therefore, we believe that it is more appropriate to use the final CY 2019 geometric mean per diem costs, by provider type, as the cost floor for use with the final calculated CY 2020 PHP geometric mean per diem costs, by provider type, because those CY 2019 per diem costs are based on very recent CMHC and hospital-based PHP claims and cost data, are the easiest to understand, and would result in proposed geometric mean per diem costs which would support access for both CMHCs and hospital-based PHPs.

We estimate the aggregate difference in the (prescaled) CMHC geometric mean per diem costs for CY 2020 from finalizing the CMHC cost floor amount of $121.62 rather than the calculated CMHC geometric mean per diem cost of $103.50 to be $1.7 million. We refer readers to section XXVII. of this final rule with comment period for payment impacts, which are budget neutral.

We received 6 comments, with those focused on CMHC rate setting summarized as follows:

Comment: Nearly all commenters supported our proposal to calculate updated per diem costs with a cost floor, to avoid fluctuations in CMHC payments and help protect access.

Response: We thank the commenters for their support. For CY 2020, we are finalizing the CY 2020 CMHC geometric mean per diem cost as $121.62, which is the cost floor amount, rather than the calculated geometric mean per diem cost of $103.50.

Comment: Two commenters 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. One 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. While CMHCs and hospital-based CMHCs provide the same clinical services, their resource use differs,

because these two provider types have different cost structures. 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, the final CY 2020 calculated geometric mean costs for providing PHP services were $103.50 per day for CMHCs, but were $233.52 per day for hospital-based PHPs. 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; 81 FR 79686 to 69687). Therefore, we do not believe we can pay CMHCs the same APC rate as hospital-based PHPs, and should calculate a CMHC APC rate based on the CMHC costs which providers supply on their cost reports. 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-and-Guidance/Guidance/Manuals/Paper-Based-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 to 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 22 of this final rule, the percentage of paid PHP days which have only three services has been relatively stable over time. As we note in section VIII.B.3.b, with only 2 years of claims data reflecting the single-tiered payment system, we do not have enough data yet to identify any trends in utilization that could be associated with the change from two-tiered to single-tiered payment. We continue to monitor the percentage of 3-service days and are also monitoring 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 noted that, in the past, CMS stated that CMHCs provide fewer services and have less costly staff than hospitals.

Response: We believe that the commenter may be referring to the CY 2011 OPPS/ASC final rule with comment period (75 FR 71991), which states that we believe that CMHCs have a lower cost structure than their hospital-based PHP counterparts because the data showed that CMHCs provide fewer PHP services in a day and use less costly staff than hospital-based PHPs. Those statements were based on CY 2009 claims and cost data, which differ from more recent claims and cost data. Each year, we calculate geometric mean per diem costs based on updated claims and cost reports. We do not have detailed labor cost data to make a direct comparison of CMHC versus hospital-based PHP staff costs, so we could not comment on whether CMHCs have lower labor costs than hospital-based PHPs. But we note that both provider types use similar types of clinical staff (see personnel qualifications in 42 CFR 485.904 for CMHCs, and in 42 CFR 482.12, 482.23, and 482.62 for hospitals). Regarding the level of services provided, we refer the commenter to the utilization data in section VIII.B.3.b. of this CY 2020 final rule with comment period for details on current level of services CMHCs provide, based on CY 2018 claims data. Table 22 shows that CMHCs provide more days with four or more services than hospital-based PHPs.

Comment: Several commenters expressed concern about the decline in the number of CMHCs and hospital-based PHPs, and the effects on beneficiary access to care. Two commenters wrote that the current payment methodology has resulted in reductions in provider access rather than protection of access. Commenters noted that these declines have occurred while the need for mental health services has increased; that the demand for mental health services is on track to outpace the supply of behavioral health care providers; and that as the number of PHPs declines, it may become even more difficult to calculate the appropriate per diems. A few commenters noted that decreased access to PHP services could result in increasing instances of patient recidivism and more inpatient psychiatric admissions. One commenter noted that beneficiaries would have their treatment alternatives limited if CMHCs closed, and therefore, be forced to use more costly hospital-based PHPs, with higher beneficiary co-payments.

A commenter expressed concerns about CMHC rate setting being based on only 41 providers, and wrote that the data are 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. The same commenter also stated that CMHCs incur extra costs to meet the CMHC conditions of participation (CoPs), have experienced an increase in bad debt expense, and the effects of sequestration.

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. We share the commenters' concerns about the decline in the number of PHPs, particularly at CMHCs, and the effect on access. Our goal is to 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. We agree that beneficiaries receiving care at a CMHC instead of a hospital-based PHP would have lower out-of-pocket costs.

We disagree that the CMHC data are skewed and that the calculations are incorrect. In the CY 2016 OPPS/ASC final rule (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 43 CMHCs used for this final rule rate setting, the calculations can be influenced by large providers. That occurred in this CY 2020 final rule rate setting, as discussed previously in this section, and we proposed and are finalizing a cost floor in CY 2020 to help protect CMHCs from this fluctuation and possible effects on access.

We are confident that the per diem costs we calculate follow the methodology we 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.

We believe that providing payment that is based upon actual provider-reported costs will not lead to provider closures. As we have noted in prior rulemaking (76 FR 74350; 79 FR 66906), the closure of PHPs may be due to any 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. It does not directly follow that closure could be due to reduced per diem payment rates alone, especially when the per diem payment rates reflect the costs of PHP providers, as stated in claims and cost data.

Furthermore, 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. The reduction to bad debt reimbursement was a result of provisions of section 3201 of the Middle Class Tax Extension 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. 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.

Finally, the reduction in payments due to sequestration has been mandated by Congress, and we are unable to remove or modify it. This mandatory payment reduction was established by the Budget Control Act of 2011 (Pub. L. 112–25) and amended by the American Taxpayer Relief Act of 2012 (Pub. L. 112–240). Sequestration is discussed in a Medicare Fee-for-Service Provider eNews article available at: *https://www.cms.gov/Outreach-and-Education/Outreach/FFSProvPartProg/Downloads/2013-03-08-standalone.pdf*. Sequestration is outside the scope of the CY 2020 OPPS/ASC proposed rule and this final rule with comment period.

Comment: One commenter suggested that CMS use value-based purchasing for paying CMHCs instead of a cost-based system. This commenter recommended that CMS look at the value provided by the quality of provided services. This commenter believed that rewarding providers for higher-quality care, as measured by selected standards, instead of rewarding providers for increasing costs, is a better way to improve the quality of any service.

Response: 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 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. However, the Hospital OQR Program does not apply to CMHCs, and there are no quality measures applied to CMHCs.

Comment: Several commenters recommended that more work be done to establish PHP rates accurately, that CMS reconsider its PHP policy positions to determine how to rebuild PHP services, or that CMS establish a task force to review and discuss the availability of PHPs for Medicare beneficiaries.

Response: 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. As part of that process, we regularly review our methodology to ensure that it is appropriately capturing the cost of care reported by providers. For example, for the CY 2016 ratesetting, we extensively reviewed the methodology used for PHP ratesetting. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70462 through 70466), we also included a detailed description of the ratesetting process to help all PHP providers record costs correctly so that we can more fully capture PHP costs in ratesetting. In this CY 2020 ratesetting, we proposed and are finalizing a policy to calculate the CY 2020 per diem costs with a cost floor. We believe that policy helps to support access, particularly for CMHCs, whose calculated costs were still below the cost floor when we ran the calculations with updated data for this final rule with comment period.

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 given in statute at 1833(t)(2) and 1833(t)(9), and depends heavily on provider-reported costs. As noted previously, 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-and-Guidance/Guidance/Manuals/Paper-Based-Manuals.html*. We also strongly encourage those CMHCs that do not file full cost reports to consider doing so, to help us in more fully capturing CMHC costs in rate setting.

We maintain positive working relationships with various industry leaders representing both CMHCs and hospital-based PHP providers with whom we have consistently met over the years to discuss industry concerns and ideas. These relationships have provided significant and valued input regarding PHP ratesetting. We also hold Hospital Outpatient Open Door Forum calls monthly, in which all individuals are welcome to participate and/or submit questions regarding specific issues, including questions related to PHPs. Furthermore, we initiate rulemaking annually, through which we receive public comments on proposals set forth in a proposed rule and respond to those comments in a final rule. All individuals are provided an opportunity to comment, and we give consideration to each comment that we receive. Given the relationships that we have established with various industry leaders and the various means for us to receive comments and recommendations, we believe that we receive adequate input regarding ratesetting and take that input into consideration when establishing the payment rates. We continue to welcome any input and information that the public is willing to provide.

After consideration of the comments, we are finalizing our proposal as proposed. Because the final CY 2020 calculated CMHC geometric mean per diem cost of $103.50 is less than the cost floor amount of $121.62, the final CY 2020 CMHC geometric mean per diem cost is $121.62.

b. Hospital-Based PHP Data Preparation: Data Trims and Exclusions

For this CY 2020 final rule with comment period, 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 2018 PHP claims included data for 436 hospital-based PHP providers for our calculations in this CY 2020 OPPS/ASC final rule with comment period.

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 with a CCR of 6.398 from our final ratesetting. However, 100 percent of the service days for this one 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, 59 hospital-based PHPs were removed for having no PHP costs and, therefore, 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, nor were any hospital-based PHPs 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-1695-FC-2019-OPPS-FR-Claims-Accounting.pdf*.)

Overall, we removed 62 hospital-based PHP providers [(1 with all service days having a CCR greater than 5) + (59 with zero daily costs and no PHP payment) + (2 with no PHP-allowable HCPCS codes)], resulting in 374 (436 total − 62 excluded) hospital-based PHP providers in the data used for calculating ratesetting. In addition, no 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 2020 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).[75] The final calculated CY 2020 hospital-based PHP APC geometric mean per diem cost for hospital-based PHP providers that provide 3 or more services per service day (hospital-based PHP APC 5863) is $233.52, which is an increase of 4.8 percent from $222.76 calculated last year for CY 2019 ratesetting (83 FR 58989 through 58991). The increase in the final CY 2020 calculated hospital-based PHP APC geometric mean per diem cost from the prior year is influenced by two large providers with updated cost data, whose costs per day increased. We believe that a hospital-based PHP APC geometric mean per diem cost of $233.52 supports ongoing access to hospital-based PHPs. This cost is nearly a 5 percent increase from the final CY 2019 hospital-based PHP geometric mean per diem cost.

In the CY 2020 OPPS proposed rule (84 FR 39516 to 39518), the calculated CY 2020 hospital-based PHP APC geometric mean per diem cost for hospital-based PHP providers that provide 3 or more services per service day (hospital-based PHP APC 5863) was $198.53, which was a decrease from $222.76 calculated last year for CY 2019 ratesetting (83 FR 58989 through 58991). 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 3 or more services per day (81 FR 79680), 89 percent of hospital-based PHP paid service days in CY 2018 were for providing 4 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 4 or more services (we refer readers to Table 22.—Percentage of PHP Days by Service Unit Frequency in the proposed rule). Therefore, the hospital-based PHP APC 5863 is actually heavily weighted to the cost of providing 4 or

[75] 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 3 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 3 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.

more services. The per diem costs for hospital-based PHP APC 5863 have been 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. We noted that we do not believe that it is likely that the cost of providing hospital-based PHP services has suddenly declined when costs generally increase over time. We were concerned by this fluctuation, which we believe was influenced by data from a single large provider that had low service costs per day.

Therefore, rather than proposing the calculated CY 2020 hospital-based PHP APC geometric mean per diem cost, we instead proposed to use the CY 2020 hospital-based PHP APC geometric mean per diem cost, calculated in accordance with our existing methodology, but with a cost floor equal to the CY 2019 final geometric mean per diem cost for hospital-based PHPs of $222.76 (83 FR 58991), as the basis for developing the CY 2020 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 2020 geometric mean per diem costs for the final rule with comment period, just as we did for CMHCs. We believe using the CY 2019 hospital-based PHP per diem cost as the floor 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.

In the CY 2020 OPPS/ASC proposed rule discussion of the proposed cost floor, we also considered proposing a 3-year rolling average calculated using the final PHP geometric mean per diem costs, by provider type, from CY 2018 (82 FR 59378) and CY 2019 (83 FR 58991), and the calculated CY 2020 geometric mean per diem cost of $198.53 discussed earlier in this section for hospital-based PHPs. As discussed previously in that proposed rule, the 3-year rolling average per diem cost floor for CMHCs would have been $122.75, but the resulting rolling average per diem cost floor for hospital-based PHPs would have been $209.79. While we believe that this option would have supported access to CMHCs, as discussed previously, it could have resulted in a geometric mean per diem cost for the hospital-based PHP APC which still would have been a decrease from the hospital-based PHP APC geometric mean per diem cost of $222.76 finalized in CY 2019 (83 FR 58991). In addition, we believed that it was necessary to recalculate the hospital-based PHP geometric mean per diem cost for the final rule using updated claims and cost data; had we simply proposed to use a 3-year rolling average per diem cost floor for the hospital-based PHP APC per diem costs for CY 2020, we could not have done so. We were concerned that the 3-year rolling average per diem cost would have continued to result in a fluctuation in the cost of a hospital providing 3 or more hospital-based PHP services per day.

We believe that it is important to support access to partial hospitalization services in both CMHCs and in hospital-based PHPs, and note that hospital-based PHPs provide 80 percent of all paid PHP service days. Therefore, we believe that it was more appropriate to have proposed to use the final CY 2019 geometric mean per diem costs, by provider type, as the cost floor for use with the calculated CY 2020 PHP geometric mean per diem costs, by provider type, because those CY 2019 per diem costs are based on very recent CMHC and hospital-based PHP claims and cost data, are the easiest to understand, and would result in final geometric mean per diem costs which would help to protect provider access by preventing wide fluctuation in the per diem costs for both CMHCs and hospital-based PHPs.

While the cost floor would have protected hospital-based PHPs if the final CY 2020 calculated hospital-based PHP APC geometric mean per diem cost were still less than $222.76, the final calculated hospital-based PHP geometric mean per diem cost of $233.52 is greater than the floor, and therefore, we are finalizing this calculated CY 2020 cost for hospital-based PHPs. We believe finalizing our proposal for CY 2020 ratesetting allows us to use the most recent or very recent hospital-based PHP claims and cost reporting data while still protecting provider access. To be clear, this policy of using a cost floor is only applied for the CY 2020 ratesetting.

In the CY 2020 OPPS/ASC proposed rule, we estimated that the aggregate difference in the (prescaled) hospital-based PHP geometric mean per diem costs for CY 2020 from proposing the hospital-based PHP cost floor amount of $222.76 rather than the calculated hospital-based PHP geometric mean per diem cost of $198.53 to be $9.3 million. However, because we are finalizing the CY 2020 calculated geometric mean per diem cost for hospital-based PHPs, there is no cost difference to Medicare from using a cost floor. We refer readers to section XXVII. of this final rule for payment impacts, which are budget neutral.

We received several comments on our proposal.

Comment: Several commenters expressed concern about the decline in the number of CMHCs and hospital-based PHPs, and the effects on beneficiary access to care. Two commenters wrote that the current payment methodology has resulted in reductions in provider access rather than protection of access. Commenters noted that these declines have occurred while the need for mental health services has increased; that the demand for mental health services is on track to outpace the supply of behavioral health care providers; that as the number of PHPs declines, it may become even more difficult to calculate the appropriate per diems; and that recent changes in OPPS rulemaking related to Section 603 of the Bipartisan Budget Act of 2015 require that the per diem for new hospital-based PHP programs must be set equal to the lower CMHC rate, which they said was not viable for hospital-based PHPs and would limit the ability to create new PHP programs. A few commenters noted that decreased access to PHP services could result in increasing instances of patient recidivism and more inpatient psychiatric admissions.

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. We share the commenters' concerns about the decline in the number of PHPs and the effect on access. Our goal is to protect access to both provider types, so beneficiaries have choices regarding where to receive treatment. We also refer readers to section VIII.B.2.a. for a similar comment and response related to CMHCs.

Regarding the effects of Section 603 of the Bipartisan Budget Act of 2015 [76] on hospital-based PHP access, we note that this provision amended the statute at section 1833(t) of the Act to require that certain items and services furnished in certain off-campus provider-based departments (PBDs) shall not be considered covered outpatient department services for purposes of OPPS, and payment for those nonexcepted items and services shall be made ''under the applicable payment system'' beginning January 1, 2017 (81 FR 79720).

These amendments do not prevent hospitals from creating new PHP programs. Instead, they provide that certain items and services are no longer

[76] Public Law 114–74.

covered OPD services payable under the OPPS, and instead must be paid under another ''applicable payment system.'' CMS adopted the Medicare Physician Fee Schedule (MPFS) as the applicable payment system for these services (81 FR 79717). Although, nonexcepted off-campus provider-based departments are no longer paid under the OPPS and payments may be lower for these departments, the section 603 changes do not prohibit these departments from creating PHP programs. Excepted off-campus provider-based departments and the main campuses of hospitals continue to be paid under the OPPS, so it is unclear for these locations why entities could not create new PHPs.

Commenters were incorrect in stating that new hospital-based PHPs are paid at the CMHC per diem rate. Only non-excepted off-campus PHPs are paid through the MPFS at the CMHC rate; new hospital-based PHPs that are on-campus are paid at the hospital-based PHP per diem rate under the OPPS.

We believe that paying non-excepted off-campus PHPs through the MPFS at the CMHC APC rate is appropriate. We note that the clinical services, staffing, and documentation requirements are similar for CMHCs and hospital-based PHPs. As discussed in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79717), when a beneficiary receives services in an off-campus department of a hospital (such as in a hospital-based PHP), the Medicare payment is generally higher than when those same services are provided in a physician's office. Similarly, when partial hospitalization services are provided in a hospital-based PHP, Medicare pays more than when those same services are provided by a CMHC. CMHCs are freestanding providers that are not part of a hospital, and that have lower cost structures than hospital-based PHPs. This is similar to the differences between freestanding entities paid under the MPFS that furnish other services also provided by hospital-based entities. We believe that paying for non-excepted hospital-based partial hospitalization services at the lower CMHC per diem rate is in alignment with section 603 amendments to the OPPS statute, while also protecting access to the PHP benefit.

Furthermore, we note that our policy of paying non-excepted off-campus PHPs at the CMHC APC 5853 per diem rate provides some relief to those off-campus PHPs since non-PHP mental health services provided by non-excepted off-campus hospital provider departments are paid through the MPFS at 40 percent of the OPPS APC amount for the same service. Paying non-excepted off-campus hospital-based PHPs at the CY 2020 CMHC APC 5853 payment rate results in a payment that is 52 percent of the CY 2020 APC 5863 OPPS payment rate for hospital-based PHPs. The final FY 2020 payment rates for PHP APCs 5853 and 5863 are in Addendum A to this final rule with comment period, which is available in the FY 2020 OPPS/ASC final rule supporting documents found on our website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html.*

Comment: One commenter suggested that CMS base PHP reimbursement on incentives determined by documented productivity results. This commenter suggested we consider Measurement-based Care and Patient Satisfaction.

Response: We believe ''measurement-based care'' that the commenter 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 commenter is asking if CMS could administer patient satisfaction surveys (like HCAHPS) and then reward high-performing PHPs.

Currently, there is no statutory language explicitly authorizing an incentive payment methodology based on productivity results or patient satisfaction for CMHCs or for outpatient hospital-based 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. 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; as finalized in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59109 to 59110), this payment reduction applies to HCPCS codes which include PHP services. 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 also refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66957 through 66958) for a discussion of the comments received and of PHP measures considered for inclusion in the Hospital OQR Program in future years.

Comment: Several commenters recommended that more work be done to establish PHP rates accurately, that CMS reconsider its PHP policy positions to determine how to rebuild PHP services, or that CMS establish a task force to review and discuss the availability of PHPs for Medicare beneficiaries.

Response: 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. As part of that process, we regularly review our methodology to ensure that it is appropriately capturing the cost of care reported by providers. For example, for the CY 2016 ratesetting, we extensively reviewed the methodology used for PHP ratesetting. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70462 through 70466), we also included a detailed description of the ratesetting process to help all PHP providers record costs correctly so that we can more fully capture PHP costs in ratesetting. In this CY 2020 ratesetting, we proposed to calculate the CY 2020 per diem costs with a cost floor. We believe that proposal helped support access, particularly for CMHCs, whose calculated costs were still below the cost floor when we ran the calculations with updated data for this final rule with comment period.

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 given in statute at 1833(t)(2) and 1833(t)(9), and depends heavily on provider-reported costs. We remind hospital-based PHPs that they are required to record PHP costs in cost center line 9399 (''Partial Hospitalization Program''), which was added to the cost report in response to commenters in prior OPPS rulemaking (81 FR 79691); this line is the primary source of the department-level CCR used for hospital-based PHP ratesetting in the Revenue

Code to Cost Center crosswalk. Line 9399 should not mix other non-PHP mental health service costs with PHP costs. PHP costs incorrectly recorded in other cost centers may not be included for PHP rate setting, thereby affecting the hospital-based PHP per diem cost amount.

We maintain positive working relationships with various industry leaders representing both CMHCs and hospital-based PHP providers with whom we have consistently met over the years to discuss industry concerns and ideas. These relationships have provided significant and valued input regarding PHP ratesetting. We also hold Hospital Outpatient Open Door Forum calls monthly, in which all individuals are welcome to participate and/or submit questions regarding specific issues, including questions related to PHPs. Furthermore, we initiate rulemaking annually, through which we receive public comments on proposals set forth in a proposed rule and respond to those comments in a final rule. All individuals are provided an opportunity to comment, and we give consideration to each comment that we receive. Given the relationships that we have established with various industry leaders and the various means for us to receive comments and recommendations, we believe that we receive adequate input regarding ratesetting and take that input into consideration when establishing the payment rates. We continue to welcome any input and information that the public is willing to provide.

We refer readers to section VIII.B.2.a. for a similar comment and response related to CMHCs.

After consideration of the comments, we are finalizing our proposal as proposed. Because the final CY 2020 calculated hospital-based PHP geometric mean per diem cost of $233.52 is greater than the cost floor amount of $222.76, the final CY 2020 hospital-based PHP geometric mean per diem cost is $233.52.

In summary, for CY 2020, we are finalizing 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, each calculated in accordance with our existing methodology, 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, as proposed. Because the final CY 2020 calculated geometric mean per diem cost for CMHCs is less than the cost floor amount of $121.62, we are finalizing a CY 2020 geometric mean per diem cost for CMHCs of $121.62. In addition, because the CY 2020 final calculated hospital-based PHP geometric mean per diem cost is greater than the hospital-based PHP cost floor amount of $222.76, we are finalizing the final calculated CY 2020 hospital-based PHP geometric mean per diem cost of $233.52. In this final rule with comment period, we used the most recent updated claims and cost data to calculate CY 2020 geometric mean per diem costs. The inclusion of a cost floor, which is based on very recent data, protected CMHCs as their final calculated per diem cost was still less than the cost floor amount, but was not needed for hospital-based PHPs.

These final CY 2020 PHP geometric mean per diem costs are shown in Table 45, and are used to derive the final CY 2020 PHP APC per diem rates for CMHCs and hospital-based PHPs. The final CY 2020 PHP APC per diem rates are included in Addendum A to this final rule with comment period (which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*).[77]

TABLE 45.—CY 2020 FINAL PHP APC GEOMETRIC MEAN PER DIEM COSTS

CY 2020 APC	Group Title	Final PHP APC Geometric Mean Per Diem Costs
5853	Partial Hospitalization (3 or more services per day) for CMHCs	$121.62
5863	Partial Hospitalization (3 or more services per day) for hospital-based PHPs	$233.52

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 2018 claims data used for this CY 2020 final rule with comment period revealed some changes in the provision of individual therapy compared to CY 2015, CY 2016, and CY 2017 claims data as shown in the Table 46.

[77] As discussed in section II.A. of this CY 2020 OPPS/ASC final rule, final OPPS APC geometric mean per diem costs (including final PHP APC geometric mean per diem costs) are divided by the final 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 this final 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/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html.*

TABLE 46.--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 4 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%
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%

As shown in Table 46A, the CY 2018 claims show that both CMHCs and hospital-based PHPs have slightly increased the provision of individual therapy on days with 4 or more services, compared to CY 2017 claims. However, on days with 3 services, CMHCs and hospital-based PHPs both decreased the provision of individual therapy compared to prior years.

b. Provision of 3-Service Days

In the CY 2018 OPPS/ASC proposed rule and final rule with comment period (82 FR 33640 and 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 providing 3 or more PHP services per day, we are continuing to monitor utilization of days with only 3 PHP services.

For this CY 2020 OPPS/ASC final rule with comment period, we used the CY 2018 claims data. Table 46A shows the utilization findings based on the final claims data.

TABLE 46A.—PERCENTAGE OF PHP DAYS BY SERVICE UNIT FREQUENCY

	CY 2015	CY 2016*	CY 2017*	CY 2018*	Percent Change**
CMHCs:					
Percent of Days with 3 services	4.7%	4.8%	5.6%	6.9%	23.2%
Percent of Days with 4 services	62.9%	70.3%	74.0%	71.2%	-3.8%
Percent of Days with 5 or more services	32.4%	24.9%	20.5%	21.9%	6.8%
Hospital-based PHPs:					
Percent of Days with 3 services	12.4%	10.9%	9.8%	12.0%	22.4%
Percent of Days with 4 services	69.8%	64.9%	56.4%	64.0%	13.5%
Percent of Days with 5 or more services	17.8%	24.1%	33.9%	24.0%	-29.2%

*May not sum to 100 percent by provider type due to rounding.
**(CY 2018 – CY 2017) / CY 2017.

As shown in Table 46A, the CY 2018 claims data used for this final rule with comment period show that utilization of 3 service days is increasing compared to the 3 prior claim years. Compared to CY 2017, in CY 2018 hospital-based PHPs provided more days with 3 services only, more days with 4 services only, and fewer days with 5 or more services. Compared to CY 2017, in CY 2018 CMHCs provided more days with 3 services, fewer days with 4 services, and more days with 5 or more services.

The CY 2017 data are the first year of claims data to reflect the change to the single-tier PHP APCs. We hope the increase in the percentage of days with 3 services is simply an anomaly rather than the start of a trend, but more data will be needed to make that determination. 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 3 services, particularly now that the single-tier PHP APCs 5853 and 5863 are established for providing 3 or more services per day for CMHCs and hospital-based PHPs, respectively.

It is important to reiterate our expectation that days with only 3 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 3 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 3 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 3 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).

We received 2 comments related to PHP utilization.

Comment: Two commenters noted that the data in Table 22 of the 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, but the updated data for this final rule showed an uptick in the percentage of 3-service days. 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

In this CY 2020 OPPS/ASC final rule with comment period, for CY 2020, we are finalizing 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. of the CY 2020 OPPS/ASC proposed rule for our general policies for hospital outpatient outlier payments (84 CFR 39434 through 39435.

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. As previously stated, 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 2020. 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 this final rule with comment period). 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 this final rule with comment period, 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 this final rule with comment period, 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. In the CY 2020 proposed rule (84 FR 39521), we proposed to continue to use the same methodology for CY 2020. Therefore, based on our CY 2020 payment estimates, CMHCs are projected to receive 0.02 percent of total hospital outpatient payments in CY 2020, 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.

CMS did not receive any comments on the CMHC outlier percentage, so we are finalizing the 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).

In the CY 2020 OPPS/ASC proposed rule (84 FR 39521), in accordance with our existing policy, 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 2020, 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))].

CMS did not receive comments on the Cutoff Point and Percentage Payment Amount, so we 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. CMS 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).

In the CY 2020 OPPS/ASC proposed rule, we proposed to continue these policies for partial hospitalization services provided through PHPs for CY 2020. 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*).

CMS did not receive comments on the Outlier Reconciliation Policy, so we 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. For CY 2019, we continued this policy in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58997).

For CY 2020 and subsequent years, we proposed to continue to apply the 8 percent CMHC outlier payment cap to the CMHC's total per diem payments (84 FR 39522).

CMS did not receive comments on the CMHC outlier payment cap, so we 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 2019 OPPS/ASC final rule with comment period (83 FR 58996 through 58997.

In the CY 2020 OPPS/ASC proposed rule (84 FR 39522), we proposed to continue this policy for CY 2020. CMS did not receive any comments on the fixed-dollar threshold, so we are finalizing our proposal as proposed.

D. Update to PHP Allowable HCPCS Codes

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 58997 through 58998), we discussed that, during the CY 2019 rulemaking, we received the Category I and III CPT codes from the AMA that were new, revised, and deleted, effective January 1, 2019. This included the deleting of the following psychological and neuropsychological testing CPT codes, which affect PHPs, as of January 1, 2019:

- CPT code 96101 (Psychological testing by psychologist/physician);
- CPT code 96102 (Psychological testing by technician);
- CPT code 96103 (Psychological testing administered by computer);
- CPT code 96118 (Neuropsychological testing by psychologist/physician)
- CPT code 96119 (Neuropsychological testing by technician); and
- CPT code 96120 (Neuropsychological test administered w/computer).

In addition, the AMA added the following psychological and neuropsychological testing CPT codes to replace the deleted codes, as of January 1, 2019:

- CPT code 96130 (Psychological testing evaluation by physician/qualified health care professional; first hour);
- CPT code 93131 (Psychological testing evaluation by physician/qualified health care professional; each additional hour);
- CPT code 96132 (Neuropsychological testing evaluation by physician/qualified health care professional; first hour);
- CPT code 96133 (Neuropsychological testing evaluation by physician/qualified health care professional; each additional hour);
- CPT code 96136 (Psychological/neuropsychological testing by

physician/qualified health care professional; first 30 minutes);

- CPT code 96137 (Psychological/neuropsychological testing by physician/qualified health care professional; each additional 30 minutes);
- CPT code 96138 (Psychological/neuropsychological testing by technician; first 30 minutes);
- CPT code 96139 (Psychological/neuropsychological testing by technician; each additional 30 minutes); and
- CPT code 96146 (Psychological/neuropsychological testing; automated result only).

As we proposed in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58997 through 58998), we included these replacement codes in Addenda B and O. As is our usual practice for including new and revised Category I and III CPT codes under the OPPS, we included interim APC assignments and status indicators for these codes and provided an opportunity under the OPPS for the public to comment on these interim assignments. That is, we included 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 status indicator assignments.

While these interim APC and status indicator assignments under the OPPS were included in Addendum B and Addendum O to the CY 2019 OPPS/ASC proposed rule and final rule with comment period, PHP providers may not have been aware of those changes because we did not also include these in the PHP discussion presented in the proposed rule; to be clear, PHP is a part of the OPPS. To ensure that PHP providers were aware of the new and replacement codes related to CMHC and hospital-based partial hospitalization programs and had the opportunity to comment on the changes, we utilized a practice similar to the one we use under the OPPS for new Level II HCPCS codes that become effective after the proposed rule is published. Therefore, in the CY 2019 OPPS/ASC final rule with comment period, we proposed to delete the same 6 CPT codes listed from the PHP-allowable code set for CMHC APC 5853 and hospital-based PHP APC 5863, and replace them with 9 new CPT codes as shown in Table 47 of the final rule with comment period, effective January 1, 2019. We also refer readers to section III.A.4. of the proposed rule for a detailed discussion of how we include new and revised Category I and III CPT codes for a related calendar year, assign interim APC and status indicator assignments, and allow for public comments on these interim assignments for finalization in the next calendar year final rule with comment period.

We solicited public comments on these proposals and since we did not receive any comments, we are finalizing our proposals as proposed.

IX. Procedures That Will Be Paid Only as Inpatient Procedures

A. Background

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74352 through 74353) for a full historical discussion of our longstanding policies on how we identify procedures that are typically provided only in an inpatient setting (referred to as the inpatient only (IPO) list) and, therefore, will not be paid by Medicare under the OPPS, and on the criteria that we use to review the IPO list each year to determine whether or not any procedures should be removed from the list. The complete list of codes that describe procedures that will be paid by Medicare in CY 2020 as inpatient only procedures is included as Addendum E to this CY 2020 OPPS/ASC final rule with comment period, which is available via the internet on the CMS website.

B. Changes to the Inpatient Only (IPO) List

1. Methodology for Identifying Appropriate Changes to IPO List

In the CY 2019 OPPS/ASC proposed rule (84 FR 39523 through 39525), for CY 2020, we proposed to use the same methodology (described in the November 15, 2004 final rule with comment period (69 FR 65834)) of reviewing the current list of procedures on the IPO list to identify any procedures that may be removed from the list. We have established five criteria that are part of this methodology. As noted in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74353), we utilize these criteria when reviewing procedures to determine whether 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 performed 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 performed in numerous hospitals on an outpatient basis.
- A determination is made that the procedure can be appropriately and safely performed in an ASC and is on the list of approved ASC procedures or has been proposed by us for addition to the ASC list.

2. Procedures Proposed for Removal From the IPO List

Using the listed criteria, for the CY 2020 OPPS/ASC proposed rule, we identified one procedure described by CPT code 27130 (Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty) with or without autograft or allograft) that met the criteria for proposed removal from the IPO list. The procedure that we proposed to remove from the IPO list for CY 2020 and subsequent years, including the CPT/HCPCS code, long descriptor, and the proposed CY 2020 payment indicator was displayed in Table 23 of the proposed rule.

For a number of years, total hip arthroplasty (THA) has been a topic of discussion for removal from the IPO list with both stakeholder support and opposition. Most recently, in the CY 2018 OPPS/ASC proposed rule (82 FR 33644 and 33645), we sought public comment on the possible removal of partial hip arthroplasty (PHA), CPT code 27125 (Hemiarthroplasty, hip, partial (for example, femoral stem prosthesis, bipolar arthroplasty)), and total hip arthroplasty (THA) or total hip replacement, CPT code 27130 (Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft from the IPO list. Both THA and PHA were placed on the original IPO list in the CY 2001 OPPS/ASC final rule with comment period (65 FR 18780).

Among those commenters expressing support in response to the CY 2018 OPPS/ASC proposed rule (which we summarized and responded to in the CY 2018 OPPS/ASC final rule with comment period (82 FR 52527 through 52528)) for removal of THA from the IPO list were several surgeons and other stakeholders who believed that, given

thorough preoperative screening by medical teams with significant experience and expertise involving hip replacement procedures, the THA procedure could be provided on an outpatient basis for some Medicare beneficiaries. These commenters noted significant success involving same day discharge for patients who met the screening criteria and whose experienced medical teams were able to perform the procedure early enough in the day for the patients to achieve postoperative goals, allowing home discharge by the end of the day. The commenters believed that the benefits of providing the THA procedure on an outpatient basis include significant enhancements in patient well-being, improved efficiency, and cost savings to the Medicare program, including shorter hospital stays resulting in fewer medical complications, improved results, and enhanced patient satisfaction.

We stated in the CY 2018 OPPS/ASC proposed rule that, like most surgical procedures, both PHA and THA need to be tailored to the individual patient's needs. Patients with a relatively low anesthesia risk and without significant comorbidities who have family members at home who can assist them may likely be good candidates for an outpatient PHA or THA procedure. These patients may also be able to tolerate outpatient rehabilitation in either an outpatient facility or at home postsurgery. On the other hand, patients with multiple medical comorbidities, aside from their osteoarthritis, would more likely require inpatient hospitalization and possibly postacute care in a skilled nursing facility or other facility. Surgeons who discussed outpatient PHA and THA procedures in public comments in response to our CY 2017 OPPS/ASC proposed rule (81 FR 45679) comment solicitation (which we summarized and responded to in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79696)) on the TKA procedure emphasized the importance of careful patient selection and strict protocols to optimize outpatient hip replacement outcomes. These protocols typically manage all aspects of the patient's care, including the at-home preoperative and postoperative environment, anesthesia, pain management, and rehabilitation to maximize rapid recovery, ambulation, and performance of activities of daily living.

Numerous commenters representing a variety of stakeholders, including physicians and other care providers, individual stakeholders, specialty societies, hospital associations, hospital systems, ASCs, device manufacturers, and beneficiaries, responded to our solicitation of comments regarding the removal of PHA and THA from the IPO list (which we summarized and responded to in CY 2018 OPPS/ASC final rule with comment period (82 FR 52527 through 52528)). The comments were diverse and some were similar to the comments we received on our proposal to remove TKA from the IPO list. Some commenters, including hospital systems and associations, as well as specialty societies and physicians, stated that it would not be clinically appropriate to remove PHA and THA from the IPO list, indicating that the patient safety profile of outpatient THA and PHA in the non-Medicare population is not well-established. Commenters representing orthopedic surgeons also stated that patients requiring a hemiarthroplasty (PHA) for fragility fractures are, by nature, a higher risk, suffer more extensive comorbidities, and require closer monitoring and preoperative optimization; therefore, it would not be medically appropriate to remove the PHA procedure from the IPO list.

Other commenters, including ambulatory surgery centers (ASCs), physicians, and beneficiaries, supported the removal of PHA and THA from the IPO list. These commenters stated that the procedures were appropriate for certain Medicare beneficiaries and most outpatient departments are equipped to provide THA to some Medicare beneficiaries. They also referenced their own personal successful experiences with outpatient THA.

a. Removal of Total Hip Arthroplasty From the Inpatient Only List

After reviewing the clinical characteristics of the procedure described by CPT code 27130, considering the public comments described earlier from past rules, additional feedback from stakeholders, and with further consultation with our clinical advisors regarding this procedure, in the CY 2020 OPPS/ASC proposed rule (84 FR 39524), we stated our belief that this procedure meets criterion 2 (the simplest procedure described by the code may be performed in most outpatient departments) and criterion 3 (the procedure is related to codes that we have already removed from the IPO list). As such, we believe that appropriately selected patients could have this procedure performed on an outpatient basis. Therefore, we proposed to remove THA from the IPO list and to assign the THA procedure (CPT code 27130) to C–APC 5115 with status indicator ''J1''. We sought public comments on our conclusion that the procedure described by CPT code 27130 meets criteria 2 and 3 and our proposal to assign the procedure to C–APC 5115 with status indicator ''J1''. We did not propose to remove PHA from the IPO list because we continue to believe that it does not meet the criteria for removal.

Comment: In response to our proposal to remove CPT code 27130 from the IPO list, we received many of the same type of comments that we received in response to our CY 2018 proposed rule comment solicitation for removing THA. Many commenters, including health care providers and medical associations, supported the proposal. The commenters recognized that with careful, appropriate selection, THA could be performed in the outpatient setting with few to no complications. One commenter, an orthopaedic specialty society, agreed with the patient selection characteristics that were noted in the proposed rule—namely, that good candidates for outpatient THA have relatively low anesthesia risk, do not have significant comorbidities, have in-home support, and are able to tolerate post-surgical outpatient rehabilitation in either an outpatient facility or in the home.

One commenter suggested that a patient that requires a revision of a prior hip replacement, and/or has other complicating clinical conditions, including multiple co-morbidities such as obesity, diabetes, heart disease, is not a strong candidate for outpatient THA and should be scheduled for an inpatient stay. Furthermore, another commenter stated that the following social factors should be considered when analyzing the implications of outpatient THA: Living alone, pain, prior hospitalization, depression, functional status, high-risk medication, and health literacy. Additionally, both supporters and opponents requested that CMS provide detailed guidance on what those selection criteria should look like.

Some commenters did not support the proposal, citing both clinical and operational concerns based on their experience with the removal of TKA from the IPO in 2018. Those commenters believe that it would be hasty to remove THA without waiting for providers and MACs to have a better handle on performing TKA in the outpatient setting and developing better skill at performing appropriate patient selection. One commenter suggested delaying the removal of THA from the IPO list for a year, until CMS could provide greater evidence, specifically, a rigorous medical literature review, that THA could be performed safely in the outpatient or ASC setting, especially for

beneficiaries with multiple co-morbidities.

Some commenters, including two major orthopaedic associations, raised concerns about whether the THA procedure meets the criteria required to be removed from the IPO list. One commenter, an orthopaedic surgery specialty society for hips and knees, shared that they do not believe THA meets criterion 2 (the simplest procedure described by the code may be performed in most outpatient departments)—they argued that there is no such thing as a simple THA and that all procedures described by CPT code 27130 have moderate risks for complications. The commenter further argues that criterion 3 (the procedure is related to codes that we have already removed from the IPO list) is also not met since they do not believe that THA and TKA are similar, except for the risks associated with each in moving the site of surgery. The commenter expressed additional concerns regarding criterion 4 (a determination is made that the procedure is being performed in numerous hospitals on an outpatient basis) and the lack of peer-reviewed literature that would provide supportive data. Finally, the commenter expressed concerns regarding criterion 5 (a determination is made that the procedure can be appropriately and safely performed in an ASC and is on the list of approved ASC procedures or has been proposed by us for addition to the ASC list), stating that there is a lack of peer-reviewed literature and the ability to guarantee excellent patient selection and education, tailored anesthetic techniques, well-done surgery, good medical care, and exceptional post-operative care coordination in the ASC setting. The commenter conceded that performance of THA in the outpatient setting is possible, but does not believe that data and guidance on appropriate patient selection and education, patient-specific anesthetic techniques, and post-operative care coordination are well demonstrated in peer-reviewed literature. This commenter did note that appropriate patient selection for outpatient THA candidates could mitigate some of its concerns.

Another orthopaedic surgery specialty society called the removal of THA from the IPO list ''rash,'' and expressed extensive concern that CMS would remove a procedure from the IPO list based on only two of the five criteria used to determine appropriate removals for the IPO list. The commenter further expressed concern that the rationale behind removing THA from the IPO list—specifically that CMS believes it meets criteria 2 and 3—fails to consider whether or not outpatient facilities are equipped and appropriate for outpatient THA, and whether or not THA is performed safely in outpatient settings a majority of the time.

Response: We thank commenters for providing public comments on the appropriateness of removing THA from the IPO list and providing it in outpatient settings. We appreciate the support for the proposal. We also recognize concerns for ensuring patient health and quality care. As we have stated numerous times, like most surgical procedures, the appropriate site of service for THA should be based on the physician's assessment of the patient and tailored to the individual patient's needs. As we stated in the proposed rule (84 FR 39524), patients with a relatively low anesthesia risk and without significant comorbidities who have family members at home who can assist them may likely be good candidates for an outpatient THA procedure. On one hand, it may be determined that these patients will also be able to tolerate outpatient rehabilitation either in an outpatient facility or at home postsurgery. On the other hand, patients that require a revision of a prior hip replacement, and/or have other complicating clinical conditions, including multiple co-morbidities such as obesity, diabetes, heart disease, may not be strong candidates for outpatient THA. We also recognize that elective THA, necessitated, for example, by osteoarthritis, for a generally healthy patient with at-home support is different than THA for a hip fracture that is performed on either an emergent or scheduled basis. While the former may be appropriate for outpatient THA if the physician believes that the patient may be safely discharged on the same or next day, the latter may be more appropriate for hospital inpatient admission.

As previously stated in the discussion of the CY 2018 OPPS/ASC final rule (82 FR 59383), we continue to believe 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. We also reiterate our previous statement that the removal of any procedure from the IPO list does not require the procedure to be performed only on an outpatient basis. That is, when a procedure is removed from the IPO, it simply means that Medicare will pay for it in either the hospital inpatient or outpatient setting; it does not mean that the procedure must be performed on an outpatient basis. The 2-midnight rule, which is discussed in section X.B. of this final rule with comment period, provides general guidance on when payment under Medicare Part A (that is, hospital inpatient) may be appropriate. However, the 2-midnight rule also recognizes the importance of the attending physician's clinical judgment regarding the appropriate setting of care for a procedure to be performed.

While we continue to expect providers who perform outpatient THA on Medicare beneficiaries to use comprehensive patient selection criteria to identify appropriate candidates for the procedure, we believe that the surgeons, clinical staff, and medical specialty societies who perform outpatient THA and possess specialized clinical knowledge and experience are most suited to create such guidelines. Therefore, we do not expect to create or endorse specific guidelines or content for the establishment of providers' patient selection protocols.

With respect to certain criteria not being met, we remind commenters that not all criteria must be met for a service to be removed from the IPO. We continue to believe that THA meets criteria 2 and 3.

Comment: Several commenters stated concerns regarding the impact of removing THA from the IPO list in light of the 2-midnight rule and subsequent RAC review. Because of past concerns with the removal of TKA from the IPO list and fear of RAC review, commenters also suggested that if THA is removed from the IPO list, that CMS should provide a two-year exemption from site-of service denials and Recovery Audit Contractor (RAC) referrals. Commenters further stated that in addition to the exemption, CMS should also educate providers that CMS policy allows for case-by-case exceptions to the 2-midnight rule in consideration of patient history, co-morbidities, and risk of adverse events.

Response: We thank the commenters for their feedback. We will again refer readers to the more extensive discussion of an exemption from site-of service denials and RAC referrals in section X.B. of this final rule with comment period. The case-by-case exception under the 2-midnight rule continues to allow for Part A payment to be made, on a case-by-case basis, where the physician does not expect the patient to remain in the hospital for at least two midnights but nonetheless determines that inpatient admission is necessary based on the clinical characteristics of

the patient and that determination is supported by the medical record.

Comment: Several commenters opposed the removal of THA due to potential detrimental impacts on hospitals participating in the Comprehensive Care for Joint Replacement (CJR) Program and the Bundled Payments for Care Initiative (BCPI). Some commenters supported the proposal, but requested that payment for THA in the context of alternative payment models be adjusted.

Response: We again refer readers to the CY 2017 OPPS/ACS final rule with comment period (81 FR 79698 through 79699) in which we originally proposed the removal of TKA procedural codes from the IPO list and sought comments on how to modify the CJR and BPCI programs to reflect the shift of some Medicare beneficiaries from an inpatient TKA procedure to an outpatient TKA procedure in the BPCI and CJR model pricing methodologies, including target price calculations and reconciliation processes, as we also believe it to be applicable to THA. As in the case of the policy change to move THAs from the IPO list, the CMS Innovation Center may consider making future changes to the CJR and BPCI Models to address the removal of THAs from the IPO list and the performance of THA procedures in the OPPS setting.

Additionally, CMS notes the concerns about appropriate patient selection raised by commenters and agrees that it is imperative that physicians and hospitals are mindful of factors that affect whether a patient would be a good candidate for outpatient THA or should instead be admitted as a hospital inpatient; however, for the reasons cited in the CY 2020 OPPS/ASC proposed rule, we continue to believe that it is appropriate to remove THA as described by CPT code 27130 from the IPO list. After consideration of the public comments we received, we are finalizing the removal of CPT code 27130, and assigning the procedure to C–APC 5115 (Level 5 Musculoskeletal Procedures) with status indicator ''J1''. In addition, we are removing anesthesia code 01214, (anesthesia for open procedures involving hip joint; total hip arthroplasty) as a conforming change.

As stated above, 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. Further, the removal of any procedure from the IPO list, including THA, does not require the procedure to be performed only on an outpatient basis. That is, when a procedure is removed from the IPO, it simply means that Medicare will pay for it in either the hospital inpatient or outpatient setting; it does not mean that the procedure must be performed on an outpatient basis. The decision to admit as an inpatient admission or to perform the procedure on a hospital outpatient basis is subject to the complex medical judgment of the physician. While we have not established patient selection criteria for THA or any other procedure, we reiterate our finding that patients with a relatively low anesthesia risk and without significant comorbidities who have family members at home who can assist them may likely be (but are not necessarily) good candidates for an outpatient THA procedure. These patients may be determined to be able to tolerate outpatient rehabilitation either in an outpatient facility or at home postsurgery. While on the other hand, patients that require a revision of a prior hip replacement, and/or has other complicating clinical conditions, including multiple co-morbidities such as obesity, diabetes, heart disease, may not be strong candidates for outpatient THA. As stated previously, we also recognize that elective THA, necessitated, for example, by osteoarthritis, for a generally healthy patient with at-home support is different than THA for a hip fracture that is performed on either an emergent or scheduled basis. While the former may be appropriate for outpatient THA if the physician believes that the patient may be safely discharged on the same or next day, the latter may be more appropriate for hospital inpatient admission.

3. Solicitation of Public Comments on the Potential Removal of Procedures Described by CPT Codes 22633, 22634, 63265, 63266, 63267, and 63268 From the IPO List

Throughout the years, we have received several public comments on additional CPT codes that stakeholders believe fit our criteria and should be removed from the IPO list. In the CY 2020 OPPS/ASC proposed rule, we sought public comment on the removal of the following procedures from the IPO list in Table 47.

TABLE 47.—IPO List CPT Codes Included in Comment Solicitation to be Potentially Removed from the IPO List

CPT Code	Long Descriptor
22633	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/ or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; lumbar;
22634	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/ or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; lumbar;| each additional interspace and segment
63265	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; cervical
63266	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; thoracic
63267	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; lumbar
63268	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; sacral

We reviewed the clinical characteristics of CPT codes 22633 and 22634 and stated that we believe they are related to codes that we have already removed from the IPO list. Specifically, stakeholders have suggested that CPT codes 22633 and 22634 are related to CPT code 22551 (Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below c2), which is currently performed in the outpatient hospital setting. During the proposed rule, we sought public comments that would provide additional information on the safety of performing CPT codes 22633 and 22634 in the outpatient hospital setting.

In addition, we reviewed CPT codes 63265, 63266, 63267, and 63268. Over the years, stakeholders indicated that this series of CPT codes should be considered minimally invasive, arguing that CPT codes 63265, 63266, 63267, and 63268 meet criteria 1 and 2 for removal from the IPO list: Most outpatient departments are equipped to provide the services to the Medicare population and the simplest procedure described by the code may be performed in most outpatient departments. We sought public comment on whether CPT codes 63265 through 63268 meet criteria to be removed from the IPO list, including information from commenters to demonstrate that the codes meet these criteria.

Comment: We received a few comments in support of the removal of the services described by CPT codes 22633, 22634, 63265, 63266, 63267, and 63268. Commenters agreed that these procedures were both related to codes that were previously removed from the IPO list and are performed safely in numerous hospitals on an outpatient basis. Commenters largely provided anecdotal experience in support of removing these services from the IPO list. One commenter provided a March 2019 published retrospective cohort study of lumbar interbody fusion to treat spinal pathology using the American College of Surgeons National Surgical Quality Improvement Program database. The commenter believed that this study provided additional insight into the perioperative safety profile and operative efficiency and efficacy of performing transforaminal lumbar interbody fusions (TLIF) at an outpatient facility.

Commenters in support of the proposal argued that physicians perform the cases regardless of the IPO list—evaluating each patient carefully to determine the best fit clinically for that patient. Several ASCs commented that they often perform all listed procedures with few to no complications in that setting. This commenter supported not only removing all six procedures from the IPO list, but also adding them to the ASC–CPL list.

Commenters further stated that although their current patient volume does not constitute a large percentage of Medicare beneficiaries, they would expect to see similar results with Medicare patients that are active, have a relatively low anesthesia risk, do not have significant comorbidities and that also have a support system at home that can assist them post-procedure. The commenters specifically supported the removal of the six procedures based on the development of less invasive techniques, improved perioperative

pain management, and expedited rehabilitation protocols.

Specifically for the services described by CPT codes 22633 and 22634, commenters agreed that related procedures and similar codes such as 22551 (Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below c2); 22612 (Arthrodesis, posterior or posterolateral technique, single level; lumbar (with lateral transverse technique, when performed); and 22614 (Arthrodesis, posterior or posterolateral technique, single level; each additional vertebral segment) were previously removed from the IPO list. One commenter specifically pointed out that performance of CPT codes 22612, 22614, and 22551 are all allowed in the ASC setting, and that their safety was reconfirmed in the review of procedures added to the ASC covered procedures list in the CY 2019 OPPS/ASC final rule (83 FR 59057).

In reference to the laminectomy codes, commenters specifically supported their removal from the IPO list based on their perceived safe and effective performance in the outpatient setting, in accordance with criterion 2.

We also received a few general comments in opposition to the prospect of removing the codes. Specifically, those who opposed removing the procedures expressed concern that all six procedures in this comment solicitation are complex procedures and that very few Medicare beneficiaries are likely to be good candidates to receive the procedures in the outpatient setting because of their complexity. The commenters further stated that removing these procedures from the IPO list and providing them in the outpatient setting may impact patient safety and outcomes, which they believe should be the primary considerations when determining which procedures can be removed from the IPO list.

Response: After reviewing clinical evidence and the public comments, including input from multiple spinal specialty societies and ASCs we have determined that the services described by CPT codes 22633, 22634, 63265, 63266, 63267, and 63268 are appropriate candidates for removal from the IPO list. CMS notes the overall support and for the reasons cited in the proposed rule, we believe that it is appropriate to remove CPT codes 22633 and 22634 from IPO list because they meet criteria one and two: Most outpatient departments are equipped to provide the services to the Medicare population and the simplest procedure described by the code may be performed in most outpatient departments. We also believe that it is appropriate to remove CPT codes 63265, 63266, 63267, and 63268 from the inpatient only list, based on criterion one; most outpatient departments are equipped to provide the services to the Medicare population. Therefore, we are finalizing the removal of CPT codes 22633, 22634, 63265, 63266, 63267, and 63268, and assigning the procedures as follows. The APC and status indicator assignments are reflected in Table 48 below.

Additional Requests for Changes to the IPO List

Comment: CMS received two additional comments recommending the removal of several procedures not originally proposed for removal from the IPO list for CY 2020. These recommended procedures related to other procedures that were recently removed from the IPO. Specifically, the commenters referenced the following anesthesia codes for removal:

Table 48—APC and Status Indicator Assignments

CPT Code	Long Descriptor	Rationale
00670	Anesthesia for extensive spine and spinal cord procedures (for example, spinal instrumentation or vascular procedures)	Associated with surgical CPT codes 22551, 22552, 22845, 22633, 22634, 63265, 63266, 63267
00802	Anesthesia for procedures on lower anterior abdominal wall; panniculectomy	The only anesthesia code associated with CPT code 15830 Excision, excessive skin and subcutaneous tissue (includes lipectomy); abdomen, infraumbilical panniculectomy.
00865	Anesthesia for extraperitoneal procedures in lower abdomen, including urinary tract; radical prostatectomy (suprapubic, retropubic)	Associated with surgical CPT code 55866, which is not on the IPO list.
00944	Anesthesia for vaginal procedures (including biopsy of labia, vagina, cervix or endometrium); vaginal hysterectomy	Associated with surgical CPT codes 58262, 58260, 58270, 58290, 58552, 58553 and 58554, which are not on the IPO list.
01214	Anesthesia for open procedures involving hip joint; total hip arthroplasty	Associated with surgical CPT code 27130.

Response: We thank the commenters for their feedback. After consideration of the public comments, we agree that the recommended anesthesia CPT codes should be removed from the IPO list, as they meet criterion 3; the procedure is related to codes that we have already removed from the IPO list. Notably, these removed anesthesia codes will be assigned a status indicator of ''N''.

Comment: Finally, we also received a comment from a provider organization that suggested that CMS eliminate the IPO list. Specifically, the commenter argued that the IPO list should to be eliminated to allow patient status to be determined by the physician based on the individual patient's clinical condition.

Response: We thank the commenters for their feedback and will consider this feedback for future rulemaking.

Table 49 contains the final changes that we are making to the IPO list for CY 2020.

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TABLE 49.—CHANGE TO THE INPATIENT ONLY (IPO) LIST FOR CY 2020

CY 2020 CPT Code	CY 2019 Long Descriptor	Final Action	CY 2020 OPPS APC Assignment	CY 2020 OPPS Status Indicator
27130	Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty) with or without autograft or allograft	Remove from the IPO	5115	J1
22633	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/ or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; lumbar;	Remove from the IPO	5115	J1
22634	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/ or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; lumbar;| each additional interspace and segment	Remove for the IPO	N/A	N
63265	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; cervical	Remove from the IPO	5114	J1
63266	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; thoracic	Remove from the IPO	5114	J1
63267	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; lumbar	Remove from the IPO	5114	J1
63268	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; sacral	Remove from the IPO	5114	J1
00670	Anesthesia for extensive spine and spinal cord procedures (for example, spinal instrumentation or vascular procedures)	Remove from the IPO	N/A	N
00802	Anesthesia for procedures on lower anterior abdominal wall; panniculectomy	Remove from the IPO	N/A	N
00865	Anesthesia for extraperitoneal procedures in lower abdomen, including urinary tract; radical prostatectomy (suprapubic, retropubic)	Remove from the IPO	N/A	N
00944	Anesthesia for vaginal procedures (including biopsy of labia, vagina, cervix or endometrium); vaginal hysterectomy	Remove from the IPO	N/A	N
01214	Anesthesia for open procedures involving hip joint; total hip arthroplasty	Remove from the IPO	N/A	N

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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 2018 OPPS/ASC final rule with comment period (82 FR 59390 through 59391) and 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, respectively), we clarified that direct supervision is required for hospital outpatient therapeutic services covered and paid by Medicare that are furnished in hospitals as well as in provider-based departments (PBDs) of hospitals, as set forth in the CY 2000 OPPS final rule with comment period (65 FR 18525). In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60575 through 60591), we finalized a technical correction to the title and text of the applicable regulation at 42 CFR 410.27 to clarify that this standard applies in critical access hospitals (CAHs) as well as hospitals. In response to concerns expressed by the hospital community, in particular CAHs and small rural hospitals, that they would have difficulty meeting this standard, on March 15, 2010, we instructed all MACs not to evaluate or enforce the supervision requirements for therapeutic services provided to outpatients in CAHs from January 1, 2010 through December 31, 2010, while the agency revisited the supervision policy during the CY 2011 OPPS/ASC rulemaking cycle.

Due to continued concerns expressed by CAHs and small rural hospitals, we extended this notice of nonenforcement (''enforcement instruction'') as an interim measure for CY 2011, and expanded it to apply to small rural hospitals having 100 or fewer beds (75 FR 72007). We continued to consider the issue further in our annual OPPS notice-and-comment rulemaking, and implemented an independent review process in 2012 to obtain advice from the HOP Panel on this matter (76 FR 74360 through 74371). Under this process used since CY 2012, the HOP Panel considers and advises CMS regarding stakeholder requests for changes in the required minimum level of supervision of individual hospital outpatient therapeutic services. In addition, we extended the enforcement

instruction through CY 2012 and CY 2013. For the period of CY 2014 through CY 2017, Congress took legislative action (Pub. L. 113–198, Pub. L. 114–112, Pub. L. 114–255, and Pub. L. 115–123) to extend nonenforcement of the direct supervision requirement for hospital outpatient therapeutic services in CAHs and small rural hospitals having 100 or fewer beds through December 31, 2017. Then in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59391), we reinstated the enforcement instruction providing for the nonenforcement of the direct supervision requirement for hospital outpatient therapeutic services in CAHs and small rural hospitals having 100 or fewer beds through December 31, 2019. The current enforcement instruction is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/Supervision-Moratorium-on-Enforcement-for-CAHs-and-Certain-Small-Rural-Hospitals.pdf.*

As discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59390 through 59391), stakeholders have consistently requested that CMS continue the nonenforcement of the direct supervision requirement for hospital outpatient therapeutic services for CAHs and small rural hospitals having 100 or fewer beds. Stakeholders stated that some small rural hospitals and CAHs have insufficient staff available to furnish direct supervision. The primary reason stakeholders cited for this request is the difficulty that CAHs and small rural hospitals have in recruiting physicians and nonphysician practitioners to practice in rural areas. These stakeholders noted that it is particularly difficult to furnish direct supervision for critical specialty services, such as radiation oncology services, that cannot be directly supervised by a hospital emergency department physician or nonphysician practitioner because of the volume of emergency patients or lack of specialty expertise. In addition, we are not aware of any supervision-related complaints from beneficiaries or providers regarding quality of care for services furnished during the several years that the enforcement instruction has been in effect.

The upcoming expiration of the latest enforcement instruction providing for the nonenforcement of the direct supervision requirement for hospital outpatient therapeutic services for CAHs and small rural hospitals having 100 or fewer beds has prompted us to consider whether to change the level of supervision for hospital outpatient therapeutic services for all hospitals and CAHs. The enforcement instructions and legislative actions that have been in place since 2010 have created a two-tiered system of physician supervision requirements for hospital outpatient therapeutic services for providers in the Medicare program, with direct supervision required for most hospital outpatient therapeutic services in most hospital providers, but only general supervision required for most hospital outpatient therapeutic services in CAHs and small rural hospitals with fewer than 100 beds.

However, we have not learned of any data or information from CAHs and small rural hospitals indicating that the quality of outpatient therapeutic services has been affected by requiring only general supervision for these services. It is important to remember that the requirement for general supervision for outpatient therapeutic services does not preclude these hospitals from providing direct supervision for outpatient therapeutic services when the physicians administering the medical procedures decide that it is appropriate to do so. Many outpatient therapeutic services 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 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.

Failure of an applicable physician to provide adequate supervision in accordance with the hospital and CAH CoPs does not cause payment to be denied for that individual service. However, consistent violations of the CoP supervision requirements can lead to a provider having to establish a corrective action plan to address supervision deficiencies, and if the provider still fails to meet the CoP requirements, the hospital or CAH can be terminated from Medicare participation.

Our experience indicates that Medicare providers will provide a similar quality of hospital outpatient therapeutic services, regardless of whether the minimum level of supervision required under the Medicare program is direct or general. We have come to believe that the direct supervision requirement for hospital outpatient therapeutic services places an additional burden on providers that reduces their flexibility to provide medical care. The issues with increased burden and reduced flexibility to provide medical care have a more significant impact on CAHs and small rural hospitals due to their recruiting and staffing challenges, as we have recognized over the years in providing for nonenforcement of the policy for these hospitals. Larger hospitals and hospitals in urban or suburban areas are less affected by the burden and reduced flexibility of the direct supervision requirement. However, given that the direct supervision requirement has not yet been enforced for CAHs and small rural hospitals, we believe it is time to end what is effectively a two-tiered system of supervision levels for hospital outpatient therapeutic services by proposing a policy that sets an appropriate and uniformly enforceable supervision standard for all hospital outpatient therapeutic services.

Therefore, we proposed to change the generally applicable minimum required level of supervision for hospital outpatient therapeutic services from direct supervision to general supervision for services furnished by all hospitals and CAHs. General supervision, as defined in our regulation at 42 CFR 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. This proposal would ensure a standard minimum level of supervision for each hospital outpatient therapeutic service furnished incident to a physician's service in accordance with the statute. We proposed to amend the existing regulation at § 410.27(a)(1)(iv) to provide that the default minimum level of supervision for each hospital outpatient therapeutic service is ''general.''

We will continue to have the HOP Panel provide advice on the appropriate

supervision levels for hospital outpatient services as described in section I.E.2. of the proposed rule. We will also retain the ability to consider a change to the supervision level of an individual hospital outpatient therapeutic service to a level of supervision that is more intensive than general supervision through notice and comment rulemaking. We solicited public comments on this proposal.

The comments and our responses to the comments are set forth below.

Comment: A majority of commenters supported our proposal to change the generally applicable minimum required level of supervision for hospital outpatient therapeutic services from direct supervision to general supervision when these services are furnished by hospitals or CAHs. The commenters appreciated that we proposed to eliminate what is effectively a two-tiered system of supervision levels for hospital outpatient therapeutic services between CAHs and small rural hospitals and all other hospitals by proposing a policy that would set an appropriate and uniformly enforceable supervision standard for all hospital outpatient therapeutic services. The commenters also agreed with our observation that the quality of outpatient therapeutic services provided by CAHs and small rural hospitals has not been adversely affected by the nonenforcement instruction. The majority of commenters stated that our proposal would reduce burden for outpatient hospital providers, especially those providers in either rural or underserved areas. The commenters stated that our proposal would allow CAHs and small rural hospitals more flexibility to provide outpatient therapeutic care for the Medicare beneficiaries that they serve than what CAHs and small rural hospitals could provide when the temporary nonenforcement instruction for direct supervision was in effect, because a permanent, rather than temporary policy, would allow them to better make long-range staffing and budgetary plans.

Numerous commenters mentioned the many safeguards noted in our proposal, including our ongoing policy that gives providers discretion to require the appropriate amount of supervision to ensure a therapeutic outpatient procedure is performed without risking a beneficiary's safety or the quality of the care a beneficiary receives. Commenters also noted that outpatient hospital and CAH CoPs and state and federal laws and regulations are present in addition to the requirements for physician supervision to ensure the safety, health, and quality standards of the outpatient therapeutic services that beneficiaries receive.

Response: We appreciate the overall support for our proposal from a majority of the commenters. We agree with the commenters that this policy would support our goal of reducing burden on providers, especially CAHs and small rural hospitals. We also appreciate the commenters' point that this policy will allow these providers to be more flexible with their staffing and in turn provide better care to the communities they serve.

We also appreciate that the commenters noted that providers and physicians have flexibility to require a higher level of physician supervision for any service they render if they believe a higher level of supervision is required to ensure the quality and safety of the procedure and to protect a beneficiary from complications that might occur. We agree with the commenters that CoPs, state and federal laws and regulations, and supervision requirements will also ensure beneficiary health and safety when receiving outpatient therapeutic services.

The CoPs for hospitals require a doctor of medicine or osteopathy (MD/DO) to be responsible for the care of every Medicare patient with respect to any medical or psychiatric problem that is present on admission or develops during hospitalization and that is not specifically within the scope of practice of other types of practitioners (such as dentists, podiatrists, chiropractors, or clinical psychologists) as that scope of practice is defined by the medical staff and permitted by state law (42 CFR 482.12(c)(4)). The CoPs also require a 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 an MD or DO to provide medical direction for the CAHs' health care activities, and consultation for, and medical supervision of, the health care staff. The responsibilities of an MD or DO in hospitals and CAHs include supervision of all services performed at those facilities. In addition, MDs and DOs must also follow state laws regarding scope of practice. State scope of practice laws are state-level regulations that apply to physicians and other health care practitioners that determine the tasks they can perform when caring for patients in healthcare settings in that state.

Comment: Two of the commenters, including MedPAC, strongly encouraged CMS to diligently monitor the impacts of our proposal on the quality and safety of outpatient therapeutic services that Medicare beneficiaries receive to ensure their quality of care is not compromised and that beneficiaries do not experience higher rates of medical errors. In addition, several commenters wrote in support of the Hospital Outpatient Payment Panel (HOP) Panel, which continues to evaluate and make recommendations on supervision levels for individual therapeutic outpatient services. These commenters also wrote in support of CMS' use of the regulatory process to set a higher minimum level of supervision for individual therapeutic services if needed.

Response: We agree with the commenters and will continue to have a system in place to change the default minimum level of physician supervision to a level of supervision higher than general supervision, which we believe will be important to the overall success of this policy. We are also committed to monitoring care furnished to Medicare beneficiaries to determine if there is any decline in the quality of therapeutic outpatient services provided to Medicare beneficiaries as a result of this policy, although we believe that the combination of the CoPs, state and federal laws and regulations, and supervision requirements will help beneficiaries to receive safe and high-quality care. We agree with commenters that the work of HOP Panel is helpful to identify individual outpatient therapeutic procedures that may require a higher minimum level of physician supervision, which can assist us in electing whether to establish higher minimum supervision levels on case-by-case basis through notice and comment rulemaking.

Comment: A few commenters were entirely opposed to our proposal to change the default level of supervision from direct to general and either requested that no changes be made to our current policy (which requires the default minimum level of physician supervision for outpatient therapeutic services to be direct supervision unless we establish a different minimum level of supervision) or requested that CMS evaluate outpatient therapeutic services individually to determine if the default minimum level of supervision should change from direct supervision to general supervision.

Several of these commenters appreciated the concerns from CAHs and small rural providers about the burden they face from the physician supervision requirements, but these

commenters believed those concerns were outweighed by the need to have qualified physicians directly supervise services, especially in the fields of radiation therapy, hyperbaric oxygen treatment, and wound care. These commenters believed the default level of supervision for outpatient therapeutic services should be the same for all outpatient hospitals and CAHs.

Other commenters expressed concerns that allowing general supervision to be the minimum default level of supervision for certain types of services, including radiation therapy, hyperbaric oxygen treatment, and wound care, could put the health and safety of Medicare beneficiaries receiving these procedures at risk. These commenters described these particular services as requiring a high level of skill to perform and having complications that, while rare, can cause serious issues for a beneficiary's health. Therefore, these commenters believed that the minimum default level of supervision for radiation therapy, hyperbaric oxygen treatment, and wound care should be direct supervision.

Response: We agree with the commenters about the importance of ensuring the quality of outpatient therapeutic services and the health and safety of the beneficiaries who receive those services. We also appreciate the concerns several commenters raised about how this proposal will affect the quality and safety of outpatient therapeutic services including radiation therapy, hyperbaric oxygen treatments, and wound care services. We believe our supervision requirements continue to provide the safeguards Medicare beneficiaries need to ensure they receive quality care when they receive outpatient hospital therapeutic services and that health and safety of beneficiaries is protected.

Providers have the flexibility to establish what they believe is the appropriate level of physician supervision for these procedures, which may well be higher than the requirements for general supervision. In addition, providers must adhere to the hospital and CAH conditions of participation, federal and state regulations for radiation therapy, hyperbaric oxygen treatments, and wound care services, and state standards for scope of practice for medical personnel who provide these services. We believe that the combination of providers' desire to ensure the safety of their patients and the regulations governing these procedures discussed by the commenters should ensure that these procedures will be appropriately supervised without risking beneficiaries' safety or the quality of the care beneficiaries receive, whether the default level of physician supervision is direct supervision or general supervision.

We reiterate a key point that the commenters who are in support of our proposal mentioned, which is that establishing general supervision as the default level of physician supervision for outpatient therapeutic services does not prevent a hospital or CAH from requiring a higher level of supervision for a particular service if they believe such a supervision level is necessary. Providers and physicians have flexibility to require a higher level of physician supervision for any service they furnish if they believe a higher level of supervision is required to ensure the quality and safety of the procedure and to protect a beneficiary from complications that might occur. We believe this flexibility for individual providers to have a higher level of physician supervision for a given service, which has always been present in our supervision policies, should address the concerns of those commenters who believe general supervision is not sufficient for certain outpatient therapeutic services. In addition, CoP, other federal and state regulations, and state standards for scope of work for medical personnel are not affected by this policy, and remain in place to ensure that hospitals provide proper medical care to all of their patients including Medicare beneficiaries.

Comment: Two commenters wanted confirmation that our proposed policy was intended to be permanent and not just for CY 2020.

Response: This policy will take effect beginning in CY 2020 and will remain in place through subsequent years unless modified in future notice and comment rulemaking.

Comment: One commenter wanted more clarification on what constitutes general supervision. The commenter does not support Medicare requirements for physician supervision that do not help with patient safety.

Response: Our policies on supervision, along with hospital conditions of participation, state scope of practice laws, and other state and federal laws and regulations, all help ensure the quality and safety of outpatient hospital therapeutic services Medicare beneficiaries receive. General supervision is defined in our regulation at 42 CFR 410.32(b)(3)(i) to mean 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.

With general supervision, our proposal would ensure a standard minimum level of supervision for each hospital outpatient therapeutic service furnished incident to a physician's service in accordance with the statute. General supervision ensures patient safety as it requires a physician to provide overall direction and control for outpatient hospital therapeutic procedures, which means the medical personnel performing the procedure are being monitored and receiving guidance from a qualified physician even if the physician is not physically present. Also, a provider may voluntarily choose to require a higher level of involvement in the medical procedure by the physician if the hospital believes it is necessary for the safety of the patient receiving the procedure.

Additionally, we solicited public comments on whether specific types of services, such as chemotherapy administration or radiation therapy, should be excepted from our proposal to change the generally applicable minimum required level of supervision for hospital outpatient therapeutic services from direct supervision to general supervision for services furnished by all hospitals and CAHs.

Comment: Multiple commenters supported our proposal to have general supervision be the minimum default level of supervision for outpatient hospital therapeutic chemotherapy and radiation therapy services. One commenter supported this policy because they were concerned that if direct supervision was required to be the default minimum level of physician supervision for chemotherapy and radiation therapy while all other outpatient hospital therapeutic services have a default minimum level of general supervision, it would be difficult to change the minimum default level of supervision for chemotherapy and radiation therapy to general supervision in the future. Another commenter wanted to know under what circumstances the minimum default supervision level for chemotherapy and radiation therapy would be direct physician supervision if the current policy has established general supervision as the minimum default level of supervision.

Response: We appreciate the feedback we received from commenters on this topic. Regarding the question from the one commenter about how the default minimum level of supervision for chemotherapy and radiation services could be direct supervision when the default minimum level of supervision is

general supervision for other outpatient therapeutic services, we note that because we are finalizing our proposal to require general supervision for all outpatient therapeutic services, the required supervision level is the same for all of these services, including chemotherapy and radiation therapy services.

After reviewing all of the public comments, we are finalizing our proposal for CY 2020 and subsequent years to change the generally applicable minimum required level of supervision for hospital outpatient therapeutic services from direct supervision to general supervision for services furnished by all hospitals and CAHs without modification. We also note all of the policy safeguards that have been in place to ensure the safety, health, and quality standards of the outpatient therapeutic services that beneficiaries receive will continue to be in place under our new policy. These safeguards include allowing providers and physicians the discretion to require a higher level of supervision to ensure a therapeutic outpatient procedure is performed without risking a beneficiary's safety or their quality of the care, as well as the presence outpatient hospital and CAH CoPs, and other state and federal laws and regulations. We are also finalizing the accompanying changes we proposed to the regulatory text at § 410.27 with several technical changes.

B. Short Inpatient Hospital Stays

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.

2. Current Policy for Medical Review of Inpatient Hospital Admissions Under Medicare Part A

In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70538 through 70549), we revised 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 above 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.

3. Change for Medical Review of Certain Inpatient Hospital Admissions Under Medicare Part A for CY 2020 and Subsequent Years

As stated earlier in this section, the procedures on the IPO list of procedures under the OPPS are not subject to the 2-midnight benchmark for purposes of inpatient hospital payment. However, the 2-midnight benchmark is applicable once procedures have been removed from the IPO list. Procedures that are removed from the IPO list are also subject to initial medical reviews of claims for short-stay inpatient

admissions conducted by Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC–QIOs).

BFCC–QIOs may also refer providers to the Recovery Audit Contractors (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.

As part of our continued effort to facilitate compliance with our payment policy for inpatient admissions, we proposed to establish a 1-year exemption from certain medical review activities for procedures removed from the IPO list under the OPPS in CY 2020 and subsequent years. Specifically, we proposed that procedures that have been removed from the IPO list would not be eligible for referral to RACs for noncompliance with the 2-midnight rule within the first calendar year of their removal from the IPO list. These procedures would not be 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 would these procedures be reviewed by RACs for ''patient status.'' During this 1-year period, BFCC–QIOs would 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 would not be denied with respect to the site-of-service under Medicare Part A. Again, information gathered by the BFCC–QIO when reviewing procedures that are newly removed from the IPO list could be used for educational purposes and would not result in a claim denial during the proposed 1-year exemption period.

In the proposed rule, we stated that we believed that a 1-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, we stated our belief that this 1-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 proposed exemption. Specifically, we stated that commenters may indicate whether and why they believe the proposed 1-year period is appropriate, or whether they believe a longer or shorter exemption period would be more appropriate.

In summary, for CY 2020 and subsequent years, we proposed to establish a 1-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, 2020. We encourage 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 note that we will monitor changes in site-of-service to determine whether changes may be necessary to certain CMS Innovation Center models.

Comment: Numerous stakeholders including medical professional societies, health systems, hospital associations, and individuals supported the proposal of a 1-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, 2020. However, many of these commenters supported an extension of the exemption policy past 1 year, with a majority of commenters recommending a period of 2 years, some commenters recommending three years or more, and others recommending that CMS permanently restrict RAC reviews of patient status for procedures removed from the IPO list in deference to physicians' clinical judgment. The commenters stated that a longer period of time is necessary for providers to adjust patterns of practice for procedures that have been removed from the IPO list and to prepare for system-wide implementation. Some commenters also requested that CMS maintain consistency with the policy finalized when total knee arthroplasty (TKA) was removed from the IPO list and limit RAC review for ''patient status'' for a period of 2 years.

Response: We appreciate the stakeholders' feedback regarding the appropriate period of time for this exemption. After considering the options recommended by commenters, we have decided to modify our proposal and exempt 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) for a period of 2 years beginning in CY 2020. We agree with the majority of commenters who stated a two-year exemption period from certain medical review activities for procedures removed from the IPO list would be more beneficial to the provider community than a 1-year exemption, as such a time period will be sufficient to help hospitals and clinicians to become used to the availability of payment under both the hospital inpatient and outpatient setting for procedures newly removed from the IPO. Further, we were persuaded by the comments explaining that a 2-year exemption period of exemption 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 a 2-year exemption time period is adequate to let providers gain experience with the application of the 2-midnight rule to these procedures. We also believe that a 2-year exemption of the medical review activities discussed above for procedures removed from the IPO list will be sufficient time for providers and BFCC–QIOs 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. At this time, we do not believe it is necessary to exempt procedures that have been removed from the IPO list from the medical review activities discussed above for a

period of longer than 2 years. With regard to comments recommending that we permanently restrict RAC reviews of ''patient status'' in deference to physicians' clinical judgment, we believe that it is necessary to allow BFCC–QIOs to resume referring providers to the RACs for further medical review due to exhibiting persistent noncompliance with Medicare payment policies after the two-year exemption period.

Comment: Some commenters also requested clarifications regarding the proposed policy with regard to BFCC–QIO reviews. One commenter questioned if the proposed 1-year exemption from certain medical review activities applied to BFCC–QIO referrals to RACs for review of patient status only or if it also applied to BFCC–QIO review of medical necessity for surgery itself. Other commenters suggested that in the first year after a service is removed from the IPO list, the procedure should be exempt from both BFCC–QIO medical review and RAC review.

Response: For clarification, as stated in the CY 2020 OPPS/ASC proposed rule (84 FR 39527), this proposal does not exempt procedures that are removed from the IPO list from the initial medical reviews of claims for short-stay inpatient admissions conducted by BFCC–QIOs. The proposal was intended to exempt procedures that are removed from the IPO list from 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, 2020. We also stated in the CY 2020 OPPS/ASC proposed rule that we encourage 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 (84 FR 39528).

Also, as 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. Accordingly, 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. BFCC–QIOs will not make referrals to RACs for noncompliance with the 2-midnight rule for procedures that are removed from the IPO list within the first two years of their removal, RACs will not conduct reviews for ''patient status'' (that is, site-of-service) for procedures that are removed from the IPO list within the first two years of their removal, and claims with 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 within the first 2 years of their removal beginning on January 1, 2020.

After considering comments received, we are finalizing our policy as proposed with one modification to the time period of the exemption. That is, for CY 2020 and subsequent years, we are finalizing a policy to exempt procedures that have been removed from the IPO list 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. These procedures will not be 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 these procedures be reviewed by RACs for ''patient status.'' 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.

C. Method To Control Unnecessary Increases in the Volume of Clinic Visit Services Furnished in Excepted Off-Campus Provider-Based Departments (PBDs)

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59004 through 59014), we adopted a method to control unnecessary increases in the volume of the clinic visit service furnished in excepted off-campus provider-based departments (PBDs) by removing the payment differential that drives the site-of-service decision and, as a result, unnecessarily increases service volume. We refer readers to the CY 2019 OPPS/ASC final rule with comment period for a detailed discussion of the background, legislative provisions, and the changes in payment policies we developed to address increases in the volume of covered outpatient department (OPD) services. Below we discuss the specific policy we finalized in the CY 2019 OPPS/ASC final rule with comment period and its application under the OPPS for CY 2020.

For the CY 2019 OPPS, using our authority under section 1833(t)(2)(F) of the Act to adopt a method to control unnecessary increases in the volume of covered outpatient department services, we applied an amount equal to the site-specific Medicare Physician Fee Schedule (PFS) payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD (the PFS payment rate) for the clinic visit service, as described by HCPCS code G0463, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act (departments that bill the modifier ''PO'' on claim lines). However, we phased in the application of the reduction in payment for the clinic visit service described by HCPCS code G0463 in the excepted provider-based department setting over 2 years. For CY 2019, the payment reduction was transitioned by applying 50 percent of the total reduction in payment that was applied if these departments were paid the site-specific PFS rate for the clinic visit service. The PFS-equivalent rate was 40 percent of the OPPS payment for CY 2019 (that is, 60 percent less than the OPPS rate). We provided for a 2-year phase-in of this policy under which one-half of the total 60-percent payment reduction (a 30-percent reduction) was applied in CY 2019. These departments are paid approximately 70 percent of the OPPS rate (100 percent of the OPPS rate minus the 30-percent payment reduction that is applied in CY 2019) for the clinic visit service in CY 2019.

For CY 2020, the second year of the 2-year phase-in, we stated that we would apply the total reduction in payment that is applied if these departments (departments that bill the modifier ''PO'' on claims lines) are paid the site-specific PFS rate for the clinic visit service described by HCPCS code G0463. The PFS-equivalent rate for CY 2020 is 40 percent of the proposed OPPS payment (that is, 60 percent less than the proposed OPPS rate) for CY 2020. Under this policy, adopted in 2019, departments would 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 2020) for the clinic visit service in CY 2020.

In addition, as we stated in the CY 2019 OPPS/ASC final rule with

comment period (83 FR 59013), for CY 2020, this policy will be implemented in a non-budget neutral manner. The estimated payment impact of this policy was displayed in Column 5 of Table 44–Estimated Impact of the Proposed CY 2020 Changes for the Hospital Outpatient Prospective Payment System in the CY 2020 OPPS/ASC proposed rule. In order to effectively establish a method for controlling the unnecessary growth in the volume of clinic visits furnished by excepted off-campus PBDs that does not simply increase other expenditures that are unnecessary within the OPPS and drive different service-distorting decisions, we believe that this method must be adopted in a non-budget neutral manner. The impact associated with this policy is further described in section XXVI. of this rule.

The comments and our responses to the comments are set forth below.

Comment: Numerous commenters, including organizations representing health insurance plans, physician associations, specialty medical associations and individual Medicare beneficiaries, supported moving forward with the phase-in of this proposal. Some of these commenters commended CMS for completing the two-year phase-in ''since it increases the sustainability of the Medicare program and reduces costs for Medicare patients.'' Commenters expressed that the alignment of payment between the outpatient and physician office setting ''is an important and necessary reform that can help reduce provider consolidation and thereby provide beneficiaries with more care options at a lower cost.'' Commenters continued to be supportive of the immediate impact this policy would have in lowering Medicare beneficiaries' out-of-pocket costs.

With respect to the policy being applied in a non-budget neutral manner, one commenter expressed support for the policy and stated that ''the Agency correctly recognized that it cannot address the payment disparity between the outpatient hospital and physician office settings as long as it applies payment changes within the OPPS in a budget-neutral manner that effectively 'traps' the potential savings from the change within the OPPS.''

Several commenters suggested that CMS ''explore additional opportunities to expand site neutral payments for all clinically appropriate outpatient services'' beyond the clinic visit service. They expressed that site neutral payment policies can create incentives for providers to make decisions that lower the cost of care for beneficiaries and the Medicare program.

Response: We appreciate the commenters' support. As we stated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59005), we continue to share the commenters' concern that the current payment incentives, rather than patient acuity or medical necessity, are affecting site-of-service decision-making. 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. 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 appreciate the comments supporting the implementation of this policy in a non-budget neutral manner. As we stated in the CY 2019 OPPS ASC final rule with comment period (83 FR 59013), we believe 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 services within the OPPS system because of payment rather than medical necessity. We also outlined in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59013) that while section 1833(t)(9)(B) of the Act requires that certain changes made under the OPPS be made in a budget neutral manner, this section does not apply to the volume control method under section 1833(t)(2)(F) of the Act. As we detailed in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59005), ''total spending under the OPPS is projected to further increase by more than $5 billion from approximately $70 billion in CY 2018 through CY 2019 to nearly $75 billion. This is approximately twice the total estimated spending in CY 2008, a decade ago.'' And as for one of the drivers of this volume increase, the ''Medicare Payment Advisory Commission (MedPAC) found that, from 2011 through 2016, combined program spending and beneficiary cost-sharing on services covered under the OPPS increased by 51 percent, from $39.8 billion to $60.0 billion, an average of 8.6 percent per year. In its 2018 report, MedPAC also noted that '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'.'' (83 FR 59006).

Section 1833(t)(9)(A) of the Act, titled ''Periodic review,'' provides, in part, that the Secretary must annually review and revise the 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'' (emphasis added). Section 1833(t)(9)(B) of the Act, titled ''Budget neutrality adjustment'' provides that if ''the Secretary makes *adjustments* under subparagraph (A), then the *adjustments* for a year may not cause the estimated amount of expenditures under this part for the year to increase or decrease from the estimated amount of expenditures under this part that would have been made if the adjustments had not been made'' (emphasis added).

However, section 1833(t)(2)(F) of the Act is not an ''adjustment'' under paragraph (2). Unlike the wage adjustment under section 1833(t)(2)(D) of the Act and the outlier, transitional pass-through, and equitable adjustments under section 1833(t)(2)(E) of the Act, section 1833(t)(2)(F) of the Act refers to a ''method'' for controlling unnecessary increases in the volume of covered OPD services, not an adjustment. Likewise, sections 1833(t)(2)(D) and (E) of the Act also explicitly require the adjustments authorized by those paragraphs to be budget neutral, while the volume control method authority at section 1833(t)(2)(F) of the Act does not. Therefore, the volume control method proposed under section 1833(t)(2)(F) of the Act is not one of the adjustments under section 1833(t)(2) of the Act that is referenced under section 1833(t)(9)(A) of the Act that must be included in the budget neutrality adjustment under section 1833(t)(9)(B) of the Act. Moreover, section 1833(t)(9)(C) of the Act specifies that, if the Secretary determines under methodologies described in paragraph (2)(F) that the volume of services paid for under this subsection increased *beyond* amounts established through those methodologies, the Secretary *may* appropriately adjust the update to the conversion factor otherwise applicable in a *subsequent year.* We continue to interpret this provision to mean that the Secretary will have implemented a volume control method under section 1833(t)(2)(F) of the Act in a nonbudget neutral manner in the year in which the method is implemented, and that the Secretary may then make further adjustments to the conversion factor in

a subsequent year to account for volume increases that are *beyond* the amounts estimated by the Secretary under the volume control method.

As detailed later in this section, after consideration of public comments, we are continuing the second year of the two-year phase-in as adopted in CY 2019 rulemaking. We will continue to take information submitted by the commenters into consideration for future analysis.

Comment: MedPAC supported the proposal to adjust the OPPS payment rate for clinic visits that are provided in excepted off-campus PBDs so that it is the same as the payment rate for clinic visits provided in nonexcepted off-campus PBDs. They note that this policy would be consistent with past Commission recommendations for site-neutral payments between HOPDs and freestanding physician offices, although the recommendations it put forth in 2012 and 2014 would have applied to several services that met certain criteria and would have adjusted payment so that it equaled the total payment had the services been furnished in a freestanding office and did not distinguish between on- and off-campus services. MedPAC further noted that it shares CMS' concerns about the rate of growth in volume and spending under the OPPS. MedPAC also stated, perhaps inadvertently, that ''CMS proposes to implement this policy in a budget-neutral manner.''

Response: We thank MedPAC for its comments and support of this policy. To clarify, this policy has been phased-in in a non-budget neutral manner.

Comment: Some commenters were concerned about the impact this payment change might have on rural providers and safety net health systems. Commenters suggested that CMS consider policy modifications to reduce the impact of the payment reduction. They said this could be accomplished by ''providing the OPPS rate to outpatient departments located in federally designated Health Professional Shortage Areas or Medically Underserved Areas.'' Some commenters also suggested that CMS monitor for any potential access to care issues in rural and underserved areas.

Response: 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. While we understand the concerns regarding rural hospitals, we believe that implementing with a phase-in has helped to mitigate the immediate impact rural hospitals might otherwise face. We will continue to monitor trends for any access to care issues and may revisit this policy in future rulemaking.

Comment: One commenter, a large medical association, stated that while it generally supported site neutral payments, it did not ''believe that it is possible to sustain a high-quality health care system if site neutrality is defined as shrinking all payments to the lowest amount paid in any setting.'' The commenter went on to state that ''any savings from site neutrality proposals derived from OPPS should be reinvested in improvements elsewhere in Part B, including payments to physicians as inflation is not a factor in annual physician payment updates and this contributes to the payment differential.'' The commenter went on to underscore its position that ''CMS should not implement site neutrality in a way that reduces payment to the lowest common denominator and should reinvest savings from lowering facility payments to other Part B services, including payments under the physician fee schedule.''

Response: We thank the commenter for its input. As we stated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59005), to the extent that similar services can be safely provided in more than one setting, we do not believe it is prudent for the Medicare program to pay more for these services in one setting than another. We believe the increase in the volume of clinic visits, in particular, is due to the payment incentive that exists to provide this service in the higher cost setting. Because these services could likely be safely provided in a lower cost setting, we believe that the growth in clinic visits paid under the OPPS is unnecessary. Further, we believe that setting the OPPS payment at the PFS-equivalent rate would be an effective method to control the volume of these unnecessary services because the payment differential that is driving the site-of-service decision will be removed.

We note that the overall amount of Medicare payments to physicians and other entities made under the PFS is determined 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 the commenter believes that the PFS rate for a particular service is misvalued relative to other PFS services, we encourage the commenter to nominate the service for review as a potentially misvalued service under the PFS.

Comment: We received numerous comments urging CMS not to move forward with the phase-in of this policy. Many commenters believed that the final rule should reflect the recent decision from the United States District Court for the District of Columbia, *American Hospital Association, et al.* v. *Azar,* No. 1:18–cv–02841–RMC (D.D.C. Sept. 17, 2019), and that CMS, at a minimum, should maintain the 2019 payments and not complete the second year of the phase-in. Others believed the litigation mandated that CMS revert back to the higher payment rates. Commenters noted that the advisory Panel on Hospital Outpatient Payment unanimously recommended that CMS freeze the payment policy for clinic visits furnished by excepted off-campus PBDs at CY 2019 rates and evaluate whether beneficiary access has been compromised and whether the volume of outpatient services has decreased. Many commenters argued 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 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.

Many commenters, including numerous state hospital associations, stated that making additional cuts to outpatient payment of the magnitude of the second year of phase-in of the clinic visit policy would be excessive and harmful. They expressed concern that the cuts could endanger the critical role that HOPDs play in their communities.

Response: We continue to believe that section 1833(t)(2)(F) of the Act grants the Secretary the 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.[78] We also continue to believe shifts in the sites of service described in CY 2019 OPPS/ASC final rule with comment period (83 FR 59013), 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 we did receive some data illustrating that certain HOPDs serve unique patient populations and provide services to medically complex beneficiaries, we continue to believe that this data has not demonstrated 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 59013), 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.

On September 17, 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.[79] On September 23, 2019, the Department of Health and Human Services (HHS) filed a motion requesting that the district court modify its order to remand the matter without vacatur or, alternatively, to stay the portion of the order vacating the rule for 60 days from the date of the order to allow the Solicitor General time to determine whether to authorize appeal. On October 21, 2019, the district court denied our motion to modify and request for stay, affirmed that the portion of the 2019 final rule that adopted the volume control method for clinic visits furnished by excepted off-campus PBDs is vacated, and entered final judgment. We acknowledge that the district court vacated the volume control policy for CY 2019 and we are working to ensure affected 2019 claims for clinic visits are paid consistent with the court's order. We do not believe it is appropriate at this time to make a change to the second year of the two-year phase-in of the clinic visit policy. The government has appeal rights, and is still evaluating the rulings and considering, at the time of this writing, whether to appeal from the final judgment.

With respect to the HOP panel, section 1833(t)(9)(A) of the Act provides that the Secretary shall consult with the Panel on policies affecting the clinical integrity of the ambulatory payment classifications and their associated weights under the OPPS. The Panel met on August 19, 2019, and recommended that CMS freeze the payment policy for off-campus clinic visits at the calendar year 2019 rates and evaluate whether beneficiary access has been compromised and whether the volume of outpatient services has decreased; the panel further recommended that CMS report its findings back to the Panel for review. We believe, for reasons outlined in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59013) and in this final rule that in order to appropriately control unnecessary increases in the volume of clinic visits services furnished in HOPDs, we must move forward with phasing-in this policy. Freezing the payment rate, even at the 2019 rate, still ''traps'' the unnecessary spending within the OPPS.

The HOP Panel's recommendations, along with public comments on provisions of the proposed rule, have been taken into consideration in the development of this final rule with comment period. While we are not accepting the HOP Panel's recommendation, we will continue to monitor and study the utilization of outpatient services as recommended by the Panel.

Comment: Many commenters referenced the ongoing litigation (described earlier in this section) in which the district court found that CMS exceeded its statutory authority by reducing payments for clinic visit services furnished in excepted off-campus PBDs as a method to control what we believe are unnecessary increases in the volume of those services. Several comments suggested that the continued implementation of this policy should be suspended until the ongoing litigation is adjudicated. They stated that ''CMS should not take in further reductions in the clinic payments for off-campus PBDs in CY 2020 or future years until the matter is resolved.''

Commenters also submitted suggestions on how CMS might remedy payments following the district court's order vacating the portion of the CY 2019 OPPS/ASC final rule with comment period that adopted the volume control method for clinic visits. Some suggested that CMS must ''make whole with interest'' affected PBDs. Others recommended that CMS ''make a lump sum payment to the facilities that were subject to the 2019 payment cut'' and requested that ''no additional copayment be required from patients'' should CMS apply a retroactive remedy. One commenter suggested that ''CMS provide as a remedy a lump sum payment to hospitals for the difference that would have been paid had the rule not been implemented.'' Some commenters stated that ''the remedy should be completed at a hospital specific level, on a claim by claim basis,'' so as to ensure hospitals are adequately paid for clinic visits.

Several commenters wrote in urging CMS to restore the higher payment rates (which they believed would be consistent with the district court decision), promptly repay hospitals for the 2019 payment cuts, and abandon the second phase of the payment cut for 2020. Many noted that should the agency move forward with the second phase of the cut, it would cause additional harm to many hospitals, and they intended to continue pursuing legal remedies.

Another commenter suggested that while the court remanded to CMS the issue of remediation of cuts that occurred since January 1, 2019, they believe ''at a minimum, the final rule should reflect the court decision and address the 30 percent cut implemented for calendar year 2019 and ensure the cuts are not finalized for 2020.''

Response: We thank the commenters for their suggestions.

As noted above, on September 23, 2019, HHS filed a motion requesting that the district court modify its order to remand the matter without vacatur or alternatively, to stay the portion of the order vacating the rule for 60 days from the date of the order to allow the Solicitor General time to determine whether to authorize appeal. This motion was denied on October 21, 2019. As we stated above, the government has appeal rights and is still evaluating the rulings and considering, at the time of this writing, whether to appeal from the final judgment. For CY 2020, CMS will be going forward with the phase-in. We respectfully disagree with the district court and continue to believe the Secretary has the authority to address unnecessary increases in the volume of outpatient services. CMS is still considering how we would remedy hospitals if we either do not appeal this ruling or do not succeed on appeal if one is so authorized.

Comment: One commenter suggested that even with the recent court decision

[78] Available at: *https://www.ssa.gov/OP_Home/ssact/title18/1833.htm.*

[79] *American Hospital Ass'n, et al.* v. *Azar,* No. 1:18-cv-02841–RMC (D.D.C. Sept. 17, 2019).

CMS should ''explore regulatory pathways to address site of service payment differentials in a budget neutral manner.'' Commenters gave the example of ''prospectively chang[ing] the manner in which hospitals allocate costs to outpatient cost centers in institutional cost reports, particularly for cost centers where similar services can be provided in physician offices which have no comparable overhead costs.'' Another commenter expressed that ''[p]atients should not be penalized and pay higher prices simply because a hospital owns the medical practice where they receive care.'' The commenter encouraged CMS to ''pursue a staunch defense of this proposal including, but not limited to, the appeal of recent court rulings that undermine these changes.'' The commenter went on to say that CMS should ''take the necessary steps to protect its authority to implement the second year of the two-year phase-in while the Agency takes an appeal to the D.C. Circuit.''

Response: We thank the commenters for their submissions and support of this policy. After consideration of public comments we received, we will be completing the phase-in of the application of the reduction in payment for HCPCS code G0463. Specifically, for CY 2020, we will apply the full amount of the reduction in payment that is applied if these departments (departments that bill the modifier ''PO'' on claims lines) are paid the site-specific PFS rate for the clinic visit service described by HCPCS code G0463. The PFS-equivalent rate for CY 2020 is 40 percent of the proposed OPPS payment (that is, 60 percent less than the proposed OPPS rate). Under this policy, 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 2020) for the clinic visit service in CY 2020. Considering the effects of estimated changes in enrollment, utilization, and case-mix, this policy results in an estimated CY 2020 savings of approximately $800 million, with approximately $640 million of the savings accruing to Medicare, and approximately $160 million saved by Medicare beneficiaries in the form of reduced copayments, when compared to 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 in light of the litigation and judicial decision as they may arise.

XI. CY 2020 OPPS Payment Status and Comment Indicators

A. CY 2020 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 2020, we did not propose to make any changes to the definitions of status indicators that were listed in Addendum D1 to the CY 2019 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-Items/CMS-1717-P.html?DLPage=1&DLEntries=10&10DLSort=2DLSortDir=descending*.

We did not receive any public comments on the proposed 2020 definitions of the OPPS status indicators. We believe that the existing definitions of the OPPS status indicators will continue to be appropriate for CY 2020. Therefore, we are finalizing our proposed policy without modifications.

The complete list of the payment status indicators and their definitions that apply for CY 2020 is displayed in Addendum D1 to this 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*.

The CY 2020 payment status indicator assignments for APCs and HCPCS codes are shown in Addendum A and Addendum B, respectively, to this 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 2020 Comment Indicator Definitions

In the proposed rule, we proposed to use four comment indicators for the CY 2020 OPPS. These comment indicators, ''CH'', ''NC'', ''NI'', and ''NP'', are in effect for CY 2019 and we proposed to continue their use in CY 2020. The CY 2020 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 2020 are listed in Addendum D2 to this 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 use of comment indicators for CY 2020. We believe that the CY 2019 definitions of the OPPS comment indicators continue to be appropriate for CY 2020. Therefore, we are continuing to use those definitions without modification for CY 2020.

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 2019 report.

A. OPPS Payment Rates Update

The March 2019 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 2019 report for a complete discussion on these recommendations, which is available for download at *www.medpac.gov.* We appreciate MedPAC's recommendations, but as MedPAC acknowledged in its March 2019 report, Congress would need to change current law to enable us to implement its recommendations. MedPAC did not comment on the proposed OPPS payment rate update. 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 2019 MedPAC ''Report to the Congress: Medicare Payment Policy'', MedPAC found that, based on its analysis of indicators of payment adequacy, the number of Medicare-certified ASCs had increased, beneficiaries' use of ASCs had increased, and ASC access to capital has been adequate.[80] As a result, for CY 2020, MedPAC stated that payments to ASCs are adequate and recommended that no payment update should be given for 2020 (that is, the update factor would be 0 *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 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 hospital market basket update for the ASC payment system. Therefore, consistent with our policy for the ASC payment system, in the CY 2020 OPPS/ASC proposed rule, we proposed to apply a 2.7 percent MFP-adjusted hospital market basket update factor to the CY 2019 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the CY 2020 ASC payment amounts.

Comment: MedPAC reiterated their previous comments in their March 2019 report; specifically, that they do not support using the hospital market basket index as an interim method for updating the ASC conversion factor because evidence indicates the hospital market basket index does not accurately reflect the cost of providing services in the ASC setting.

Response: We believe providing ASCs with the same rate update mechanism as hospitals could encourage the migration of appropriate services from the hospital setting to the ASC setting and increase the presence of ASCs in health care markets or geographic areas where previously there were none or few, thus promoting better beneficiary access to care. As published in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42343), based on IGI's 2019 second quarter forecast with historical data through the first quarter of 2019, the hospital market basket update is 3.0 percent, and the MFP adjustment is 0.4 percentage point. Therefore, for this CY 2020 OPPS/ASC final rule with comment period we are finalizing the application of a 2.6 percent MFP-adjusted hospital market basket update factor to the CY 2019 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the CY 2020 ASC payment amounts, as discussed at section XXVI of this final rule with comment period.

C. ASC Cost Data

In the March 2019 MedPAC ''Report to the Congress on 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.[81]

Comment: MedPAC reiterated their previous comments in their March 2019 report and requested that CMS use available authority to act quickly in gathering ASC cost data to inform ASC input costs and determine whether an existing Medicare price index is an appropriate proxy for ASC costs or whether an ASC-specific market basket index should be developed. Additionally, MedPAC asserts there is sufficient evidence that ASCs are capable of submitting cost data to CMS.

Response: We did not propose any cost reporting requirements for ASCs in the CY 2020 OPPS/ASC proposed rule and are not finalizing any cost reporting requirements for ASCs in this final rule.

The full March 2019 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 and 2019 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; and 83 FR 59028 through 59080, 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 42 CFR 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 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. 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

[80] Medicare Payment Advisory Committee. March 2019 Report to the Congress. Chapter 5: Ambulatory surgical center services. Available at: *http://www.medpac.gov/docs/default-source/reports/mar19_medpac_ch5_sec.pdf?sfvrsn=0.*

[81] Medicare Payment Advisory Committee. March 2019 Report to the Congress. Chapter 5: Ambulatory surgical center services. Available at: *http://www.medpac.gov/docs/default-source/reports/mar19_medpac_ch5_sec.pdf?sfvrsn=0.*

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 § 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 (§ 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 (including all procedures newly proposed for removal from the OPPS inpatient list), 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 (72 FR 42477).

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.

The comments and our responses to the comments are set forth below.

Comment: Commenters supported our revised definition and recommended that we modify our definition of an ASC covered surgical procedure for CY 2020 and subsequent years.

Response: We thank the commenters for their support. In review of the public comments we received, we realized that our modified definition of an ASC covered surgical procedure was initially

finalized in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59029 through 59030) but that we only referenced CY 2019 and did not reference subsequent years. While we did not specifically propose to continue our modified definition of surgery for CY 2020 in the CY 2020 OPPS/ASC proposed rule, we did not propose to remove any procedures from the ASC list of covered surgical procedures that we had added as a result of our modified definition of a surgical procedure, and, therefore, we intended to continue our modified definition. For this final rule with comment period, after consideration of the public comments we are adopting a policy to continue to apply the modified definition of a surgical procedure for CY 2020, which was finalized for CY 2019 in our CY 2019 OPPS/ASC final rule with comment period (83 FR 59029 through 59030). We intend to address subsequent calendar years in future rulemaking.

B. ASC Treatment of New and Revised Codes

1. Background on Current Process for Recognizing New and Revised HCPCS Codes

Payment for ASC items and services 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 codes, a numeric and alphanumeric coding system maintained by the 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 alphanumeric 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 42535) to evaluate each year all new 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 2020 OPPS/ASC final rule with comment period.

We have separated our discussion below based on when the codes are released and whether we solicited public comments in the proposed rule (and respond to those comments in this CY 2020 OPPS/ASC final rule with comment period) or whether we are soliciting public comments in this CY 2020 OPPS/ASC final rule with comment period (and will respond to those comments in the CY 2021 OPPS/ASC final rule with comment period).

We note that we sought public comments in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59034 through 59035) on the new and revised Level II HCPCS codes effective October 1, 2018 or January 1, 2019. These new and revised codes were flagged with comment indicator ''NI'' in Addenda AA and BB to the CY 2019 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 2019 OPPS/ASC final rule with comment period. In the CY 2019 OPPS/ASC proposed rule, we stated that we will finalize the treatment of these codes under the ASC payment system in this CY 2020 OPPS/ASC final rule with comment period.

2. April 2019 HCPCS Codes for Which We Solicited Public Comments in the Proposed Rule

For the April 2019 update, there were no new CPT codes, however, there were several new Level II HCPCS codes. In the April 2019 ASC quarterly update (Transmittal 4263, CR 11232, dated March 22, 2019), we added eight new Level II HCPCS codes to the list of covered ancillary services. Table 25 of the CY 2020 OPPS/ASC proposed rule displayed the new Level II HCPCS codes that were implemented on April 1, 2019, along with their proposed payment indicators for CY 2020.

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 2019 through the quarterly update CRs, as listed in Table 25 of the CY 2020 OPPS/ASC proposed rule. We proposed to finalize their payment indicators in the CY 2020 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 2019. Therefore, we are finalizing the proposed ASC payment indicator assignments for these codes, as indicated in Table 50 below. We note that several of the temporary drug HCPCS C-codes have been replaced with permanent drug HCPCS J-codes, effective January 1, 2020. Their replacement codes are also listed in Table 50. 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 50.—NEW LEVEL II HCPCS CODES FOR ANCILLARY SERVICES EFFECTIVE ON APRIL 1, 2019

CY 2019 HCPCS Code	CY 2020 HCPCS Code	CY 2020 Long Descriptor	Final CY 2020 PI
C9040	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)	K2
C9041	C9041	Injection, coagulation factor Xa (recombinant), inactivated (andexxa), 10 mg	K2
C9042*	J9036	Injection, bendamustine hydrochloride, (Belrapzo/bendamustine), 1 mg	D5
C9043	J0642	Injection, khapzory, 0.5 mg	K2
C9044	J9119	Injection, cemiplimab-rwlc, 1 mg	K2
C9045	J9313	Injection, moxetumomab pasudotox-tdfk, 0.01 mg	K2
C9046	C9046	Cocaine hydrochloride nasal solution for topical administration, 1 mg	K2
C9141**	J7208	Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl, (jivi), 1 i.u.	K2

*HCPCS code C9042, which was effective April 1, 2019, was deleted June 30, 2019 and replaced with HCPCS code J9036 (Injection, bendamustine hydrochloride, (Belrapzo/bendamustine), 1 mg) effective July 1, 2019.

**HCPCS code C9141, which was effective April 1, 2019, was deleted June 30, 2019 and replaced with HCPCS code J7208 (Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl, (jivi), 1 i.u.), 1 mg) effective July 1, 2019.

3. July 2019 HCPCS Codes for Which We Solicited Public Comments in the Proposed Rule

In the July 2019 ASC quarterly update (Transmittal 4076, Change Request 10788, dated June 14, 2019), we added several separately payable Category III CPT and Level II HCPCS codes to the list of covered surgical procedures and ancillary services. Table 26 of the CY 2020 OPPS/ASC proposed rule displayed the new HCPCS codes that were effective July 1, 2019.

In addition, through the July 2019 quarterly update CR, we also implemented an ASC payment for one new Category III CPT code as an ASC covered ancillary service, effective July 1, 2019. This code was listed in Table 27 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 2019 through the quarterly update CRs, as listed in Tables 25, 26, and 27 of the proposed rule.

We did not receive any other public comments on the proposed ASC payment indicator assignments for the new Category III CPT codes or Level II HCPCS codes implemented in July 2019. Therefore, we are finalizing the proposed ASC payment indicator assignments for these codes, as indicated in Table 51 and 52 below. We note that several of the HCPCS C-codes have been replaced with HCPCS J-codes, effective January 1, 2020. Their replacement codes are listed in Table 51. 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).

TABLE 51.—NEW LEVEL II HCPCS CODES FOR COVERED SURGICAL PROCEDURES AND ANCILLARY SERVICES EFFECTIVE ON JULY 1, 2019

CY 2019 HCPCS Code	CY 2020 HCPCS Code	CY 2020 Long Descriptor	Final CY 2020 PI
C9047	C9047	Injection, caplacizumab-yhdp, 1 mg	K2
C9048	J1096	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg	K2
C9049	J9269	Injection, tagraxofusp-erzs, 10 micrograms	K2
C9050	J9210	Injection, emapalumab-lzsg, 1 mg	K2
C9051	J0121	Injection, omadacycline, 1 mg	K2
C9052	J1303	Injection, ravulizumab-cwvz, 10 mg	K2
J7208	J7208	Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl, (jivi), 1 i.u.	K2
J9030	J9030	BCG live intravesical instillation, 1 mg	K2
J9036	J9036	Injection, bendamustine hydrochloride, (Belrapzo/bendamustine), 1 mg	K2
J9356	J9356	Injection, trastuzumab, 10 mg and Hyaluronidase-oysk	K2
0548T*	0548T*	Transperineal periurethral balloon continence device; bilateral placement, including cystoscopy and fluoroscopy	J8
0549T	0549T	Transperineal periurethral balloon continence device; unilateral placement, including cystoscopy and fluoroscopy	J8
0550T	0550T	Transperineal periurethral balloon continence device; removal, each balloon	G2
0551T	0551T	Transperineal periurethral balloon continence device; adjustment of balloon(s) fluid volume	R2

*The predecessor code for CPT code 0548T was HCPCS code C9746 (Transperineal implantation of permanent adjustable balloon continence device, with cystourethroscopy, when performed and/or fluoroscopy, when performed), which was effective July 1, 2017 and deleted on June 30, 2019.

TABLE 52.—NEW CATEGORY III CPT CODE FOR COVERED ANCILLARY SERVICE EFFECTIVE ON JULY 1, 2019

CY 2019 HCPCS Code	CY 2019 Long Descriptor	CY 2020 CI	CY 2020 PI
0558T	Computed tomography scan taken for the purpose of biomechanical computed tomography analysis	NP	Z2

4. October 2019 HCPCS Codes for Which We Are Soliciting Public Comments in This CY 2020 OPPS/ASC 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 2020 OPPS/ASC proposed rule (84 FR 39534), for CY 2020, consistent with our established policy, we proposed that the Level II HCPCS codes that will be effective October 1, 2019 would be flagged with comment indicator ''NI'' in Addendum BB to the CY 2020 OPPS/ASC final rule with comment period to indicate that we have assigned the codes an interim ASC payment indicator for CY 2020. We did not receive any public comments on our proposal. As we stated that we would do in the CY 2020 OPPS/ASC proposed rule, we are inviting public comments in this CY 2020 OPPS/ASC final rule with comment period on the interim ASC payment indicator for these codes that we intend to finalize in the CY 2021 OPPS/ASC final rule with comment period.

5. January 2020 HCPCS Codes

a. New Level II HCPCS Codes for Which We Are Soliciting Public Comments in the CY 2020 OPPS/ASC Final Rule With Comment Period

Consistent with past practice, we are soliciting comment on the new Level II HCPCS codes that are effective January 1, 2020 in the CY 2020 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 2020 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, these Level II HCPCS codes will be released to the public through the CY 2020 OPPS/ASC final rule with comment period, January 2020 ASC Update CR, and the CMS HCPCS website.

In addition, for CY 2020, we proposed to continue our established policy of assigning comment indicator ''NI'' in Addendum AA and Addendum BB to the CY 2020 OPPS/ASC final rule with comment period to the new Level II HCPCS codes that will be effective January 1, 2020 to indicate that we are assigning them an interim payment indicator, which is subject to public comment. We are inviting public comments in the CY 2020 OPPS/ASC final rule with comment period on the payment indicator assignments, which would then be finalized in the CY 2021 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 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 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 2020 OPPS update, we received the CPT codes that will be effective January 1, 2020 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 2020 OPPS/ASC proposed rule. We note that the new and revised CPT codes were assigned to comment indicator ''NP'' in Addendum AA and Addendum BB of the CY 2020 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 current calendar year with a proposed ASC payment 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 were short descriptors and did not accurately 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 2020 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 2020 OPPS/ASC Proposed Rule 5-Digit AMA Placeholder Code''. The final CPT code numbers are included in this CY 2020 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, 2020 that were received in time to be included in the CY 2020 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 2020 OPPS/ASC final rule with comment period. We note that we received comments on the ASC payment indicator for certain new CPT codes that will be effective January 1, 2020. These comments, and our responses, can be found in section XIII.C.1.a.(2). of this final rule with comment period.

Also, we note that we inadvertently omitted new CPT and new HCPCS codes effective January 1, 2020 from Table 32 (Proposed Additions to the List of ASC Covered Surgical Procedures for CY 2020) of the CY 2020 OPPS/ASC proposed rule (84 FR 39544), however, we included these 12 procedures in

Addendum AA to the proposed rule. The procedures described by the 12 new CPT and HCPCS codes are displayed in Table 53 of this CY 2020 OPPS/ASC final rule with comment period.

Finally, shown in Table 28 of the CY 2020 OPPS/ASC proposed rule (84 FR 39565) and reprinted in Table 53 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.

TABLE 53.—COMMENT AND FINALIZATION TIMEFRAMES FOR NEW AND REVISED HCPCS CODES

ASC Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 2019	HCPCS (CPT and Level II codes)	April 1, 2019	CY 2020 OPPS/ASC proposed rule	CY 2020 OPPS/ASC final rule with comment period
July 2019	HCPCS (CPT and Level II codes)	July 1, 2019	CY 2020 OPPS/ASC proposed rule	CY 2020 OPPS/ASC final rule with comment period
October 2019	HCPCS (CPT and Level II codes)	October 1, 2019	CY 2020 OPPS/ASC final rule with comment period	CY 2021 OPPS/ASC final rule with comment period
January 2020	CPT Codes	January 1, 2020	CY 2020 OPPS/ASC proposed rule	CY 2020 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2020	CY 2020 OPPS/ASC final rule with comment period	CY 2021 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 performed 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 2020 to Covered Surgical Procedures Designated as Office-Based

In developing the CY 2020 OPPS/ASC proposed rule, 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, including their potential designation as office-based.

We reviewed CY 2018 volume and utilization data and the clinical characteristics for all covered surgical procedures that are assigned payment indicator ''G2'' (Nonoffice-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) in CY 2018, as well as for those procedures assigned one of the temporary office-based payment indicators, specifically ''P2'', ''P3'', or ''R2'' in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59039 through 59040).

Our review of the CY 2018 volume and utilization data resulted in our identification of 9 covered surgical procedures that we believed met the criteria for designation as permanently office-based. We understood the data to indicate that these procedures are performed more than 50 percent of the time in physicians' offices, and we believed that the services are 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 2020 were listed in Table 29 of the CY 2020 OPPS/ASC proposed rule, which is reprinted below as Table 54.

TABLE 54.—ASC COVERED SURGICAL PROCEDURES THAT WERE PROPOSED TO BE NEWLY DESIGNATED AS PERMANENTLY OFFICE-BASED FOR CY 2020

CY 2020 CPT Code	CY 2020 Long Descriptor	CY 2019 ASC Payment Indicator	Proposed CY 2020 ASC Payment Indicator*
31298	Nasal/sinus endoscopy, surgical; with dilation of frontal and sphenoid sinus ostia (e.g., balloon dilation)	G2	P2*
31634	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, with assessment of air leak, with administration of occlusive substance (e.g., fibrin glue), if performed	G2	P3*
31647	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, when performed, assessment of air leak, airway sizing, and insertion of bronchial valve(s), initial lobe	G2	R2*
36465	Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; single incompetent extremity truncal vein (e.g., great saphenous vein, accessory saphenous vein)	G2	P2*
36466	Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; multiple incompetent truncal veins (e.g., great saphenous vein, accessory saphenous vein), same leg	G2	P2*
36482	Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (e.g., cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; first vein treated	G2	P3*

CY 2020 CPT Code	CY 2020 Long Descriptor	CY 2019 ASC Payment Indicator	Proposed CY 2020 ASC Payment Indicator*
50727	Revision of urinary-cutaneous anastomosis (any type urostomy)	G2	R2*
59414	Delivery of placenta (separate procedure)	G2	R2*
61880	Revision or removal of intracranial neurostimulator electrodes	G2	R2*

* 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 2020 PFS proposed rule.

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.

In reviewing the CY 2018 volume and utilization data for CPT code 36902 we determined that the procedure was performed more than 50 percent of the time in physicians' offices based on 2018 volume and utilization data.

However, the office-based utilization for CPT code 36902 has 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. As previously stated in the CY 2019 OPPS/ASC final rule (83 FR 59036), when we believe that the available data for our review process are inadequate to make a determination that a procedure should be office-based, we either make no change to the procedure's payment status or make the change on a temporary basis, and reevaluate our decision when more data become available for our next evaluation. 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 believe it may be premature to assign office-based payment status to CPT code 36902 at this time.

Therefore, for CY 2020, we did not propose to designate CPT code 36902 as an office-based procedure, but proposed to continue to assign CPT code 36902 a payment indicator of ''G2''—nonoffice-based surgical procedure paid based on OPPS relative weights.

The CY 2018 volume and utilization data for CPT code 36905 show the procedure was not performed more than 50 percent of the time in physicians' offices. Therefore, in the CY 2020 OPPS/ASC proposed rule, we did not propose to assign an office-based designation for CPT code 36905. Therefore the procedure will retain its payment indicator of ''G2''—non office-based surgical procedure based on OPPS relative weights.

The comments and our responses to the comment are set forth below.

Comment: Commenters supported our decision to refrain from proposing to designate CPT code 36902 as an office-based procedure and to continue to assign both CPT codes 36902 and 36905 a payment indicator of ''G2''—nonoffice-based surgical procedure paid based on OPPS relative weights.

Response: We thank commenters for their support of our proposal. After reviewing the public comments we received, we are finalizing our proposal to assign CPT code 36902 a payment indicator of ''G2''—nonoffice-based surgical procedure paid based on OPPS relative weights.

Comment: Some commenters suggested that CPT codes 31634, 31647, 50727, 59414, and 61880 should not be designated as office-based procedures and that the level of complexity is not consistent with other procedures performed routinely in physicians' offices

Response: We agree with the commenters. We inadvertently proposed to assign office-based designations to CPT codes 31634, 31647, 50727, 59414, and 61880. The volume and utilization data for these procedures do not suggest the procedures are performed more than 50 percent of the time in physicians' offices, and we do not believe that the services are of a level of complexity consistent with other procedures performed routinely in physicians' offices. Therefore, CPT codes 31634, 50727, 59414, 61880 are assigned payment indicators ''G2''—non office-based surgical procedure based on OPPS relative weights—for CY 2020. Additionally, as CPT code 31647 exceeds our device offset percentage threshold of 30 percent for device-intensive designation, we are assigning this procedure a payment indicator of ''J8''—device-intensive procedure; paid at adjusted rate—for CY 2020. These procedures and their assigned payment indicators can be found in Addendum AA to the CY 2020 OPPS/ASC final rule with comment period (which is available via the internet on the CMS website).

After consideration of the public comments we received, we are finalizing our proposal with modification, to designate the four ASC covered surgical procedures in Table 55 as permanently office-based for CY 2020 and subsequent years.

TABLE 55.—ASC COVERED SURGICAL PROCEDURES TO BE NEWLY DESIGNATED AS PERMANENTLY OFFICE-BASED FOR CY 2020

CY 2020 CPT Code	CY 2020 Long Descriptor	CY 2019 ASC Payment Indicator	CY 2020 ASC Payment Indicator*
31298	Nasal/sinus endoscopy, surgical; with dilation of frontal and sphenoid sinus ostia (e.g., balloon dilation)	G2	P2*
36465	Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; single incompetent extremity truncal vein (e.g., great saphenous vein, accessory saphenous vein)	G2	P2*
36466	Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; multiple incompetent truncal veins (e.g., great saphenous vein, accessory saphenous vein), same leg	G2	P2*
36482	Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (e.g., cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; first vein treated	G2	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 2020 PFS final rule.

We also reviewed CY 2018 volume and utilization data and other information for 12 procedures designated as temporarily office-based in Tables 57 and 58 in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59039 through 59040). Of these 12 procedures, there were very few claims in our data and no claims data for 11 procedures described by CPT codes 10005, 10007, 10009, 10011, 11102, 11104, 11106, 65785, 67229, 0402T and 0512T. Consequently, we proposed to maintain the temporary office-based designations for these 11 CPT codes for CY 2020. The procedures for which the proposed office-based designations for CY 2020 are temporary are also indicated by asterisks in Addendum AA to the proposed and final rule (which are available via the internet on the CMS website).

The volume and utilization data for the one remaining procedure that has a temporary office-based designation for CY 2019, described by CPT code 38222 (Diagnostic bone marrow; biopsy(ies) and aspiration(s)), are sufficient to indicate that this covered surgical procedures was not performed predominantly in physicians' offices and, therefore, we proposed to assign a nonoffice-based payment indicator—''G2''—to this code for CY 2020.

We did not receive any public comments on our proposal. Therefore, we are finalizing our proposal, without modification, to designate the procedures shown in Table 56 below as temporarily office-based. The procedures for which the office-based designation for CY 2020 is temporary are indicated by an asterisk in Addendum AA to this final rule with comment period (which is available via the internet on the CMS website).

TABLE 56.— CY 2020 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED IN THE CY 2019 OPPS/ASC FINAL RULE WITH COMMENT PERIOD

CY 2020 CPT/HCPCS Code	CY 2020 Long Descriptor	CY 2019 ASC Payment Indicator	CY 2020 ASC Payment Indicator*
10005	Fine needle aspiration biopsy, including ultrasound guidance; first lesion	P3	P3*
10007	Fine needle aspiration biopsy, including fluoroscopic guidance; first lesion	P3	P3*
10009	Fine needle aspiration biopsy, including CT guidance; first lesion	P2	P2*
10011	Fine needle aspiration biopsy, including MR guidance; first lesion	R2	R2*
11102	Tangential biopsy of skin (e.g., shave, scoop, saucerize, curette); single lesion	P3	P3*
11104	Punch biopsy of skin (including simple closure, when performed); single lesion	P2	P2*
11106	Incisional biopsy of skin (e.g., wedge) (including simple closure, when performed); single lesion	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 (e.g., retinopathy of prematurity), photocoagulation or cryotherapy	R2	R2*

CY 2020 CPT/HCPCS Code	CY 2020 Long Descriptor	CY 2019 ASC Payment Indicator	CY 2020 ASC Payment Indicator*
0402T	Collagen cross-linking of cornea (including removal of the corneal epithelium and intraoperative pachymetry when performed)	R2	R2*
0512T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound	R2	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 2020 PFS final rule.

For CY 2020, we proposed to designate 7 new CY 2020 CPT codes for ASC covered surgical procedures as temporarily office-based, as displayed in Table P31X. After reviewing the clinical characteristics, utilization, and volume of related procedure codes, we determined that the procedures in Table 30 of the CY 2020 OPPS/ASC proposed rule described by the new CPT codes would be predominantly performed in physicians' offices. We stated that we believed the procedure described by CPT codes 93X00 (Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete bilateral study) and 93X01 (Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete unilateral study) was clinically similar to HCPCS code G0365 (Vessel mapping of vessels for hemodialysis access (services for preoperative vessel mapping prior to creation of hemodialysis access using an autogenous hemodialysis conduit, including arterial inflow and venous outflow)), which is currently on the list of covered surgical procedures and assigned a proposed payment indicator ''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—for CY 2020. As such, we proposed to add CPT codes 93X00 and 93X01 in Table 30 of the CY 2020 OPPS/ASC proposed rule to the list of temporarily office-based covered surgical procedures.

Because we have no utilization data for the procedures specifically described by these new CPT codes, we proposed to make the office-based designation temporary rather than permanent, and we will reevaluate the procedures when data become available. The procedures for which the proposed office-based designation for CY 2020 is temporary are indicated by asterisks in Addendum AA to the CY 2020 OPPS/ASC proposed rule (which is available via the internet on the CMS website).

We did not receive any public comments on our proposal. Therefore, we are finalizing our proposal, without modification, to designate the procedures shown in Table 57 below as temporarily office-based. The procedures for which the office-based designation for CY 2020 is temporary are indicated by an asterisk in Addendum AA to this final rule with comment period (which is available via the internet on the CMS website).

TABLE 57.— CY 2020 PAYMENT INDICATORS FOR NEW CY 2020 CPT CODES FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED

CY 2020 CPT Code	CY2020 OPPS/ASC proposed rule 5-digit CMS placeholder code	CY 2020 Long Descriptor	CY 2020 ASC Payment Indicator**
64454	64XX0	Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed	P3**
64624	64XX1	Destruction by neurolytic agent, genicular nerve branches, including imaging guidance, when performed	P3**
93985	93X00	Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete bilateral study	P2**
93986	93X01	Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete unilateral study	P2**
0551T		Transperineal periurethral balloon continence device; adjustment of balloon(s) fluid volume	R2**
0566T	05X4T	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	0X71T	Revision or removal of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming,	R2**

CY 2020 CPT Code	CY2020 OPPS/ASC proposed rule 5-digit CMS placeholder code	CY 2020 Long Descriptor	CY 2020 ASC Payment Indicator**
		and imaging guidance when performed, posterior tibial nerve	

**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 MPFS rates, we refer readers to the CY 2020 PFS proposed rule.

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 2020

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 involving 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 2020, 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 2020, are assigned payment indicator ''J8'' and are included in ASC Addendum AA to the CY 2020 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 2020 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). In addition, we note that in our CY 2019 OPPS/ASC proposed rule (83 FR 37158 through 37159), we proposed to apply our device-intensive procedure payment methodology to device-intensive procedures under the ASC payment system only when the device-intensive procedure is furnished with a surgically-inserted or implanted device (including single-used medical devices). We inadvertently omitted language finalizing this policy for CY 2019. For CY 2020 and subsequent calendar years, we proposed to only apply our device-intensive procedure payment methodology to device-intensive procedures under the ASC payment system when the device-intensive procedure is furnished with a surgically

inserted or implanted device (including single use medical devices). The payment rate under the ASC payment system for device-intensive procedures furnished with an implantable or inserted medical device would be calculated by applying the device offset percentage based on the standard OPPS APC ratesetting methodology to the OPPS national unadjusted payment 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 revised ASC payment system. (82 FR 59409)

The comments and our responses to the comments are set forth below.

Comment: Commenters continued to support the policy we implemented last year to lower the device offset percentage threshold to 30 percent for purposes of designating device-intensive procedures.

Response: We thank commenters for their support.

Comment: Some commenters requested that device implants, which we interpret to mean surgically inserted or implanted, single-use devices, be included in ASC payment at invoice price based on manufacturer reported pricing or at device pass-through payment as described in section IV.A of this final rule with comment period so that the payment rate for these device-intensive procedures would more appropriately reflect the cost of care and encourage migration from the more expensive hospital setting to the ASC setting.

Response: We thank the commenters for their recommendation. As discussed in this section, the ASC payment rate for surgical procedures includes payment for device costs, which are packaged into the procedure payment. For device-intensive procedures and procedures using pass-through devices, the device portion is held equal to the device portion under the OPPS using the standard ratesetting methodology. We believe this methodology provides consistency with device-intensive policies under the OPPS and provides an appropriate payment for the device costs for device-intensive procedures in the ASC setting.

Comment: Some commenters stated that we calculate the device portions of a service in two ways. The first, using the device offset from APC payment rates developed under the comprehensive ratesetting methodology, and, the second using the device offset from the APC payment rates developed under the standard (non-comprehensive) ratesetting methodology. Commenters requested that we designate device-intensive procedures using only our standard (non-comprehensive) ratesetting methodology for determining whether the cost of a device exceeds our device-intensive threshold of 30 percent as they believed that method is more consistent with the overall ASC payment system.

Response: As we stated in the CY 2015 OPPS/ASC final rule with comment period (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. ''Device-intensive'' 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. The device offset percentage for device-intensive procedures under the OPPS are based on the comprehensive ratesetting methodology. However, 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 exceeds the 30 percent threshold as calculated using our standard ratesetting methodology as stated in 42 CFR 416.171(b)(2). Additionally, for purposes of the ASC payment system, the device amount is calculated by applying the device offset percentage calculated under our standard ratesetting methodology to the APC payment weights calculated under our standard ratesetting methodology.

Comment: One commenter requested that we re-evaluate the device-intensive designation for CPT code 22869 (Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level). The commenter stated the ASC payment rate was too low to reflect the cost of the device in ASCs in California, and, therefore, the device offset should be increased.

Response: After reviewing the most recently available claims data for the CY 2020 OPPS/ASC final rule with comment period, CPT code 22869 has a device offset percentage of 74.0 percent and a device offset amount of $8,383.12. The offset percentage increased by 2.9 percentage points from 71.1 percent in the CY 2020 OPPS/ASC proposed rule and the device offset amount increased by 3.0 percent from $8,141.12. We note that device cost information for CPT code 22869 has only been available from CY 2017 claims (for CY 2019 ratesetting) and CY 2018 claims (for CY 2020 ratesetting) and therefore we are unable to draw any historical comparisons to determine if the CY 2020 device offset is inconsistent with historical device offsets for this procedure. For this CY 2020 OPPS/ASC final rule with comment period, the device cost of $8,383.12 for CPT code 22869 is based on 372 claims and we believe represents our best estimate of the cost of devices for performing the surgical procedure in CY 2020. Further, we note that 50 percent of the final ASC payment rate (both the device portion and non-device portion) is adjusted by the ASC wage index to reflect variation in labor costs. We believe the ASC payment rate for CPT code 22869 provides an appropriate payment for both device and non-device costs for facilities in all areas of the country.

Comment: One commenter requested that CPT code 50590 (Lithotripsy, extracorporeal shock wave) be assigned device-intensive status.

Response: We thank the commenter for its request. Based on the most recently available claims data for this CY 2020 OPPS/ASC final rule with comment period, the device offset percentage for CPT code 50590 continues to be below the 30 percent threshold and, therefore, is ineligible to be assigned device-intensive status.

c. Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices

Our ASC payment policy for costly devices implanted in ASCs at no cost/full credit or partial credit, as set forth in § 416.179 of our regulations, is consistent with the OPPS policy that was in effect until CY 2014. Specifically, the OPPS policy that was in effect through CY 2013 provided a reduction in 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 (77 FR 68356 through 68358). The established ASC policy reduces payment to ASCs when a specified device is furnished without cost or with full credit or partial credit for the cost of the device for those ASC covered surgical procedures that are assigned to APCs under the OPPS to which this policy applies. We refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68742 through 68744) for a full discussion of the ASC payment adjustment policy for no cost/full credit and partial credit devices.

In the CY 2019 OPPS/ASC proposed rule (83 FR 37159), we noted that, as discussed in section IV.B. of the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005 through 75006), we finalized our proposal to modify our former policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. Formerly, under the OPPS, our policy was to reduce OPPS payment by 100 percent of the device offset amount when a hospital furnished a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital received partial credit in the amount of 50 percent or more (but less than 100 percent) of the cost for the specified device. For CY 2014, we finalized our proposal to reduce OPPS payment for applicable APCs by the full or partial credit a provider receives for a replaced 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.

All ASC covered device-intensive 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 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 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.

In the CY 2019 OPPS/ASC final rule with comment period (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 replacement 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 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 replacement 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 2020 OPPS/ASC proposed rule, we did not propose any changes to these policies and we are finalizing continuing our existing policies for CY 2020.

d. Additions to the List of ASC Covered Surgical Procedures

(1) Additions to the List of ASC Covered Surgical Procedures for CY 2020

As finalized in section XII.A.3. of the CY 2019 OPPS/ASC final rule with comment period (83 FR 59029 through 59030), we revised our definition of ''surgery'' for CY 2019 to include certain ''surgery-like'' procedures that are assigned codes outside the CPT surgical range. For CY 2020 and subsequent years we proposed to adopt the modified definition we finalized for CY 2019, to include procedures that are described by Category I CPT codes that are not in the surgical range but directly crosswalk or are clinically similar to procedures in the Category I CPT code surgical range 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 also proposed to continue to include in our definition of surgical procedures those procedures 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.

We conducted a review of HCPCS codes that currently are paid under the OPPS, but not included on the ASC CPL, and that meet our proposed definition of surgery to determine if changes in technology or medical practice affected the clinical appropriateness of these procedures for the ASC setting. Based on this review, we proposed to update the list of ASC covered surgical procedures by adding total knee arthroplasty, a knee mosaicplasty procedure and three coronary intervention procedures (as well as the three associated add-on codes for the coronary intervention procedures) to the list for CY 2020, as was shown in Table 32 of the CY 2020 OPPS/ASC proposed rule. After

reviewing the clinical characteristics of these procedures and consulting with stakeholders and our clinical advisors, we determined that these eight procedures 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. The regulations at § 416.166(c) list general exclusions from the list of ASC covered surgical procedures based primarily on factors relating to safety, including procedures that generally result in extensive blood loss, require major or prolonged invasion of body cavities, or directly involve major blood vessels. We assessed each of the proposed added procedures against the regulatory safety criteria and determined that these procedures meet each of the criteria. Although the proposed coronary intervention procedures may involve blood vessels that could be considered major, as stated in the August 2, 2007 ASC final rule (72 FR 42481), we believe the involvement of major blood vessels is best considered in the context of the clinical characteristics of individual procedures, and we do not believe that it is logically or clinically consistent to exclude certain cardiac procedures from the list of ASC covered surgical procedures on the basis of the involvement of major blood vessels, yet continue to provide ASC payment for similar procedures involving major blood vessels that have a history of safe performance in ASCs, such as CPT code 36473 (Mechanicochemical destruction of insufficient vein of arm or leg, accessed through the skin using imaging guidance) and CPT code 37223 (Insertion of stents into groin artery, endovascular, accessed through the skin or open procedure). 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 these procedures can be safely performed in an ASC. Therefore, we proposed to include these three coronary intervention procedures on the list of ASC covered surgical procedures for CY 2020. We also proposed to add their respective add-on procedures which are packaged under the ASC payment system.

In the CY 2018 OPPS/ASC proposed rule, we solicited public comments on whether the total knee arthroplasty (TKA) procedure, CPT code 27447 (Arthroplasty, knee, condyle and plateau; medial and lateral compartments with or without patella resurfacing (total knee arthroplasty)), should be added to the ASC CPL. In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59411 through 59412) we noted that some commenters stated that many ASCs are equipped to perform these procedures and orthopedic surgeons in ASCs are increasingly performing these procedures safely and effectively on non-Medicare patients and appropriate Medicare patients. However, other commenters noted that the majority of ASCs were not well-equipped to safely perform TKA procedures on patients and that the majority of Medicare patients are not suitable candidates to receive joint arthroplasty procedures in an ASC setting. For CY 2018, we did not finalize adding TKA to the ASC covered surgical procedures list, but noted that we would take the suggestions and recommendations into consideration for future rulemaking.

In this CY 2020 OPPS/ASC final rule, we continue to promote site-neutrality, where possible, between the hospital outpatient department and ASC settings. Further, we agree with commenters that there is a small subset of Medicare beneficiaries who may be suitable candidates to receive TKA procedures in an ASC setting based on their clinical characteristics. For example, based on Medicare Advantage encounter data, we estimate over 800 TKA procedures were performed in an ASC on Medicare Advantage enrollees in 2016. We believe that beneficiaries not enrolled in an MA plan should also have the option of choosing to receive the TKA procedure in an ASC setting based on their physicians' determinations.

As we stated in the August 2, 2007 final rule (72 FR 42483 through 42484), we exclude procedures that would otherwise pose a significant safety risk to the typical Medicare beneficiary. However, we believe physicians should continue to play an important role in exercising their clinical judgment when making site-of-service determinations, including for TKA. In light of the information commenters submitted in support of adding TKA to the ASC CPL in response to our CY 2018 public comment solicitation, we proposed to add TKA to the ASC CPL in CY 2020.

We note that TKA procedures were still predominantly performed in the inpatient hospital setting in CY 2018 (82 percent of the time) based on professional claims data, and we are cognizant of the fact that the majority of beneficiaries may not be suitable candidates to receive TKA in an ASC setting. We believe that appropriate limits are necessary to ensure that Medicare Part B payment will only be made for TKA procedures performed in the ASC setting when that setting is clinically appropriate. Therefore, we solicited public comment on the appropriate approach to provide safeguards for Medicare beneficiaries who should not receive the TKA procedure in an ASC setting. Specifically, we solicited public comment on methods to ensure beneficiaries receive surgical procedures in the ASC setting only as clinically appropriate. For instance, we stated that CMS could issue a new modifier that indicates the physician believes that the beneficiary would not be expected to require active medical monitoring and care at midnight following a particular procedure furnished in the ASC setting. CMS could require that such a modifier be included on the claims line for a surgical procedure performed in an ASC. Alternatively, given the importance of post-operative care in making determinations about whether the ASC is an appropriate setting for a procedure, CMS could require that an ASC has a defined plan of care for each beneficiary following a surgical procedure. We also stated that we could establish certain requirements for ASCs that choose to perform certain surgical procedures on Medicare patients, such as requiring an ASC to have a certain amount of experience in performing a procedure before being eligible for payment for performing the procedure under Medicare. We solicited comment on these options, and other options, for ensuring that beneficiaries receive surgical procedures, including TKA, that do not pose a significant safety risk when performed in an ASC.

In light of the information we received from commenters in support of adding TKA to the ASC CPL in response to our comment solicitation in the CY 2018 OPPS/ASC proposed rule, we stated our belief that TKA would meet our regulatory requirements established under §§ 416.2 and 416.166(b) for covered surgical procedures in the ASC setting. Therefore, we proposed to add TKA to the ASC CPL as shown in Table 32 in the CY 2020 OPPS/ASC proposed rule. At that time we stated our intent to consider appropriate safeguards and limitations for surgical procedures furnished in the ASC setting based on public comments we receive.

As we stated in the CY 2019 OPPS/ASC proposed rule (83 FR 59054 through 59055), 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 can be safely performed in an ASC, and to

review and update the ASC covered surgical procedures list at least every 2 years.

We also solicited comment on how CMS should think about the role of the ASC CPL compared to state regulations and market forces in providing payment for certain surgical procedures in an ASC and whether any modifications should be made to the ASC CPL. Comments on this topic could help formulate the basis for future policy development regarding how we determine what procedures are payable for Medicare fee-for-service beneficiaries in the ASC setting and maintain the balance between safety and access. Finally, we solicited comment on how our proposed additions to the list of ASC covered surgical procedures might affect rural hospitals to the extent rural hospitals rely on providing such procedures.

The comments and our responses to the comments are set forth below.

Comment: Many commenters supported our proposal to add three coronary intervention procedures as well as the additional three procedures that represented their associated add-on procedures to the ASC CPL. They stated that our proposed additions meet our criteria to be included on the ASC CPL and that claims analyses, clinical trials, expert consensus and clinical guidelines, among other materials supported the inclusion of such coronary intervention procedures on the ASC CPL. Further, many ASC commenters contended that ASCs are well-equipped to safely perform these procedures on Medicare beneficiaries. However, some commenters stated that without defined criteria for risk stratification, beneficiaries would be exposed to significant risk if these procedures were added to the ASC CPL. Additionally, some commenters believed the percutaneous coronary intervention procedures should be performed in a hospital setting where there is an available on-site cardiac surgical backup and intensive care unit in the event of an emergency.

Response: We thank the commenters for their support. We assessed each of the procedures we proposed to add to the ASC CPL against the regulatory safety criteria and determined that these procedures meet each of the criteria. Although the proposed coronary intervention procedures may involve blood vessels that could be considered major, as stated in the August 2, 2007 ASC final rule (72 FR 42481), we believe the involvement of major blood vessels is best considered in the context of the clinical characteristics of individual procedures. We do not believe that it is appropriate to exclude certain cardiac procedures from the list of ASC covered surgical procedures because they involve major blood vessels, yet continue to provide ASC payment for similar procedures involving major blood vessels that have a history of safe performance in ASCs, such as CPT code 36473 (Mechanicochemical destruction of insufficient vein of arm or leg, accessed through the skin using imaging guidance) and CPT code 37223 (Insertion of stents into groin artery, endovascular, accessed through the skin or open procedure). 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 these three coronary intervention procedures (CPT codes 92920, 92928, and HCPCS code C9600) and three associated add-on procedures (CPT code 92921, 92929, and HCPCS code C9601) can be safely performed in the ASC setting, for certain Medicare patients and note that the physician should determine whether a particular case would be a good candidate to be furnished in the ASC setting rather than the hospital setting based on the clinical assessment of the patient. We agree with commenters who stated that expert consensus, clinical guidelines, and clinical studies establish that percutaneous coronary interventions can be safely performed in an ASC setting. While we acknowledge that a majority of Medicare beneficiaries may not be suitable candidates to receive these procedures in an ASC setting due to factors such as age and comorbidities, we believe it is important to make these procedures payable in the ASC setting, in order to ensure access to these coronary intervention procedures for those beneficiaries who are appropriate candidates to receive them in an ASC setting.

Therefore, in this final rule with comment period, we are finalizing our proposal without modification to add three coronary intervention procedures as well as three associated add-on procedures. These procedures are:

- CPT code 92920 (Percutaneous transluminal coronary angioplasty; single major coronary artery or branch),
- CPT code 92921 (Percutaneous transluminal coronary angioplasty; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)),
- CPT code 92928 (Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch),
- CPT code 92929 (Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)),
- CPT code C9600 (Percutaneous transcatheter placement of drug eluting intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch), and
- CPT code C9601 (Percutaneous transcatheter placement of drug-eluting intracoronary stent(s), with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)) to the ASC CPL.

Comment: Many commenters supported our proposal to add TKA to the ASC CPL for CY 2020 and subsequent years.

Response: We thank commenters for their support of our proposal.

Comment: One commenter requested that we delay adding TKA to the ASC CPL until more data can be collected on the impact of case-mix and patient populations for participants in the CMS Innovation Center's Bundled Payments for Care Improvement Initiative.

Response: We believe there are a small number of less medically complex TKA patients that could appropriately receive TKA in an ASC setting. Because we believe this group will be small, we do not believe our proposal would have a substantial impact on the patient-mix for the Bundled Payments for Care Improvement Advanced (BPCI Advanced) or the Initiative and Comprehensive Care Joint Replacement (CJR) models. Therefore, we do not believe any delay in the implementation of our proposed addition to the ASC CPL is warranted.

Comment: Some commenters opposed our proposal to add TKA to the ASC CPL. These commenters stated that the Medicare population would not be suitable candidates to receive TKA in an ASC setting and that complications arising from TKA could be devastating and life-threatening if not performed in a hospital setting. Specifically, patients could be at risk for the development of deep vein thrombosis with the potential to propagate lethal pulmonary embolus, anesthesia-related risks, as well as other risks. Some commenters also noted that CMS eliminated the requirement that ASCs have a written transfer agreement with a nearby hospital and the requirement that their physicians have admitting privileges at a hospital. Further, some commenters noted that in the absence of the physician self-referral law, which does not apply to

procedures performed in an ASC, there will be no other safeguard against a physician's profitable, but clinically inappropriate, referral to an ASC in which the physician has an ownership interest.

Response: We agree with commenters that the majority of Medicare beneficiaries would not be suitable candidates to receive TKA procedures in an ASC setting. Factors such as age, comorbidity, and body mass index are among the many factors that must be taken into account to determine if performing a TKA procedure in an ASC would be appropriate for a particular Medicare beneficiary. However, we believe there are a small number of less medically complex beneficiaries that could appropriately receive the TKA procedure in an ASC setting and we believe physicians should continue to play an important role in exercising their clinical judgment when making site-of-service determinations, including for TKA. While we acknowledge that the physician self-referral law does not apply to TKA performed in an ASC, physicians should be aware of other Federal and state laws that may potentially limit this activity, such as the Anti-Kickback Statute.

Comment: Commenters also noted that beneficiary coinsurance for TKA procedures could be higher in the ASC setting and therefore did not support our proposal, or recommended that we notify beneficiaries that the coinsurance for a TKA procedure could be lower in a hospital outpatient setting.

Response: We are aware that beneficiaries may incur greater cost-sharing for TKA procedures in an ASC setting under our proposal. However, this would not be an occurrence that is unique to TKA. Section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure paid under the OPPS (including items such as drugs and biologicals) performed in a year to the amount of the inpatient hospital deductible for that year. We note that this section of the Act does not apply to the ASC payment system. Rather, ASC cost-sharing is described by 1833(a)(4) of the Act and there may be instances where beneficiary cost-sharing in an ASC may be higher than beneficiary cost-sharing in a hospital outpatient department for the same procedure. We note that the ASC payment rate for a TKA procedure is $8,609.17 for CY 2020 while the CY 2020 OPPS payment rate is $11,899.39. This means that ASC coinsurance would be $1,721.83 while hospital OPPS coinsurance would have been $2,379.88, but for the statutory cap limiting it to the inpatient deductible amount ($1,364 in CY 2019). However, the payment rates are publicly available and despite the higher cost-sharing, some beneficiaries, especially those with supplemental insurance, may still choose to have their procedure performed in the ASC setting.

In addition, 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) 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 allows beneficiaries to be informed of potential cost-sharing amounts and therefore mitigates the commenters' concern about providing payment for procedures in an ASC setting even if the beneficiary cost-sharing in an ASC would be greater than in the hospital outpatient department setting.

Comment: Some commenters suggested that CMS work closely with specialty societies regarding best practices and any appropriate limitations or conditions for Medicare Part B payment for TKA in the ASC setting. Other commenters stated that our suggestions, such as requiring a modifier or a plan of care, were unnecessary and would increase administrative burden by complicating the processes for scheduling, performing and billing for ASCs, without improving beneficiary safety because physicians are best-equipped to determine the clinical appropriateness of the site of service for their patients. Some commenters did not support our suggested approaches and believed that such requirements would be superfluous and provide no beneficial oversight to ensure patient safety. Two orthopedic specialty societies supported the concept of having defined plans of care for each beneficiary following a surgical procedure. One orthopedic specialty society requested that we re-establish the requirement that ASCs have formal arrangements with a nearby hospital in case a patient is unable to go home following a procedure. Other commenters suggested that a defined plan of care requirement is already an existing Condition for Coverage for ASCs.

Response: We agree with commenters that ASCs are currently required to follow the discharge protocols following a surgical procedure, as set out at 42 CFR 416.52(c). For example, our regulations require that each patient be provided written discharge instructions and overnight supplies; prescription and physician contact information; and post-operative instructions; and that patients be discharged in the company of a responsible adult, except those patients exempted by the attending physician.

We remind ASCs that beneficiaries should receive discharge care instructions that meet our requirements following a TKA procedure as well as other surgical procedures. ASCs should also review our State Operations Manual for further guidance on this condition for coverage, as well as others.

With respect to reinstating the requirement that ASCs have a formal transfer agreement with a nearby hospital, we note that such issue is related to Conditions for Coverage and is outside the scope of this final rule with comment.

After considering the public comments we received, and in response to commenters' support for this proposal, we are finalizing our proposal without modification to add TKA, CPT code 27447 (Arthroplasty, knee, condyle and plateau; medial and lateral compartments with or without patella resurfacing (total knee arthroplasty)), to the ASC CPL for CY 2020 and subsequent years.

Based on the public comments we received, we are not finalizing any of the additional requirements on which we sought comment, such as adding a modifier or requiring an ASC to have a certain amount of experience in performing a procedure before being eligible for payment for performing the procedure under Medicare.

Comment: Commenters who responded to the CY 2020 OPPS/ASC proposed rule also requested that CMS add several additional procedures to the ASC CPL, which we had not proposed to add to the ASC CPL in the CY 2020 OPPS/ASC proposed rule. These additional procedures are listed in Table 58.

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TABLE 58.— PROCEDURES REQUESTED BY COMMENTERS FOR ADDITION TO THE CY 2020 LIST OF ASC COVERED SURGICAL PROCEDURES

CY 2020 CPT Code	CY 2020 Long Descriptor
27412	Autologous chondrocyte implantation, knee
57267	Insertion of mesh or other prosthesis for repair of pelvic floor defect, each site (anterior, posterior compartment), vaginal approach (list separately in addition to code for primary procedure)
57282	Colpopexy, vaginal; extra-peritoneal approach (sacrospinous, iliococcygeus)
57283	Colpopexy, vaginal; intra-peritoneal approach (uterosacral, levator myorrhaphy)
57425	Laparoscopy, surgical, colpopexy (suspension of vaginal apex)
62290	Injection procedure for discography, each level; lumbar
62291	Injection procedure for discography, each level; cervical or thoracic
62365	Removal of subcutaneous reservoir or pump, previously implanted for intrathecal or epidural infusion
62367	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); without reprogramming or refill
62368	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming
92960	Cardioversion, elective, electrical conversion of arrhythmia; external
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)
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)

CY 2020 CPT Code	CY 2020 Long Descriptor
93312	Echocardiography, transesophageal, real-time with image documentation (2d) (with or without m-mode recording); including probe placement, image acquisition, interpretation and report
93313	Echocardiography, transesophageal, real-time with image documentation (2d) (with or without m-mode recording); placement of transesophageal probe only
93315	Transesophageal echocardiography for congenital cardiac anomalies; including probe placement, image acquisition, interpretation and report
93463	Pharmacologic agent administration (eg, inhaled nitric oxide, intravenous infusion of nitroprusside, dobutamine, milrinone, or other agent) including assessing hemodynamic measurements before, during, after and repeat pharmacologic agent administration, when performed (list separately in addition to code for primary procedure)
93530	Right heart catheterization, for congenital cardiac anomalies
93531	Combined right heart catheterization and retrograde left heart catheterization, for congenital cardiac anomalies
93563	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective coronary angiography during congenital heart catheterization (list separately in addition to code for primary procedure)
93564	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective opacification of aortocoronary venous or arterial bypass graft(s) (eg, aortocoronary saphenous vein, free radial artery, or free mammary artery graft) to one or more coronary arteries and in situ arterial conduits (eg, internal mammary), whether native or used for bypass to one or more coronary arteries during congenital heart catheterization, when performed (list separately in addition to code for primary procedure)
93565	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective left ventricular or left atrial angiography (list separately in addition to code for primary procedure)
93566	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective right ventricular or right atrial angiography (list separately in addition to code for primary procedure)

CY 2020 CPT Code	CY 2020 Long Descriptor
93567	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for supravalvular aortography (list separately in addition to code for primary procedure)
93568	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for pulmonary angiography (list separately in addition to code for primary procedure)
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)

Response: We appreciate the commenters' recommendations. We reviewed all of the services that commenters requested that we add to the ASC CPL. Of these procedures, we did not consider procedures that are unconditionally packaged under the OPPS (identified by status indicator ''N'' in addendum B of this final rule with comment period) as such procedures would not meet our requirement for ASC covered surgical procedures at § 416.166(b) that the procedure be separately paid under the OPPS.

Of the procedures listed in Table 58, CPT codes 57267, 62290, 62291, 92938, 92973, 92978, 92979, 93463, 93563, 93564, 93565, 93566, 93567, 93568, 93571, 93572, and C9605 are unconditionally packaged under the ASC payment system. For the procedures identified by CPT codes 92960, 93312, 93313, 93315, and 93530, we do not believe these procedures meet our criteria as established under § 416.166(b) and would pose a significant safety risk to beneficiaries if performed in an ASC setting. For the procedures identified by CPT codes 27412, 57282, 57283, 57425, 62365, 62367, and 62368, we will continue to review whether these procedures meet the criteria to be added to the ASC CPL and take commenters input into consideration in future rulemaking.

(2) Comment Solicitation on Coronary Intervention Procedures

For CY 2020, as discussed above, we proposed to add three coronary intervention procedures (along with the codes describing their respective add-on procedures) that involve major blood vessels that we believe can be safely performed in an ASC setting and would not pose a significant safety risk to beneficiaries if performed in an ASC setting. In the CY 2020 OPPS/ASC proposed rule, in addition to the three coronary intervention procedures (and their three add-on codes) we proposed to add to the ASC CPL, we also reviewed several other coronary intervention procedures. While we did not believe the procedures included in Table P33 of the CY 2020 OPPS/ASC proposed rule met our criteria for inclusion on the ASC CPL at that time, and we did not propose to add such procedures to the ASC CPL for CY 2020, we solicited public comments on whether stakeholders believe these procedures can be safely performed in an ASC setting. Additionally, we requested that commenters provide any materials supporting their position, in particular information and data that specifically address the requirements in our regulations at §§ 416.2 and 416.166 (84 FR 39544). For example, we requested that commenters provide information that supports their position as to whether each of these procedures would be expected to pose a significant risk to beneficiary safety when performed in an ASC, whether standard medical practice dictates that the beneficiary would typically be expected to require active medical monitoring and care at midnight following the procedure (''overnight stay''), and whether the procedure would fall under our general exclusions for covered surgical procedures at § 416.166(c) (for example, would it generally result in extensive blood loss). We stated that we would consider public comments we receive in future rulemaking cycles.

TABLE 59.— PROCEDURES ON WHICH WE REQUESTED COMMENT FOR ADDITION TO THE ASC LIST OF COVERED SURGICAL PROCEDURES

CY 2020 CPT Code	CY 2020 Long Descriptor
92924	Percutaneous transluminal coronary atherectomy, with coronary angioplasty when performed; single major coronary artery or branch
92925	Percutaneous transluminal coronary atherectomy, with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)
92933	Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch
92934	Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)
92937	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of intracoronary stent, atherectomy and angioplasty, including distal protection when performed; single vessel
92938	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of 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)
92943	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; single vessel

CY 2020 CPT Code	CY 2020 Long Descriptor
92944	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; each additional coronary artery, coronary artery branch, or bypass graft (list separately in addition to code for primary procedure)
92973	Percutaneous transluminal coronary thrombectomy mechanical (list separately in addition to code for primary procedure)
C9602	Percutaneous transluminal coronary atherectomy, with drug eluting intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch
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
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)
C9607	PCI of chronic total occlusion, any method(s), with drug-eluting stent
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 corona

Comment: Some commenters supported adding all of the procedures listed in Table 33 of the CY 2020 OPPS/ASC proposed rule. Other commenters recommended adding CPT codes 92937, 92938, 92973, C9604, and C9605. These commenters stated these percutaneous transluminal revascularization procedures through coronary artery bypass graft meet our established criteria for addition to the ASC CPL and that claims data, clinical trials, and clinical guidelines support their addition.

Other commenters did not support adding any of the procedures list in Table 59 as listed above. The commenters stated that these procedures often carry the risk of serious possible complications, such as in-facility death, damage to or perforations of coronary arteries, and intramural hematoma, among others. Therefore, commenters indicated, such procedures should only be performed in hospital settings that include rapid access to on-site cardiac surgery as well as intensive care units.

Response: We appreciate the commenters' feedback and recommendations. Additionally, we note that we had the incorrect long descriptor for CPT 92973 displayed in our CY 2020 OPPS/ASC proposed rule. In the proposed rule, we had the long descriptor as ''Percutaneous transcatheter placement of drug eluting intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch.'' The correct long descriptor for CPT 92973 should be ''Percutaneous transluminal coronary thrombectomy mechanical (list separately in addition to code for primary procedure)'' and is displayed in Table 59 of this final rule with comment period.

Based on the public comments we received, we believe the procedures listed in Table 59 would expose beneficiaries to significant safety risk if performed in an ASC setting at this time and would not meet our criteria established under § 416.166(b). Specifically, we believe that transluminal revascularization of a bypass graft carries an inherent higher risk of complication and may require the assistance of on-site cardiac surgical backup. Additionally, we believe atherectomy procedures carry a greater risk of complication than coronary intervention procedures without an atherectomy procedure. Therefore, at this time, we believe that adding any of the procedures identified in Table 59 of this final rule with comment period to the ASC CPL would expose

beneficiaries to significant risk. We believe that such procedures should be performed in a hospital setting with an immediate response available in case of emergencies.

We received no comments on our proposal to add CPT code 29867 (Arthroscopy, knee, surgical; osteochondral allograft (for example, mosaicplasty)) to the ASC CPL for CY 2020 and subsequent years.

After consideration of the public comments we received, we are finalizing our proposal without modification to add CPT codes: 27447, 29867, 92920, 92921, 92928, 92929, and HCPCS codes C9600 and C9601 to the ASC CPL. We have determined these procedures would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, that standard medical practice would not dictate that the beneficiary would typically be expected to require active medical monitoring and care at midnight following the procedure, and are separately paid under the OPPS. The 8 procedures we are adding to the ASC CPL, including the long descriptors and the final CY 2020 payment indicators, are displayed in Table 60.

Additionally, we note that we inadvertently omitted new CPT and new HCPCS codes effective January 1, 2020 from Table 32, Proposed Additions to the List of ASC Covered Surgical Procedures for CY 2020, of our CY 2020 OPPS/ASC proposed rule (84 FR 39544); however, we included these 12 procedures in Addendum AA to our proposed rule. The procedures described by the 12 new CPT and HCPCS codes meet our criteria established under §§ 416.2 and 416.166 for addition to the ASC CPL and are displayed in Table 60. These 12 procedures include—

- CPT code 15769 (Grafting of autologous soft tissue, other, harvested by direct excision (for example, fat, dermis, fascia));
- CPT code 15771 (Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; 50 cc or less injectate);
- CPT code 15773 (Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; 25 cc or less injectate);
- CPT code 33016 (Pericardiocentesis, including imaging guidance, when performed);
- CPT code 46948 (Hemorrhoidectomy, internal, by transanal hemorrhoidal dearterialization, 2 or more hemorrhoid columns/groups, including ultrasound guidance, with mucopexy, when performed);
- CPT code 62328 (Spinal puncture, lumbar, diagnostic; with fluoroscopic or CT guidance);
- CPT code 62329 (Spinal puncture, therapeutic, for drainage of cerebrospinal fluid (by needle or catheter); with fluoroscopic or CT guidance);
- CPT Code 64451 (Injection(s), anesthetic agent(s) and/or steroid; nerves innervating the sacroiliac joint, with image guidance (that is, fluoroscopy or computed tomography));
- CPT Code 64625 (Radiofrequency ablation, nerves innervating the sacroiliac joint, with image guidance (that is, fluoroscopy or computed tomography));
- CPT Code 66987 (Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (for example, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (for example, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with endoscopic cyclophotocoagulation);
- CPT Code 66988 (Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (for example, irrigation and aspiration or phacoemulsification); with endoscopic cyclophotocoagulation); and
- CPT code 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).

We did not receive comments on the addition of these codes to the ASC CPL and are finalizing without modification. The table below shows all additions to the ASC CPL for CY 2020, these additions are also reflected in Addendum AA.

TABLE 60.— ADDITIONS TO THE LIST OF ASC COVERED SURGICAL PROCEDURES FOR CY 2020

CY 2020 CPT/ HCPCS Code	CY 2020 Long Descriptor	CY 2020 ASC Payment Indicator
15769	Grafting of autologous soft tissue, other, harvested by direct excision (eg, fat, dermis, fascia)	G2
15771	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; 50 cc or less injectate	G2
15773	Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; 25 cc or less injectate	G2
27447	Arthroplasty, knee, condyle and plateau; medial and lateral compartments with or without patella resurfacing (total knee arthroplasty)	J8
29867	Arthroscopy, knee, surgical; osteochondral allograft (eg, mosaicplasty)	J8
33016	Pericardiocentesis, including imaging guidance, when performed	G2
46948	Hemorrhoidectomy, internal, by transanal hemorrhoidal dearterialization, 2 or more hemorrhoid columns/groups, including ultrasound guidance, with mucopexy, when performed	G2
62328	Spinal puncture, lumbar, diagnostic; with fluoroscopic or CT guidance	G2
62329	Spinal puncture, therapeutic, for drainage of cerebrospinal fluid (by needle or catheter); with fluoroscopic or CT guidance	G2

CY 2020 CPT/ HCPCS Code	CY 2020 Long Descriptor	CY 2020 ASC Payment Indicator
64451	Injection(s), anesthetic agent(s) and/or steroid; nerves innervating the sacroiliac joint, with image guidance (ie, fluoroscopy or computed tomography)	G2
64625	Radiofrequency ablation, nerves innervating the sacroiliac joint, with image guidance (ie, fluoroscopy or computed tomography)	G2
66987	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with endoscopic cyclophotocoagulation	J8
66988	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification); with endoscopic cyclophotocoagulation	J8
92920	Percutaneous transluminal coronary angioplasty; single major coronary artery or branch	J8
92921	Percutaneous transluminal coronary angioplasty; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)	N1
92928	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch	J8
92929	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)	N1
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	J8
C9600	Percutaneous transcatheter placement of drug eluting intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch	J8

CY 2020 CPT/ HCPCS Code	CY 2020 Long Descriptor	CY 2020 ASC Payment Indicator
C9601	Percutaneous transcatheter placement of drug-eluting intracoronary stent(s), with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)	N1

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2. Covered Ancillary Services

Consistent with the established ASC payment system policy (72 FR 42497), we proposed to update the ASC list of covered ancillary services to reflect the payment status for the services under the CY 2020 OPPS. We stated in the proposed rule that maintaining consistency with the OPPS may result in proposed changes to ASC payment indicators for some covered ancillary services because of changes that are being proposed under the OPPS for CY 2020. For example, if a covered ancillary service was separately paid under the ASC payment system in CY 2019, but is proposed for packaged status under the CY 2020 OPPS, to maintain consistency with the OPPS, we would also propose to package the ancillary service under the ASC payment system for CY 2020. We proposed to continue this reconciliation of packaged status for subsequent calendar years. Comment indicator ''CH'', which is discussed in section XIII.F. of the CY 2020 OPPS/ASC proposed rule, is used in Addendum BB to the CY 2020 OPPS/ASC proposed rule (which is available via the internet on the CMS website) to indicate covered ancillary services for which we proposed a change in the ASC payment indicator to reflect a proposed change in the OPPS treatment of the service for CY 2020.

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.

Response: Services listed in our list of covered ancillary services must be integral to the performance of a covered surgical procedure. 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 2020.

All ASC covered ancillary services and their proposed payment indicators for CY 2020 are included in Addendum BB to the CY 2020 OPPS/ASC proposed 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 fully 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 standard ratesetting methodology. In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59028 through 59080), we updated the CY 2018 ASC payment rates for ASC covered surgical procedures with payment indicators of ''A2'', ''G2'', and ''J8'' using CY 2017 data, consistent with the CY 2019 OPPS update. We also updated payment rates for device-intensive procedures to incorporate the CY 2019 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 2018 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 2018 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 2018 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 2020

We proposed to update ASC payment rates for CY 2020 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 the CY 2020 OPPS/ASC proposed rule. Because the proposed OPPS relative payment weights are generally based on geometric mean costs, the ASC system would generally use geometric means 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 2020 OPPS/ASC proposed rule. Therefore, we proposed to update the payment amount for the service portion of the device-intensive procedures using the ASC standard rate setting methodology and the payment amount for the device portion based on the proposed CY 2020 OPPS 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 2020 MPFS nonfacility PE RVU-based amount or the proposed CY 2020 ASC payment amount calculated according to the ASC standard ratesetting methodology.

As we did for CYs 2014 through 2019, for CY 2020, 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 these procedures and would continue to be paid separately under the ASC payment system.

Our responses to the comments are set forth below.

Comment: We received several comments from professional societies expressing concern about assigning CPT codes 36465, 36466, and 31298 to a P2 payment indicator and CPT code 36482 to a P3 payment indicator. Commenters also expressed concerns with the appropriateness of the ASC payment policy to assign procedures to the lowest published payment rate across multiple payment systems, based upon CMS's determination that the level of complexity for a procedure is consistent with procedures performed in a physician's office. Commenters agreed with the proposal not designate CPT code 36902 as an office-based procedure and continue to assign CPT code 36902 a payment indicator of ''G2''—nonoffice-based surgical procedure paid based on OPPS relative weights.

Response: We appreciate the commenters' input. Based on our analysis of the latest hospital outpatient and ASC claims data used for this final rule with comment period, we are updating ASC payment rates for CY 2020 using the established rate calculation methodologies under § 416.171 of the regulations and using our finalized modified definition of device-intensive procedures, as discussed in section XIII.C.1.b of this final rule with comment period. We do not generally make additional payment adjustments to specific procedures. As such, we are finalizing the proposed APC assignment and payment indicators for CPT codes 36465, 36466, 31298, 36482, and 36902 as discussed in XIII.C.1.A of this final rule with comment period.

Comment: Several commenters disagreed with the proposed CY 2020 ASC payment rates for the surgical procedures described by the following CPT/HCPCS codes, requesting that CMS increase payment in the ASC setting:

- HCPCS code 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)
- HCPCS code C9755 (Creation of arteriovenous fistula, percutaneous using magnetic-guided arterial and venous catheters and radiofrequency energy, including flow-directing procedures (for example, 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)
- CPT code 37243 (Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction)
- CPT code 53854 (Transurethral destruction of prostate tissue by radiofrequency generated water vapor thermotherapy)
- CPT code 22869 (Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level)
- CPT code 22870 (Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; second level (List separately in addition to code for primary procedure)

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. ASC payment is dependent upon the APC assignment for each procedure. 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 2020 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 2020 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 HCPCS codes C9754 and C9755 and CPT codes 37243, 53854, 22869, and 22870 for CY 2020.

Comment: One commenter recommended that CMS eliminate the prohibition against 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. Therefore, such procedures are not currently payable under the ASC payment system. As discussed in the August 2, 2008 final rule (72 FR 42484 through 42486), it is not possible to know what specific procedure would be represented by an unlisted code. We are required to evaluate each surgical procedure for potential safety risk and the expected need for overnight monitoring and to exclude such procedures from ASC payment. It is not possible to evaluate procedures reported by unlisted CPT codes according to these criteria. 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 2020 payment rates for ASC covered surgical procedures according to our established methodologies using the modified definition of device-intensive procedures. For covered office-based surgical procedures, the payment rate is the lesser of the final CY 2020 MPFS nonfacility PE RVU-based amount or the final CY 2020 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, 2020. For a discussion of the PFS rates, we refer readers to the CY 2020 PFS final rule with comment period.

c. Limit on ASC Payment Rates for Low Volume Device-Intensive Procedures

As stated in section XIII.D.1.b. of the CY 2020 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 the CY 2020 OPPS/ASC proposed rule.

While we believe this policy generally helps to provide more appropriate payment for low-volume device-intensive procedures, these procedures can still have data anomalies as a result of the limited data available for these procedures in our ratesetting process. For the Level 5 Intraocular APC, which includes only HCPCS code 0308T (insj ocular telescope prosth), based on the CY 2018 claims data available for the proposed rule, the geometric mean cost and median cost under the standard ASC ratesetting methodology is $67,946.51 and $111,019.30, respectively. As described in section IV.B.5. of the CY 2020 OPPS/ASC proposed rule, a device-intensive procedure that is assigned to a clinical APC with fewer than 100 total claims for all procedures is considered ''low-volume'' and the cost of the procedure is based on calculations using the APC's median cost instead of the APC's geometric mean cost. Since this APC meets the criteria for low-volume device-intensive procedure designation, the ASC relative weight would be based on the median cost rather than the geometric mean cost. We note that this median cost for this APC is significantly higher than either the OPPS geometric mean cost or median cost based on the OPPS comprehensive ratesetting methodology, which are $28,122.51 and $19,269.55, respectively. This very large difference in cost calculations between these two settings is largely attributable to the APC's low claims volume and to the comprehensive methodology used under the OPPS which is not utilized in ratesetting under the ASC payment system. The cost calculation for this APC under the ASC payment system is primarily based on charges from one hospital with a significantly higher device cost center cost-to-charge ratio and significantly higher charges when compared to other hospitals providing the procedure.

If the ASC payment system were to base the CY 2020 payment rate for HCPCS code 0308T on the median cost of $111,019.30, the ASC payment rate would be several times greater than the OPPS payment rate for HCPCS code 0308T. We note that the median cost under the OPPS ratesetting methodology based on CY 2018 claims data is closer to the historical average for the median cost of HCPCS code 0308T (approximately $19,000). In addition, given that the outpatient hospital setting is generally considered to have higher costs than the ASC setting and that the payment rates for both settings are based on hospital outpatient cost data, we do not believe there should be a scenario where the payment rate for a low-volume device-intensive procedure under the ASC payment system is significantly greater than payment under the OPPS.

Therefore, for CY 2020 and subsequent years, we proposed 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 this proposal, 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 proposed to establish an ASC payment rate for such procedures equal to the OPPS payment rate for the same procedure. In the CY 2020 OPPS/ASC proposed rule, we noted that this policy would only affect HCPCS code 0308T, which has very low claims volume (7 claims used for ratesetting in the OPPS). We proposed to amend § 416.171(b) of the regulations to reflect the proposed new limit on ASC payment rates for low-volume device-intensive procedures. CMS' existing regulation at § 416.171(b)(2) requires the payment of the device portion of a device-intensive procedure at an amount derived from the payment rate for the equivalent item under the OPPS using our standard ratesetting methodology. We proposed to add 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.

Covered surgical procedures and their proposed payment rates for CY 2020 are listed in Addendum AA of the CY 2020 OPPS/ASC proposed rule (which is available via the internet on the CMS website).

Comment: One commenter requested that CMS consider adopting a consistent payment methodology for low volume procedures, regardless of whether a procedure is assigned to a clinical or New Technology APC. The commenter noted that 0308T is one of only two procedures to which CMS has applied

either of the low volume payment methodologies. The commenter suggested CMS could determine the payment rate for low volume, device-intensive procedures in clinical APCs by using 4 years of claims data and gathering input through the public comment period on whether arithmetic mean, geometric mean, or median should be the basis for the payment amount.

Response: We appreciate the stakeholder's comments regarding changes in estimated costs based on the claims data available for ratesetting. In our CY 2017 OPPS/ASC final rule with comment period (81 FR 79660 through 79661), we finalized our 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. We believe using the median cost instead of the geometric mean cost has generally provided an appropriate payment for low-volume device-intensive procedures in cases where there are no data anomalies. However, we note that we are adding paragraph (b)(4) to § 416.171 to require that, notwithstanding paragraph (b)(2), low volume device-intensive procedures where the otherwise applicable ASC 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 to address such data anomalies in the future.

Additionally, as we noted in our CY 2020 OPPS/ASC proposed rule (84 FR 39453–39454), one of the objectives of establishing New Technology APCs is to generate sufficient claims data for a new procedure so that it can be assigned to an appropriate clinical APC. In cases where procedures are assigned to New Technology APCs have very low annual volume, we may use up to 4 years of claims data in calculating the applicable payment rate for the prospective year. We believe our payment policy for low-volume new technology procedures provides an appropriate payment for new technology procedures so that they may be assigned to an appropriate clinical APC in the future. Further, we believe this payment policy should only be applicable to procedures assigned to New Technology APCs and not to all clinical APCs since we believe it would be less common for a clinical APC to have fewer than 100 total claims than a new technology APC.

After consideration of the public comment we received, we are finalizing our proposed policy without modification, to limit the ASC payment rate for a low-volume device-intensive procedure to a payment rate equal to the OPPS payment rate for that procedure, including our proposed regulation text at § 416.171(b)(4).

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 the CY 2020 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 2020 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 (42 CFR 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.

b. Payment for Covered Ancillary Services for CY 2020

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 2020 OPPS and ASC payment rates and subsequent year payment rates. We also proposed to continue to set the CY 2020 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 2020 and subsequent year payment rates.

We note that stakeholders requested that we propose to add CPT code 91040 (Esophageal balloon distension study, diagnostic, with provocation when performed) to the ASC Covered Procedures List (CPL) and ASC list of covered ancillary services as it is integral to the performance of covered surgical procedures such as CPT code 43235 (Esophagogastroduodenoscopy, flexible, transoral; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)) and 43239 (Esophagogastroduodenoscopy, flexible, transoral; with biopsy, single or multiple). Based on available data and other information related to CPT code 91040, we do not believe this diagnostic test is integral to the covered surgical procedures of CPT codes 43235 or 43239. Therefore, we did not propose to add CPT code 91040 as a covered ancillary service.

Covered ancillary services and their proposed payment indicators for CY 2020 are listed in Addendum BB of the CY 2020 OPPS/ASC proposed rule (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 proposed payment indicators and rates set forth in the proposed rule are based on a comparison using the proposed PFS rates effective January 1, 2020. For a discussion of the PFS rates, we refer readers to the CY 2020 PFS proposed 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 2020 ASC Packaging Policy for Non-Opioid Pain Management Treatments

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.

In the CY 2019 OPPS/ASC final rule with comment period, we noted that we will continue to analyze the issue of access to non-opioid alternatives in the OPPS and ASC settings as we implement section 6082 of the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT for Patients and Communities Act or SUPPORT Act) (Pub. L. 115–271), enacted on October 24, 2018. We also discussed 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 when furnished in the ASC setting in section II.A.3.b. of the CY 2019 OPPS/ASC final rule with comment period (83 FR 58854 through 58860). As required under section 6082(b) of the SUPPORT Act, we will continue to review and revise ASC payments for non-opioid alternatives for pain management, as appropriate. For more information on our implementation of section 6082 of the SUPPORT for Patients and Communities Act and related proposals, we refer readers to section II.A.3.b. of the CY 2020 OPPS/ASC proposed rule.

The comments and our responses 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 unpackage and pay separately for the cost of non-opioid pain management drugs that function as surgical supplies, such as Exparel, in the ASC setting for CY 2020. These commenters believed that packaged payment for non-opioid alternatives presents a barrier to care and that separate payment for non-opioid pain management drugs would be an appropriate response to the opioid drug abuse epidemic.

Other commenters, including MedPAC, did not support this proposal and stated that the policy was counter to the OPPS packaging policies created to increase the size of payment bundles in the OPPS, which increases incentives for efficient delivery of care. MedPAC noted that they prefer a policy that maintains the packaging of drugs that function as supplies in surgical procedures.

Response: We appreciate these comments. After reviewing the information provided by the commenters, 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 2020. We note that preliminary data suggest that utilization of Exparel has increased significantly in the ASC setting in 2019. We intend to continue to monitor Exparel utilization in the ASC setting and monitor whether there is an associated decrease under Part B or D in opioids once more data are available.

Comment: Several commenters supported the assignment of status indicator ''K'' (Nonpass-Through Drugs and Nonimplantable Biologicals, Including Therapeutic Radiopharmaceuticals) and continuing to pay separately for the drug Prialt (HCPCS J2278, injection, ziconitide), a non-narcotic pain reliever administered via intrathecal injection. The commenters discussed data indicating that Prialt potentially could lower opioid use, including opioids such as morphine. In addition to continued separate payment, several commenters recommended CMS reduce or eliminate the coinsurance for the drug in order to increase beneficiary access. The commenters noted due to the drug's significant cost, the 20 percent coinsurance would put the drug out of reach for beneficiaries. Additionally, the commenters discussed that there is not enough financial incentive for providers to use Prialt in their patients compared to lower cost opioids. Commenters claimed that Prialt is only paid at invoice costs, which they believe discourages provider use.

Response: We thank commenters for their feedback and for their support of the continued assignment of status indicator ''K'' to HCPCS J2278. The corresponding ASC payment indicator for HCPCS J2278 would be ''K2''. Prialt is paid at its average sales price (ASP) plus 6 percent according to the ASP methodology under the OPPS, and therefore, is also paid at ASP plus 6 percent in the ASC setting. We note that under 1833(a)(1)(G) of the Act, the payment is subject to applicable deductible and coinsurance, and we are unaware of statutory authority to alter beneficiary coinsurance for payments made in the ASC setting. We note that because the dollar value of beneficiary coinsurance is directly proportionate to the payment rate (which is ASP+6 percent for HCPCS code J2278), a lower sales price for the drug (which would lead to a lower Medicare payment rate under the current policy) would be necessary for beneficiaries to have a lower coinsurance amount.

Comment: Many commenters requested that the drug Omidria (HCPCS code C9447, injection, phenylephrine ketorolac), be excluded from the packaging policy 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 the available data and multiple peer-reviewed articles on Omidria support the packaging exclusion. Commenters asserted the use of Omidria decreases patients' need for fentanyl during surgeries and another commenter believes that Omidria reduces opioid use after cataract surgeries. In addition, commenters asserted that the OPPS and ASC payment system do not address the cost of packaged products used by small patient populations. Therefore, the OPPS and ASC payment structures for packaged supplies creates an access barrier and patients are forced to use inferior products that have increased complication risk and require the continued use of opioids to manage pain. One commenter referenced the results of a study that Omidria reduces the need for opioids during cataract surgery by nearly 80 percent while decreasing pain scores by more than 50 percent.

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 ASC payment system. Subsequently, Omidria's pass-through status under the OPPS was reinstated in October 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 continues to be paid separately under the ASC payment system through September 30, 2020. While our analysis supports the commenter's assertion that there was a decrease in the utilization of Omidria in 2018 following its pass-through expiration, we note that there could be many reasons that utilization declines after the pass-through period, including the availability of other alternatives on the market (many of which had been used for several years before Omidria came on the market and are sold for a lower price), the lack of separate payment being available, or physician preference.

Further, our clinical advisors' review of the clinical evidence submitted concluded that the study the commenter submitted was not sufficiently compelling or authoritative to overcome contrary evidence. 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. As a result, we do not have compelling evidence to exclude Omidria from packaging after its current pass-through expires on September 30, 2020. While we were not able to perform similar analysis using ASC data, we expect that the results may be similar. We will continue to analyze the evidence and monitor utilization of this drug.

Comment: One commenter requested that MKO Melt, a non FDA-approved, compounded drug comprised of midazolam/ketamine/ondansetron for exclusion from the packaging policy per section 1833(t)(22)(A)(i) of the Act. The commenter contended that MKO Melt is a drug functioning as surgical supply in the ASC setting. The commenter provided a reference to a study titled, ''Anesthesia for opioid addicts: Challenges for perioperative physician''

by Goyal et al., on the need for pain management in the opioid-dependent patient. The commenter also referenced a review article, ''Perioperative Management of Acute Pain in the Opioid-dependent Patient,'' by Mitra et al., on the special needs of opioid-dependent patients in surgeries and the potential opioid relapse in those patients who are recovering from opioid use disorder. Additionally, the commenter referenced a clinical trial registered in *clinicaltrials.gov* (NCT03653520) that supports sublingual MKO Melt for use during cataract surgeries to replace opioids. The study looked at 611 patients that were divided into three arms: (1) MKO melt arm, (2) diazepam/tramadol/ondansetron arm, (3) diazepam only arm. The study concluded that the MKO melt arm had the lowest incidence for supplemental injectable anesthesia to control pain.

Response: We thank the commenter for the comment. Based on information submitted, we are not able to validate that MKO Melt reduces the use of opioids. We note that ketamine, one component of MKO melt, exhibits some addictive properties. Moreover, we did not identify any evidence that MKO Melt is effective for patients with a prior opioid addiction nor did we receive any data demonstrating that the current ASC packaging policy incentivized providers to use opioids over MKO Melt. In accordance with section 1833(i)(8) of the Act, the fact that there is no HPCPS code for the drug, and lack of FDA approval, we were not able to identify any compelling evidence that MKO Melt should be excluded from packaged payment.

Comment: Several commenters, including individual physicians, medical associations, and device manufacturers commented supporting separate payment for continuous peripheral nerve blocks as they significantly reduce opioid use. One commenter suggested that CMS provide separate payment for HCPCS code A4306 (Disposable drug delivery system, flow rate of less than 50 ml per hour) in the hospital outpatient department setting and the ASC setting because packaging represents a cost barrier for providers. The commenter contended that continuous nerve block procedures have been shown in high quality clinical studies to reduce the use of opioids, attaching studies for review. They believe that separate payment for A4306 will remove the financial disincentive for HOPDs and ASCs, encouraging continuous nerve blocks as a non-opioid alternative for post-surgical pain management.

Response: We appreciate the commenter's suggestion. We examined the data for A4306 and noted an overall trend of increasing utilization from CY 2014 through CY 2017. Additionally, the geometric mean cost for A4306 was approximately $30 each year during that four-year period. We acknowledge that use of these items may help in the reduction of opioid use. However, we note that packaged payment of such an item does not prevent the use of these items. We do not believe that the current utilization trends for HCPCS code A4306 in the ASC setting suggest that the packaged payment is preventing use and remind readers that payment for packaged items is included in the payment for the primary service. We share the commenter's concern about the need to reduce opioid use and will take the commenter's suggestion regarding the need for separate payment for HCPCS code A4306 in the ASC setting into consideration for future rulemaking.

Comment: Multiple commenters identified other non-opioid pain management alternatives that they believe decrease the dose, duration, and/or number of opioid prescriptions beneficiaries receive during and following an outpatient visit or procedure (especially for beneficiaries at high-risk for opioid addiction) and may warrant separate payment for CY 2020. Commenters representing various stakeholders requested separate payments for various non-opioid pain management treatments, such as continuous nerve blocks (neuromodulation, radiofrequency ablation, implants for lumbar stenosis, protocols (ERAS®) IV acetaminophen, IV ibuprofen, Polar ice devices for postoperative pain relief, THC oil, acupuncture, and dry needling procedures.

For neuromodulation, several commenters noted that spinal cord stimulators (SCS) may lead to a reduction in the use of opioids for chronic pain patients. One manufacturer of SCS devices commented that SCS provides the opportunity to potentially stabilize or decrease opioid usage and that neuromodulation retains its efficacy over multiple years. Regarding barriers to access, the commenter noted that Medicare beneficiaries often do not have access to SCS until after they have exhausted other treatments, which often includes opioids. The commenter presented evidence from observational studies that use of SCS earlier in a patient's treatment could help reduce opioid use while controlling pain, and suggested that CMS look for ways to incorporate SCS earlier in the treatment continuum, suggesting CMS develop additional education and outreach efforts and incentives for appropriate referrals of patients with chronic pain to comprehensive pain management practices for consultation and evaluation prior to the administration of opioids. The commenter suggested that CMS could provide alerts to providers regarding the benefits of pain management consultation with a qualified pain management professional prior to the administration of opioids for chronic conditions.

Another commenter asserted that the standard endpoints, such as a greater than 50 percent reduction in pain, that are used to determine if a neuromodulation-based non-opioid pain alternative therapy is effective are well-established and validated in all types of clinical trials and that CMS should establish a general, national coverage determination for neuromodulation-based non-opioid pain therapy based on these endpoints, rather than taking the time to create and process specific national coverage determinations or local coverage determinations. The commenter suggested that this would be a much faster and streamlined process for enhancing Medicare beneficiary access to neuromodulation-based pain management therapies.

One manufacturer of a high-frequency SCS device stated that additional payment was warranted for non-opioid pain management treatments because they provide an alternative treatment option to opioids for patients with chronic leg or back pain. The commenter provided supporting studies which claimed that patients treated with their high-frequency SCS device reported a statistically significant average decrease in opioid use compared to the control group. This commenter also submitted data that showed a decline in the mean daily dosage of opioid medication taken and that fewer patients were relying on opioids at all to manage their pain when they used the manufacturer's device.

Other commenters wrote regarding their personal experiences in regards to radiofrequency ablation for sacral iliac joints and knees. One commenter referenced several studies, one of which found a decrease in analgesic medications associated with radiofrequency ablation; however, it did not provide evidence regarding a decrease in opioid usage.

One national hospital association commenter recommended that while ''certainly not a solution to the opioid epidemic, unpackaging appropriate non-opioid therapies, like Exparel, is a low-cost tactic that could change long-

standing practice patterns without major negative consequences.'' This same commenter suggested that Medicare consider separate payment for IV acetaminophen, IV ibuprofen, and Polar ice devices for postoperative pain relief after knee procedures. The commenter also noted that therapeutic massage, topically applied THC oil, acupuncture, and dry needling procedures are very effective therapies for relief of both postoperative pain and long-term and chronic pain. Several other commenters expressed support for IV acetaminophen.

Response: We appreciate the detailed responses from commenters on this topic. At this time, we have not found compelling evidence for other non-opioid pain management alternatives described above to warrant separate payment under the OPPS or ASC payment systems for CY 2020, 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 note that some of the items and services mentioned by commenters are not covered by Medicare, and we do not intend to establish payment for noncovered items and services. 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 or opioid abuse or misuse during or after an outpatient visit or procedure.

After reviewing the non-opioid pain management alternatives suggested by the commenters as well as the studies and other data provided to support the request for separate payment, we have not determined that separate payment is warranted at this time for most of the non-opioid pain management alternatives discussed above. However, we continue to believe the separate payment is appropriate for non-opioid pain management drugs that function as surgical supplies, like Exparel, when furnished in the ASC setting and are finalizing this policy for CY 2020.

Comment: Several commenters addressed payment barriers that may inhibit access to non-opioid pain management treatments previously discussed throughout this section. Several commenters disagreed with CMS's assessment that current payment policies do not represent barriers to access for certain non-opioid pain management alternatives. One commenter encouraged CMS to provide timely insurance coverage for evidence-informed interventional procedures early in the course of treatment when clinically appropriate, noting that they hope CMS will reconsider its position and provide mechanisms for separate payment and patient access to evidence-based, FDA approved and cleared medical device enabled interventions that would provide alternatives to opioid pain management interventions. Several other commenters encouraged CMS to more broadly evaluate all of its packaging policies to help ensure patient access to appropriate therapies and to assess how packaging affects the utilization of a medicine and use the results of that evaluation to guide future policy development.

Response: We appreciate the various, insightful comments we received from stakeholders regarding barriers that may inhibit access to non-opioid alternatives for pain treatment and management in order to more effectively address the opioid epidemic. We will take these comments into consideration for future consideration. Many of these comments have been previously addressed throughout this section.

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 2020 as proposed. We will continue to analyze the issue of access to non-opioid alternatives in the OPPS and ASC settings as we implement section 6082 of the SUPPORT Act and section 1833(i)(8). 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 42 CFR 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 2020

We did not receive any requests for review to establish a new NTIOL class for CY 2020 by March 1, 2019, the due date published in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59072).

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 proposing to

revise the payment adjustment amount for CY 2020.

The comments and our responses to the comments are set forth below.

Comment: Two commenters 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. One commenter requested that the $50 be inflated to 2020 dollars and updated by inflation in subsequent years. Another commenter requested that we updated the $50 payment adjustment to $100, which is the approximate dollar amount of our $50 payment adjustment had we increased the adjustment based on the increase in CPI–U for medical care.

Response: We thank the commenters for their recommendation. We did not propose revising the payment adjustment amount for CY 2020. However, we will take commenters recommendations into consideration in future rulemaking.

After consideration of the public comments we received, we are finalizing our proposal to maintain the payment adjustment of a new NTIOL class at $50 per lens for CY 2020 without modification.

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 2020

In the CY 2020 OPPS/ASC proposed rule, 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 2020 and any new and existing Level II HCPCS codes with substantial revisions to the code descriptors for CY 2020 compared to the CY 2019 descriptors are included in ASC Addenda AA and BB to this 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.

In the CY 2020 OPPS/ASC proposed rule, we stated that we would respond to public comments on ASC payment and comment indicators and finalize their ASC assignment in the CY 2020 OPPS/ASC final rule with comment period. We referred readers to Addenda DD1 and DD2 of the CY 2020 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 2020 update. We did not receive any public comments on the ASC payment and comment indicators. Therefore, we are finalizing their use as proposed without modification. Addenda DD1 and DD2 to this final rule with comment period (which are available via the internet on the CMS website) contain the complete list of ASC payment and comment indicators for CY 2020.

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 the CY 2020 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 2020, the proposed CY 2020 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 2020 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). Consistent with our established policy, we proposed to scale the CY 2020 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 2018, we proposed to compare the total payment using the CY 2019 ASC relative payment weights with the total payment using the CY 2020 ASC relative payment weights to take into account the changes in the OPPS relative payment weights between CY 2019 and CY 2020. We proposed to use the ratio of CY 2019 to CY 2020 total payments (the weight scalar) to scale the ASC relative payment weights for CY 2020. The proposed CY 2020 ASC weight scalar is 0.8452 and scaling would apply to the ASC relative payment weights of the 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 proposed rule, we had available 98 percent of CY 2018 ASC claims data.

The comments and our responses to the comments are set forth below.

Comment: A majority of 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, which would hurt beneficiaries and limit their access to high-quality outpatient surgical care. They suggested that eliminating the secondary rescaling that is currently applied to ASC payments would allow ASCs to continue to provide quality surgical care for Medicare patients.

Several commenters requested that CMS apply the same OPPS relative weights to ASC services and discontinue rescaling the ASC relative weights. They provided that while they understand the additional scaling factor that CMS applies to the ASC APC weight 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 note that applying the weight scalar in calculation of ASC payment rates, for this final rule with comment period it is 0.8550, ensures that the ASC payment system remains budget neutral. We understand the commenters do not believe that calculation of the weight scalar in the ASC is necessary and their belief that its application leads to large payment differentials for similar services between the OPPS and ASC payment systems. 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 are unsure of the actual differences in costs between the two sites of service. We have not witnessed beneficiary access issues when it comes to receiving care in an ASC and note that there are more ASCs than there are hospitals; we do not agree that the current ASC payment methodology has created an access to care issue for ASCs. Additionally, the ASC payment system was not designed to mirror that of the OPPS; a large part of the value of ASCs is that they provide a lower cost option for surgical procedures than some other 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 2017 ASC claims by ASC and by HCPCS code. We used the National Provider Identifier for the purpose of identifying unique ASCs within the CY 2018 claims data. We used the supplier zip code reported on the claim to associate state, county, and CBSA with each ASC. This file, available to the public as a supporting data file for the proposed rule, is posted on the CMS website at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/ASCPaymentSystem.html.*

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 2020, we calculated the proposed adjustment for the ASC payment system by using the most recent CY 2018 claims data available and estimating the difference in total payment that would be created by introducing the proposed CY 2020 ASC wage indexes. Specifically, holding CY 2018 ASC utilization, service-mix, and the proposed CY 2020 national payment rates after application of the weight scalar constant, we calculated the total adjusted payment using the CY 2019 ASC wage indexes and the total adjusted payment using the proposed CY 2020 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 2019 ASC wage indexes to the total adjusted payment calculated with the proposed CY 2020 ASC wage

indexes and applied the resulting ratio of 1.0008 (the proposed CY 2020 ASC wage index budget neutrality adjustment) to the CY 2019 ASC conversion factor to calculate the proposed CY 2020 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 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 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 2020 OPPS/ASC proposed rule (84 FR 39552), the hospital market basket update for CY 2020 was to be 3.2 percent, as published in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19402), based on IHS Global Inc.'s (IGI's) 2018 fourth quarter forecast with historical data through the third quarter of 2018. For this CY 2020 OPPS/ASC final rule with comment period, as published in the FY 2019 IPPS/LTCH PPS final rule (84 FR 42343), based on IGI's 2019 second quarter forecast with historical data through the first quarter of 2019, the hospital market basket update for CY 2020 is 3.0 percent.

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 2020 OPPS/ASC proposed rule (84 FR 39553), the proposed MFP adjustment for CY 2020 was projected to be 0.5 percentage point, as published in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19402) based on IGI's 2018 fourth quarter forecast. For this CY 2020 OPPS/ASC final rule with comment period, as published in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42343) based on IGI's 2019 second quarter forecast, the final MFP adjustment for CY 2020 is 0.4 percentage point.

For CY 2020, we proposed to utilize the hospital market basket update of 3.2 percent minus the MFP adjustment of 0.5 percentage point, resulting in an MFP-adjusted hospital market basket update factor of 2.7 percent for ASCs meeting the quality reporting requirements. Therefore, we proposed to apply a 2.7 percent MFP-adjusted hospital market basket update factor to the CY 2019 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the CY 2020 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 referred 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 the CY 2020 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 3.2 percent reduced by 2.0 percentage points for ASCs that do not meet the quality reporting requirements and then subtract the 0.5 percentage point MFP adjustment. Therefore, we proposed to apply a 0.7 percent MFP-adjusted hospital market basket update factor to the CY 2019 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 and MFP), we would use such data, if appropriate, to determine the CY 2020 ASC update for the CY 2020 OPPS/ASC final rule with comment period.

For CY 2020, we proposed to adjust the CY 2019 ASC conversion factor ($46.532) by the proposed wage index budget neutrality factor of 1.0008 in addition to the MFP-adjusted hospital market basket update factor of 2.7 percent discussed above, which results in a proposed CY 2020 ASC conversion factor of $47.827 for ASCs meeting the quality reporting requirements. For ASCs not meeting the quality reporting requirements, we proposed to adjust the CY 2019 ASC conversion factor ($46.532) by the proposed wage index budget neutrality factor of 1.0008 in addition to the quality reporting/MFP-adjusted hospital market basket update factor of 0.7 percent discussed above, which results in a proposed CY 2020 ASC conversion factor of $46.895.

The comments 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 aligning the update factors between the OPPS and ASC settings will encourage the migration of care to the ASC setting by making ASC payment more competitive with hospital payment, while other commenters supported the decision as it would promote site-neutrality between the two settings of care through more competitive payment. However, other commenters, despite their support for the use of the hospital market basket to update ASC payment rates, believed that the migration of services to ASCs would be limited due to the ASC budget neutrality adjustments. Commenters stated that CMS' current approach to maintaining budget neutrality in the ASC payment system caused increasing differentials in payment for 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 noted that widening the gap in payments could make it economically difficult for ASCs to perform certain procedures, discouraging ASCs from furnishing those procedures and thereby discouraging the migration of services from the HOPD to the ASC setting. MedPAC did not support using the hospital market basket index as an interim method for updating the ASC

conversion factor, noting that evidence has indicated the hospital market basket index does not accurately reflect the costs of ASCs. MedPAC noted the differences in cost structure between the HOPD and ASC settings could be attributed to a number of factors, including different patient populations, expenses, employee compensation, and regulations.

Response: We appreciate the commenters' support. We believe providing ASCs with the same rate update as hospitals encourages the migration of services from the hospital setting to the ASC setting and could 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 also gives both physicians and beneficiaries greater choice in selecting the best care setting.

In addition, we acknowledge MedPAC's comment regarding the collection of ASC cost data and differences in cost structure between the HOPD and ASC settings. We appreciate these comments and will take these comments into consideration in future policy development.

Comment: Multiple commenters expressed their opposition to collecting ASC cost data, due to the anticipated administrative burden associated with collecting this data. Commenters suggested that collecting ASC cost data would prevent ASCs from providing efficient low-cost care. MedPAC suggested that CMS begin collecting ASC cost data immediately, forgoing the final four years of its planned five-year period to assess the feasibility of collaborating with stakeholders to collect ASC cost data in a minimally burdensome manner and potentially to propose a plan to collect such information. MedPAC suggested that CMS use its existing authority and resources to act quickly in gathering ASC cost data. MedPAC noted that beneficial information could be gathered to inform ASC payment updates and asserted that there is sufficient evidence that ASC can capably submit cost data.

Response: We thank the commenters for their input. As discussed in the CY 2019 OPPS/ASC final rule with comment period, we intend 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 over a 5-year period (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 2020 ASC update for the CY 2020 OPPS/ASC final rule with comment period, we are incorporating more recent data to determine the final CY 2020 ASC update. Therefore, for this CY 2020 OPPS/ASC final rule with comment period, the hospital market basket update for CY 2020 is 3.0 percent, as published in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42343), based on IGI's 2019 second quarter forecast with historical data through the first quarter of 2019. The MFP adjustment for this CY 2020 OPPS/ASC final rule with comment period is 0.4 percentage point, as published in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42343) based on IGI's 2019 second quarter forecast.

For CY 2020, we are finalizing 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 apply a 2.6 percent MFP-adjusted hospital market basket update factor to the CY 2019 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the CY 2020 ASC payment rates.

3. Display of Final CY 2020 ASC Payment Rates

Addenda AA and BB to this final rule (which are available on the CMS website) display the final updated ASC payment rates for CY 2020 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 final rule are based on a comparison using the finalized PFS rates that would be effective January 1, 2020. For a discussion of the PFS rates, we refer readers to the CY 2020 PFS final 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 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 proposed CY 2020 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 2020. 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.

The values displayed in the column titled ''Final CY 2020 Payment Weight'' are the proposed relative payment weights for each of the listed services for CY 2020. The proposed 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 2020 payment rate displayed in the ''Final CY 2020 Payment Rate'' column, each ASC payment weight in the ''Final CY 2020 Payment Weight'' column was multiplied by the final CY 2020 conversion factor of $47.747. 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 2020 ASC conversion factor uses the CY 2020 MFP-adjusted hospital market basket update factor of 2.6 percent (which is equal to the projected hospital market basket update of 3.0 percent minus a projected MFP adjustment of 0.4 percentage point).

In Addendum BB, there are no relative payment weights displayed in the ''Final CY 2020 Payment Weight'' column for items and services with predetermined national payment amounts, such as separately payable drugs and biologicals. The ''Final CY 2020 Payment'' column displays the proposed CY 2020 national unadjusted ASC payment rates for all items and services. The proposed CY 2020 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 2019.

Addendum EE provides the HCPCS codes and short descriptors for surgical procedures that are proposed to be excluded from payment in ASCs for CY 2020.

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, formerly known as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program.

We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 58820 through 58822) where we discuss our Meaningful Measures Initiative and our approach in evaluating quality program measures.

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; and 83 FR 59080 through 59110) for the regulatory history of the Hospital OQR Program. We have codified certain requirements under the Hospital OQR Program at 42 CFR 419.46.

B. Hospital OQR Program Quality Measures

1. Considerations in the Selection of 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 in the CY 2020 OPPS/ASC proposed rule (84 FR 39554).

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) whereby quality measures adopted in a previous year's rulemaking are retained in the Hospital OQR Program for use in subsequent years unless otherwise specified. For more information regarding this policy, we refer readers to that final rule with comment period. We codified this policy at 42 CFR 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 in the CY 2020 OPPS/ASC proposed rule (84 FR 39554).

3. Removal of Quality Measures From the Hospital OQR Program Measure Set

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60635), we finalized a process 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.[82] We codified this policy at 42 CFR 419.46(h)(3) in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59082). We did not propose any changes to these policies in the CY 2020 OPPS/ASC proposed rule (84 FR 39554).

a. Considerations in Removing Quality Measures From the Hospital OQR Program

(1) Immediate Removal

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60634 through 60635), we finalized a process for immediate retirement, which we later termed ''removal,'' of Hospital OQR Program measures, based on evidence that the continued use of the measure as specified raises patient safety concerns.[83] We codified this policy at 42 CFR 419.46(h)(2) in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59082). We did not propose any changes to these policies in the CY 2020 OPPS/ASC proposed rule (84 FR 39554).

(2) Consideration Factors for Removing Measures

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59083 through 59085), we clarified, finalized, and codified at 42 CFR 419.46(h)(2) and (3) an updated set of factors[84] 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. The factors are:

- Factor 1. Measure performance among hospitals is so high and

[82] 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.

[83] 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.

[84] 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.

unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped out'' measures).

- Factor 2. Performance or improvement on a measure does not result in better patient outcomes.
- Factor 3. A measure does not align with current clinical guidelines or practice.
- Factor 4. The availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic.
- Factor 5. The availability of a measure that is more proximal in time to desired patient outcomes for the particular topic.
- Factor 6. The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic.
- Factor 7. Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.
- Factor 8. The costs associated with a measure outweigh the benefit of its continued use in the program.

b. Removal of Quality Measure From the Hospital OQR Program Measure Set: OP–33: External Beam Radiotherapy (NQF# 1822)

In the CY 2020 OPPS/ASC proposed rule (84 FR 39554 through 39556), we proposed to remove one measure from the Hospital OQR Program for the CY 2022 payment determination as discussed below. Specifically, beginning with the CY 2022 payment determination, we proposed to remove OP–33: External Beam Radiotherapy for Bone Metastases under removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program.

We refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70507 through 70510), where we adopted OP–33: External Beam Radiotherapy (NQF# 1822), beginning with the CY 2018 payment determination and for subsequent years. This measure assesses the ''percentage of patients (all-payer) with painful bone metastases and no history of previous radiation who receive External Beam Radiotherapy (EBRT) with an acceptable dosing schedule.'' [85] We adopted this measure to address the performance gap in EBRT treatment variation, ensure appropriate use of EBRT, and prevent the overuse of radiation therapy (80 FR 70508).

We believe that removing OP–33 from the Hospital OQR Program is appropriate at this time because the costs associated with this measure outweigh the benefit of its continued use in the program (removal Factor 8). The Hospital OQR Program implemented the OP–33 measure using ''radiation delivery'' Current Procedural Terminology (CPT) codes, which are appropriate for hospital-level measurement. We have identified issues with reporting this measure, finding that more questions are received about how to report the OP–33 measure than about any other measure in the program. In addition, the measure steward has received feedback on data collection of the measure in the outpatient setting, and has indicated new and significant concerns regarding the ''radiation delivery'' CPT coding used to report the OP–33 measure in the Hospital OQR Program including complicated measure exclusions, sampling concerns, and administrative burden.

''Radiation delivery'' CPT codes require complicated measure exclusions, and the use of ''radiation delivery'' CPT codes causes the administration of EBRT to different anatomic sites to be considered separate cases for this measure. The numerator for this measure includes all patients, regardless of age, with painful bone metastases, and no previous radiation to the same anatomic site who receive EBRT with any of the following recommended fractionation schemes: 30Gy/10fxns, 24Gy/6fxns, 20Gy/5fxns, and 8Gy/1fxn. The denominator for this measure includes all patients with painful bone metastases and no previous radiation to the same anatomic site who receive EBRT.[86] As noted above, each anatomic site is considered a different case, and as a result it is necessary to determine when EBRT has been administered to different anatomic sites. This determination is not possible without completing a detailed manual review of the patient's record, creating burden and difficulty in determining which sites and instances of EBRT administration are considered cases and should be included in the denominator for the measure. These challenges in determining which cases are included in the denominator for the measure result in difficulty in determining if sample size requirements for the measure are being met.

Further, current information systems do not automatically calculate the total dose provided, so manual review of patient records by practice staff is also required in order to determine the total dose and fractionation scheme, which in turn is used to determine which cases fall into the numerator for this measure. This manual review of patient records is a labor-intensive process that contributes to burden and difficulty in reporting this measure. As a result, we believe that the complexity of reporting this measure places substantial administrative burden on facilities. This also reflects observations made by the measure steward that implementing the measure in the outpatient setting has proven overly burdensome, given that facilities have noted confusion regarding when the administration of EBRT to different numbers and locations of bone metastases are considered separate cases. These issues identifying cases have led to questions about sampling and difficulty determining if sample size requirements are met. Additional burdens associated with this measure have come to our attention, including complicated measure exclusions, sampling concerns, and administrative burden. These challenges cause difficulty in tracking and reporting data for this measure and additional administrative burden, as evidenced by numerous questions about how to report this measure received by CMS and its contractors.

This EBRT measure was also adopted into another CMS quality reporting program, the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program (79 FR 50278 through 50279). That program initially used ''radiation planning'' CPT codes billable at the physician level, but beginning in March 2016, the PCHQR program updated the measure to enable the use of ''radiation delivery'' CPT codes.[87] In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42513), we finalized the removal of the measure from the PCHQR Program because the burden associated with the measure outweighs the value of its inclusion in the PCHQR Program. Specifically, the PCHQR Program removed the measure because it is overly burdensome and because the measure steward is no longer maintaining the measure. As such, the PCHQR Program stated it can no longer ensure that the measure is in line with clinical guidelines and standards (84 FR 42513). We note that while the version of the measure using ''radiation planning'' CPT codes is less burdensome, Hospital Outpatient

[85] 80 FR 70508.

[86] National Quality Forum. NQF #1822 External Beam Radiotherapy for Bone Metastases. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=70374.*

[87] QualityNet. 2018 EBRT Measure Information Form. Available at: *https://www.qualitynet.org/dcs/ContentServer?cid=1228774479863&pagename=QnetPublic%2FPage%2FQnetTier4&c=Page.*

Departments (HOPDs) do not have access to physician billing data, and so it is not operationally feasible to use ''radiation planning'' CPT codes (as opposed to the current ''radiation delivery'' CPT codes) for the EBRT measure in the Hospital OQR Program.

This measure was originally adopted to address the performance gap in EBRT treatment variation, ensure appropriate use of EBRT, and prevent the overuse of radiation therapy. While we still believe that these goals are important, the benefits of this measure have diminished. Stakeholder feedback has shown that this measure is burdensome and difficult to report. Since the measure steward is no longer maintaining this measure,[88] we no longer believe that we can ensure that the measure is in line with clinical guidelines and standards. Thus, considering these circumstances, we believe the costs associated with this measure outweigh the benefit of its continued use in the program (removal Factor 8).

Therefore, in the CY 2020 OPPS/ASC proposed rule (84 FR 39554 through 39556), we proposed to remove the measure beginning with October 2020 encounters used in the CY 2022 payment determination and for subsequent years. We wish to clarify here in this final rule that the measure would be removed beginning with CY 2020 encounters (January 2020) used in the CY 2022 payment determination and for subsequent years rather than beginning in October 2020 as incorrectly noted in the proposed rule. We refer readers to our response to comments below. We considered removing this measure beginning with the CY 2021 payment determination, but we decided to propose to delay removal until the CY 2022 payment determination to be sensitive to facilities' planning and operational procedures given that data collection for this measure began during CY 2019 for the CY 2021 payment determination. We believe that this proposed removal date balances reporting burden while recognizing that HOPDs must use resources to modify information systems and reporting processes to discontinue reporting the measure.

In summary, we proposed to remove OP–33: External Beam Radiotherapy for Bone Metastases (NQF #1822) from the Hospital OQR Program beginning with the CY 2022 payment determination and for subsequent years under removal Factor 8.

We provided a summary of the comments received and our responses to those comments.

Comment: Many commenters supported the proposal to remove EBRT for Bone Metastases (OP–33) from the Hospital OQR Program beginning in CY 2022. Several commenters stated that they support the removal of OP–33 from the Hospital OQR Program for the reasons CMS outlined in the proposed rule. Specifically, several commenters stated that they support the removal of OP–33 from the Hospital OQR Program because the measure is burdensome and because it is no longer being maintained by the measure steward so it may no longer be aligned with clinical guidelines. A few commenters stated that they support the removal of OP–33 to align with the removal of the measure from PCHQR and because the measure is no longer endorsed by the National Quality Forum (NQF).

Response: We thank the commenters for their support to remove EBRT for Bone Metastases (OP–33) from the Hospital OQR Program due to burden and alignment issues. While NQF endorsement is not a requirement for measure inclusion in the Hospital OQR Program, it can be considered when assessing a measure (section 1833(t)(17)(C)(i) of the Act).

Comment: Several commenters requested that CMS clarify the last reporting date for EBRT for Bone Metastases (OP–33) if it is removed and recommended that removal should begin with January 1, 2020 encounters rather than October 2020 encounters. A few commenters requested that the removal of OP–33 begin with the Calendar Year 2021 payment determination rather than the Calendar Year 2022 payment determination due to the significant burden of the reporting requirements. One commenter recommended CMS to remove OP–33 as soon as possible.

Response: Regarding the timeframe for measure removal, in the CY 2020 OPPS/ASC proposed rule (84 FR 39554 through 39556), we proposed to remove OP–33: External Beam Radiotherapy for Bone Metastases (NQF #1822) from the Hospital OQR Program beginning with the CY 2022 payment determination and for subsequent years under removal Factor 8. We chose this timeframe to be sensitive to facilities' planning and operational procedures given that data collection for this measure began during CY 2019 for the CY 2021 payment determination. We realize that in our proposal on pages 84 FR 39554 through 39556, we inadvertently stated that we wished to remove the measure beginning with October 2020 encounters used in the CY 2022 payment determination and for subsequent years. We refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70521 through 70522) where we finalized that beginning with the CY 2017 payment determination, hospitals must report data submitted via a Web-based tool between January 1 and May 15 of the year prior to the payment determination with respect to the encounter period of January 1 to December 31 of 2 years prior to the payment determination year. For the CY 2022 payment determination, the data submission window for this measure would then be January 1, 2021 to May 15, 2021 for the January 1, 2020 through December 31, 2020 encounter period. Thus, as OP–33 is a Web-based measure, its removal from the Hospital OQR Program beginning with the CY 2022 payment determination would also begin with January 1, 2020 encounters rather than October 2020 encounters. So, we are finalizing a modification of what was proposed to correct that we are removing the measure beginning with January 2020 encounters used for the CY 2022 payment determination and for subsequent years. For the OP–33 measure, the final data submission of data collected for CY 2019 encounters will be required by May 15, 2020 for use toward CY 2021 payment determinations; hospitals would not be required to collect data for OP–33 as of January 1, 2020 encounters.

Comment: A few commenters expressed concern about the proposal to remove EBRT for Bone Metastases (OP–33) from the Hospital OQR Program. One commenter stated that the OP–33 measure gives valuable information for monitoring hospital performance improvement. One commenter stated that the OP–33 measure is valuable because it gauges overuse of health services in a setting where overuse exposes people unnecessarily to radiation, putting patients at risk of harm. This commenter stated that though one of the reasons provided for the removal of OP–33 is that it is difficult and burdensome for healthcare providers to report; the commenter recommends that CMS adopt a measurement framework that prioritizes consumer needs over industry preference. The commenter also stated that because the measure steward is no longer maintaining the measure, CMS should either continue to maintain the measure or identify an entity to act as the measure steward to allow the

[88] See language about measure steward no longer maintaining this measure in the FY 2020 IPPS/LTCH PPS proposed rule at 84 FR 19502 through 19503.

measure to remain in the Hospital OQR Program.

Response: We thank the commenters for these suggestions regarding EBRT for Bone Metastases (OP–33). We agree that ensuring appropriate use of EBRT and preventing the overuse of radiation therapy which were goals of the OP–33 measure are important for safeguarding patients and consumers. We proposed to remove OP–33 under removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program as stakeholder feedback has shown that this measure is burdensome and difficult to report. Regarding measure maintenance, as stated, the measure steward is no longer maintaining this measure and there are issues with the measure as specified. We do not seek to become the steward for this measure as we do not believe that we can maintain this measure in the Hospital OQR Program in a way that ensures that the measure is in line with clinical guidelines and standards and has specifications that are not overly burdensome for which to collect data. Our Meaningful Measures Initiative provides a measurement framework that prioritizes patient and consumer needs while limiting provider burden. Consistent with this framework, we note that the Hospital OQR Program continues to have quality measures that assess appropriate use of radiation (OP–8: MRI Lumbar Spine for Low Back Pain, OP–10: Abdomen CT—Use of Contrast Material, OP–13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery, and 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).

After consideration of the public comments, we are finalizing a modification of what was proposed for the removal of OP–33 from the Hospital OQR Program. Instead of removing the measure beginning with October 2020 encounters as inadvertently stated, we are finalizing removal beginning with January 2020 encounters used in the CY 2022 payment determination and for subsequent years.

4. Summary of Hospital OQR Program Measure Sets for the CY 2022 Payment Determination

We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59099 through 59102) for a summary of the previously finalized Hospital OQR Program measure sets for the CY 2020 and CY 2021 payment determinations and subsequent years.

We did not propose to add any measures; however, we did propose and are finalizing the removal of one measure for the CY 2022 payment determination and subsequent years for the Hospital OQR Program. Table 61 summarizes the finalized Hospital OQR Program measure set for the CY 2022 payment determination and subsequent years (including previously adopted measures and excluding one measure finalized for removal in this final rule).

TABLE 61.--Hospital OQR Program Measure Set for the CY 2022 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

TABLE 61.--Hospital OQR Program Measure Set for the CY 2022 Payment Determination and Subsequent Years

NQF #	Measure Name
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).

5. Hospital OQR Program Measures and Topics for Future Consideration

In the CY 2020 OPPS/ASC proposed rule (84 FR 39557), we requested comment on the potential future adoption of four patient safety measures as well as future outcome measures generally.

a. Request for Comment on the Potential Future Adoption of Four Patient Safety Measures

In the CY 2020 OPPS/ASC proposed rule (84 FR 39557) we sought comment on the potential future adoption of four patient safety measures for the Hospital OQR Program that were previously adopted for the ASCQR Program: ASC–1: Patient Burn; ASC–2: Patient Fall; ASC–3: Wrong Site, Wrong Side, Wrong Procedure, Wrong Implant; and ASC–4: All-Cause Hospital Transfer/Admission.[89] We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74497 through 74499), where we adopted these measures (referred to as NQF #0263, NQF #0266, NQF #0267, and NQF #0265 at the time) in the ASCQR Program. We note that data collection for these measures was suspended in the ASCQR Program due to concerns with their data submission method using quality data codes (QDCs) in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59117 through 59123; 59134 through 59135); however, we refer readers to section XV.B.5. of the CY 2020 OPPS/ASC proposed rule (84 FR 39567), in which the ASCQR Program requested public comment on updating the submission method for these measures in the future. We requested public comment on potentially adding these measures with the updated submission method using a CMS online data submission tool, to the Hospital OQR Program in future rulemaking. These measures are currently specified for the ASC setting. If specified for the hospital outpatient setting, we would seek collaboration with the measure steward.

We believe these measures could be valuable to the Hospital OQR Program because they would allow us to monitor these types of events and prevent their occurrence to ensure that they remain rare, and because they provide critical data to beneficiaries and further transparency for care provided in the outpatient setting that could be useful in choosing a HOPD. In addition, these measures address an important Meaningful Measure Initiative quality priority, Making Care Safer by Reducing Harm Caused in the Delivery of Care.[90] There has been broad stakeholder support for these measures in the ASC setting; stakeholders believe these measures provide important data for facilities and patients because they are serious and the occurrence of these events should be zero (83 FR 59118). A few commenters noted in the CY 2019 OPPS/ASC final rule with comment period that it would be beneficial to also include these ASCQR Program measures in the Hospital OQR Program in order to provide patients with more meaningful data to compare sites of service (83 FR 59119). The future addition of these measures would further align the Hospital OQR and ASCQR Programs, which would benefit patients because these are two outpatient settings that patients may be interested in comparing, especially if they are able to choose in which of these two settings they receive care.

Although NQF endorsement for these ASC measures was removed (in February 2016 for the All-Cause Hospital Transfer/Admission measure;[91] in May 2016 for the Patient

[89] ASCQR Specifications Manual, discussing these measures, available at: *http://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228772475754.*

[90] Centers for Medicare & Medicaid Services. Meaningful Measures Hub. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html.*

[91] National Quality Forum. 0265 All-Cause Hospital Transfer/Admission. Available at: *http://www.qualityforum.org/QPS/0265.*

Burn [92] and the Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant [93] measures; and in June 2018 for the Patient Fall measure [94]), as one commenter pointed out in the CY 2019 OPPS/ASC final rule with comment period, the NQF endorsement of the ASC measures was removed as endorsement was allowed to lapse by the measure steward, not because they failed the endorsement maintenance process (83 FR 59119). If specified for the HOPD setting, we plan to coordinate with the measure steward to seek NQF endorsement for those measures. These measures are discussed in more detail below.

(1) Patient Burn

The ASCQR Patient Burn measure assesses the percentage of admissions experiencing a burn prior to discharge. The numerator for this measure is defined as ASC admissions experiencing a burn prior to discharge and the denominator is defined as all ASC admissions.[95] We believe this measure, if specified for the hospital outpatient setting, would allow HOPDs, Medicare beneficiaries, and other stakeholders to develop a better understanding of the incidence of these events. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74497 through 74498), we adopted this measure for the ASCQR Program because ASCs serve surgical patients who may face the risk of burns during ambulatory surgical procedures and we believe monitoring patient burns is valuable to patients and other stakeholders. HOPDs also serve surgical patients who may face the risk of burns during outpatient procedures, so we believe this measure would be valuable for the HOPD setting. Further, we have reviewed studies demonstrating the high impact of monitoring patient burns because patient burns are serious reportable events in healthcare [96] and because patient burns are preventable.[97] [98]

(2) Patient Fall

The ASCQR Program Patient Fall measure assesses the percentage of admissions experiencing a fall. The numerator for this measure is defined as ASC admissions experiencing a fall within the confines of the ASC and excludes ASC admissions experiencing a fall outside the ASC. The denominator is defined as all ASC admissions and excludes ASC admissions experiencing a fall outside the ASC.[99] We believe this measure, if specified for the hospital outpatient setting, would enable HOPDs to take steps to reduce the risk of falls. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74498), we adopted this measure for the ASCQR Program because falls, particularly in the elderly, can cause injury and loss of functional status; because the use of anxiolytics, sedatives, and anesthetic agents may put patients undergoing outpatient surgery at increased risk for falls; and because falls in healthcare settings can be prevented through the assessment of risk, care planning, and patient monitoring. These same risks for patient falls are a concern in the HOPD setting. Further, we have reviewed studies demonstrating the high impact of monitoring patient burns because patient falls are serious reportable events in healthcare [100] and because patient falls are preventable.[101]

(3) Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant

The ASCQR Program Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant measure assesses the percentage of admissions experiencing a wrong site, wrong side, wrong patient, wrong procedure, or wrong implant. The numerator for this measure is defined as ASC admissions experiencing a wrong site, a wrong side, a wrong patient, a wrong procedure, or a wrong implant, and the denominator is defined as all ASC admissions.[102] We believe this measure, if specified for the hospital outpatient setting, would provide important HOPD information about surgeries and procedures performed on the wrong site/side, and wrong patient. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74498 through 74499), we adopted this measure for the ASCQR Program because surgeries and procedures performed on the wrong site/side, and wrong patient can result in significant impact on patients, including complications, serious disability or death. We also stated that while the prevalence of such serious errors may be rare, such events are considered serious reportable events. These same significant impacts on patients apply for the HOPD setting. Further, we have reviewed studies demonstrating the high impact of monitoring wrong site, wrong side, wrong patient, wrong procedure, wrong implant procedures and surgeries because these types of errors are serious reportable events in healthcare [103] and because these errors are preventable.[104]

(4) All-Cause Hospital Transfer/Admission

The All-Cause Hospital Transfer/Admission measure assesses the rate of admissions requiring a hospital transfer or hospital admission upon discharge. The numerator for this measure is defined as ASC admissions requiring a hospital transfer or hospital admission upon discharge from the ASC and the denominator is defined as all ASC admissions.[105] We believe this measure, if specified for the hospital outpatient setting, would be valuable for HOPDs. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74499), we adopted this measure for ASCs because the transfer or admission of a surgical patient from an outpatient setting to an acute care setting can be an indication of a complication, serious medical error,

[92] National Quality Forum. 0263 Patient Burn. Available at: *http://www.qualityforum.org/QPS/0263*.

[93] National Quality Forum. 0267 Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant. Available at: *http://www.qualityforum.org/QPS/0267*.

[94] National Quality Forum. 0266 Patient Fall. Available at: *http://www.qualityforum.org/QPS/0266*.

[95] ASC Quality Collaboration. Quality measures developed and tested by the ASC Quality Collaboration. Available at: *http://ascquality.org/documents/2019-Summary-ASC-QC-Measures.pdf*.

[96] National Quality Forum. Serious Reportable Events in Healthcare 2006 Update. Washington, DC: NQF, 2007. Available at: *https://www.qualityforum.org/Publications/2007/03/Serious_Reportable_Events_in_Healthcare%E2%80%932006_Update.aspx*.

[97] ECRI Institute. New clinical guide to surgical fire prevention. Health Devices 2009 Oct;38(10):314–32.

[98] 170. National Fire Protection Association (NFPA). NFPA 99: Standard for health care facilities. Quincy (MA): NFPA; 2005.

[99] ASC Quality Collaboration. Quality measures developed and tested by the ASC Quality Collaboration. Available at: *http://ascquality.org/documents/2019-Summary-ASC-QC-Measures.pdf*.

[100] National Quality Forum. Serious Reportable Events in Healthcare—2006 Update: A Consensus Report. March 2007. Available at: *https://www.qualityforum.org/Publications/2007/03/Serious_Reportable_Events_in_Healthcare%E2%80%932006_Update.aspx*.

[101] Boushon B, Nielsen G, Quigley P, Rutherford P, Taylor J, Shannon D. Transforming Care at the Bedside How-to Guide: Reducing Patient Injuries from Falls. Cambridge, MA: Institute for Healthcare Improvement; 2008.

[102] ASC Quality Collaboration. Quality measures developed and tested by the ASC Quality Collaboration. Available at: *http://ascquality.org/documents/2019-Summary-ASC-QC-Measures.pdf*.

[103] National Quality Forum. Serious Reportable Events in Healthcare—2006 Update: A Consensus Report. March 2007. Available at: *https://www.qualityforum.org/Publications/2007/03/Serious_Reportable_Events_in_Healthcare%E2%80%932006_Update.aspx*.

[104] American College of Obstetricians and Gynecologists. ACOG committee opinion #464: patient safety in the surgical environment. Obstet Gynecol. 2010;116(3):786–790.

[105] ASC Quality Collaboration. Quality measures developed and tested by the ASC Quality Collaboration. Available at: *http://ascquality.org/documents/2019-Summary-ASC-QC-Measures.pdf*.

or other unplanned negative patient outcome. We also stated that while acute intervention may be necessary in these circumstances, a high rate of such incidents may indicate suboptimal practices or patient selection criteria. These same potential negative patient outcomes apply to the HOPD setting. Further, we have reviewed studies demonstrating the high impact of monitoring patient transfers and admissions because facilities can take steps to prevent and reduce these types of events.[106] [107]

We have provided a summary of the comments received and our responses to those comments.

Comment: Many commenters were supportive of the potential future specification of ASC–1, ASC–2, ASC–3, and ASC–4 for the hospital outpatient setting and the potential future addition of these measures to the Hospital OQR Program. Several commenters stated that these four measures should be adopted in the Hospital OQR Program in order to align with the ASCQR Program and to provide meaningful data for patients to compare performance in ASCs and HOPDs. A few commenters stated that these four patient safety measures should be adopted in the Hospital OQR Program because they focus on areas of critical importance. A few commenters supported the plan for CMS to work with the measure developer to improve the data submission methods and to ensure the measures are appropriately specified for the hospital outpatient setting. A few commenters recommended expedited development and implementation of these measures in the hospital outpatient setting.

Response: We thank the commenters for their support for the potential future specification of ASC–1, ASC–2, ASC–3, and ASC–4 for the hospital outpatient setting and the potential future addition of these measures to the Hospital OQR Program.

Comment: Many commenters provided recommendations regarding potentially specifying ASC–1, ASC–2, ASC–3, and ASC–4 for the hospital outpatient setting and potentially adding these measures to the Hospital OQR Program in the future. Several commenters stated that decisions made by the NQF about these measures should be considered and prioritized by CMS. Several commenters suggested that these measures should be specified for the HOPD setting, field tested, reliability tested, and reviewed by the Measure Applications Partnership (MAP) before inclusion in the Hospital OQR Program. Several commenters suggested that, with respect to ASC–4, CMS should consider overlap with OP–36 Hospital Visits after Hospital Outpatient Surgery and should assess the need for clinical risk adjustment in the HOPD setting. A few commenters provided recommendations about potential data submission methods for these measures in the Hospital OQR Program, with some specifically supporting the use of an online data submission tool such as QualityNet. However, several commenters did not support using the QualityNet online tool (or a similar online tool) for submission, and one commenter suggested that if a manual abstraction process is required, hospitals should be provided ample time to test and implement the measures. One commenter recommended that CMS work with HOPDs and ASCs to identify current forums where these safety issues are documented, discussed, and remedied. One commenter recommended that these measures should apply to all adult patients, not just Medicare fee-for-service patients.

Response: We thank the commenters for their recommendations regarding potentially specifying ASC–1, ASC–2, ASC–3, and ASC–4 for the hospital outpatient setting, interface with existing ASCQR Program measures, data submission methods, risk adjustment issues, and potentially adding these measures to the Hospital OQR Program in the future. We note that as currently specified, these measures apply to all patients and they are not limited to fee-for-service Medicare patients.[108]

Comment: Many commenters expressed concern to the potential future specification of ASC–1, ASC–2, ASC–3, and ASC–4 for the hospital outpatient setting and the potential future addition of these measures to the Hospital OQR Program. Several expressed concern that the measures are not endorsed by the National Quality Forum. A few commenters stated that they believe because these measures were designed specifically for ASCs, they would not be appropriate for use in the hospital outpatient setting. Several commenters expressed concern about adding these measures to the Hospital OQR Program because the events of interest are already rare, and a few pointed out that hospitals are already required to implement policies and processes to mitigate the risk of these events and several states have mandatory reporting of these types of events. A few commenters stated concerns about the burden that would be created if these measures are added to the Hospital OQR Program. One commenter stated that because these events are rare in the outpatient setting, the data is at risk of becoming identifiable if disclosed and publicly reported. One commenter stated that adding these measures to the Hospital OQR Program would not contribute to the CMS Meaningful Measurement goal.

Response: We thank the commenters for their recommendations and raising these important concerns regarding the use of the ASC–1 through ASC–4 measures for the Hospital OQR Program. We will take these suggestions into consideration as we consider adding these measures to the Hospital OQR Program in the future.

b. Future Outcome Measures

In the CY 2020 OPPS/ASC proposed rule (84 FR 39558), we also requested public comment on future measure topics for the Hospital OQR Program. Specifically, we requested public comment on any outcome measures that would be useful to add as well as feedback on any process measures that should be eliminated from the Hospital OQR Program to further our goal of developing a comprehensive set of quality measures for informed decision-making and quality improvement in HOPDs. We are moving towards greater use of outcome measures and away from use of clinical process measures across our Medicare quality reporting programs to better assess the results of care. The current measure set for the Hospital OQR Program includes measures that assess process of care, imaging efficiency patterns, care transitions, (Emergency Department) ED throughput efficiency, Health Information Technology (health IT) use, care coordination, and patient safety. Measures are of various types, including those of process, structure, outcome, and efficiency. Through future rulemaking, we intend to propose new measures that support our goal of achieving better health care and improved health for Medicare beneficiaries who receive health care in the HOPD setting, while aligning quality measures across the Medicare program to the extent possible.

[106] Coley KC, Williams BA, DaPos SV, Chen C, Smith RB. Retrospective evaluation of unanticipated admissions and readmissions after same day surgery and associated costs. J Clin Anesth. 2002 Aug; 14(5):349–53.

[107] Junger A, Klasen J, Benson M, Sciuk G, Hartmann B, Sticher J, Hempelmann G. Factors determining length of stay of surgical day-case patients. Eur J Anaesthesiol. 2001 May;18(5):314–21.

[108] ASCQR Specifications Manuals are available at *https://www.qualitynet.org/asc/specifications-manuals.*

Comment: A few commenters recommended that CMS add more measures to the Hospital OQR Program that would align with the ASCQR Program. One commenter suggested that CMS incorporate patient experience, safety and reliability, clinical quality, and provider engagement measures in the Hospital OQR Program. One commenter recommended that CMS include the Adult Immunization Status measure in the Hospital OQR Program.

Response: We thank the commenters for these recommendations for additional measures for the Hospital OQR Program. We agree that alignment with the ASCQR Program is an important consideration; to that end, as discussed in section XIV.B.a of this final rule with comment period, we requested comment on the use of the ASCQR Program's ASC–1 through ASC–4 measures for the Hospital OQR Program.

We thank the commenters for their responses and will take these suggestions into consideration as we develop future Hospital OQR Program measures and topics.

6. 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 for 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 in the CY 2020 OPPS/ASC proposed rule (84 FR 39558).

7. Public Display of Quality Measures

We refer readers to the CY 2014 and CY 2017 OPPS/ASC final rules with comment period (78 FR 75092 and 81 FR 79791 respectively) for our previously finalized policies regarding public display of quality measures. In the CY 2020 OPPS/ASC proposed rule (84 FR 39558), we did not propose any changes to our previously finalized public display policies.

C. Administrative Requirements

1. QualityNet Account and Security Administrator

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 42 CFR 419.46(a) in that final rule with comment period. We did not propose any changes to our requirements for the QualityNet account and security administrator in the CY 2020 OPPS/ASC proposed rule (84 FR 39559).

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 42 CFR 419.46(a) and (b). We did not propose any changes to our participation status policies in the CY 2020 OPPS/ASC proposed rule (84 FR 39559).

D. Form, Manner, and Timing of Data Submitted for the Hospital OQR Program

1. Hospital OQR Program Annual Payment Determinations

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75110 through 75111) and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70519 through 70520), we specified our data submission deadlines. We codified these submission requirements at 42 CFR 419.46(c).

We refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70519 through 70520), where we finalized our proposal to shift the quarters upon which the Hospital OQR Program payment determinations are based beginning with the CY 2018 payment determination. The deadlines for the CY 2022 payment determination and subsequent years are illustrated in Table 62.

TABLE 62.--CY 2022 Payment Determination and Subsequent Years

Patient Encounter Quarter	Clinical Data Submission Deadline
Q2 2020 (April 1 - June 30)	11/1/2020
Q3 2020 (July 1 – September 30)	2/1/2021
Q4 2020 (October 1 - December 31)	5/1/2021
Q1 2021 (January 1 - March 31)	8/1/2021

In the CY 2018 OPPS/ASC final rule with comment period, we finalized a policy to align the initial data submission timeline for all hospitals that did not participate in the previous year's Hospital OQR Program and made conforming revisions at 42 CFR 419.46(c)(3). We did not propose any changes to these policies in the CY 2020 OPPS/ASC proposed rule (84 FR 39559).

2. Requirements for Chart-Abstracted Measures Where Patient-Level Data Are Submitted Directly to CMS for the CY 2022 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 in the CY 2020 OPPS/ASC proposed rule (84 FR 39559).

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 2022 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 in the CY 2020 OPPS/ASC proposed rule (84 FR 39559).

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 2022 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. In the CY 2020 OPPS/ASC proposed rule (84 FR 39560), 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) and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70521) and the CMS QualityNet website (*https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1205442125082*) for a discussion of the requirements for measure data submitted via the CMS QualityNet website 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. In the CY 2020 OPPS/ASC proposed rule (84 FR 39560), we did not propose any changes to our policies regarding the submission of measure data submitted via a web-based tool. However, as discussed in section XIV.B.3.b. of this final rule, we are finalizing our proposal with modification to remove OP–33: EBRT for Bone Metastases beginning with the CY 2022 payment determination and for subsequent years; so the following previously finalized quality measures will require data to be submitted via a web-based tool for the CY 2022 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) (via CMS' QualityNet website);
- OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658) (via CMS' QualityNet website); and
- OP–31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536) (via CMS' QualityNet website).

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 our population and sampling requirements for chart-abstracted measures in the CY 2020 OPPS/ASC proposed rule (84 FR 39560).

7. Hospital OQR Program Validation Requirements

We refer readers to 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 42 CFR 419.46(e) for our policies regarding validation. We did not propose any changes to these policies in the CY 2020 OPPS/ASC proposed rule (84 FR 39560).

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 our ECE policy in the CY 2020 OPPS/ASC proposed rule (84 FR 39560).

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 42 CFR 419.46(f) for our reconsideration and appeals procedures. We did not propose any changes to our reconsideration and appeals procedures in the CY 2020 OPPS/ASC proposed rule (84 FR 39560).

E. Payment Reduction for Hospitals That Fail To Meet the Hospital OQR Program Requirements for the CY 2020 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).

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 proposed rule.

2. Reporting Ratio Application and Associated Adjustment Policy for CY 2020

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 2020 annual payment update factor. For the CY 2020 OPPS/ASC proposed rule (84 FR 39560), the proposed reporting ratio was 0.980, which when multiplied by the proposed full conversion factor of $81.398 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 $79.770. We proposed to continue to apply the reporting ratio to all services calculated using the OPPS conversion factor. For the CY 2020 OPPS/ASC proposed rule (84 FR 39560), we proposed 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.

For the CY 2020 OPPS/ASC final rule, the final reporting ratio is 0.981, which when multiplied by the final full conversion factor of 80.784 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 79.250. We also are finalizing the remainder of our proposals regarding the payment reduction for hospitals that fail to meet the Hospital OQR Program requirements for CY 2019 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 this final rule with comment period 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 discuss our Meaningful Measures Initiative and our approach in 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 seek to promote higher quality and more efficient health care for beneficiaries. This effort is supported by the adoption of widely accepted quality of care measures. We have collaborated with relevant stakeholders to define such measures in most healthcare settings and currently measure some aspect of care for almost all settings of care available to Medicare beneficiaries. These measures assess structural aspects of care, clinical processes, patient experiences with care, and clinical outcomes. We have implemented quality measure reporting programs for multiple healthcare settings. To measure the quality of ASC services and to make such information publicly available, we implemented the ASCQR Program. We refer readers to the CYs 2014 through 2019 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; and 83 FR 59110 through 59139, 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).

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 ASCQR Program quality measure selection. We did not propose any changes to these policies in the CY 2020 OPPS/ASC proposed rule (84 FR 39562).

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 they 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 in the CY 2020 OPPS/ASC proposed rule (83 FR 39562).

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 [109] and the process for removing measures from the ASCQR Program. The factors are:

- Factor 1. Measure performance among ASCs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped-out'' measures).
- Factor 2. Performance or improvement on a measure does not result in better patient outcomes.
- Factor 3. A measure does not align with current clinical guidelines or practice.
- Factor 4. The availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic.
- Factor 5. The availability of a measure that is more proximal in time to desired patient outcomes for the particular topic.
- Factor 6. The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic.
- Factor 7. Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.

[109] We note that we previously referred to these factors as ''criteria'' (for example, 79 FR 66967 through 66969); we now use the term ''factors'' in order to align the ASCQR Program terminology with the terminology we use in other CMS quality reporting and pay-for-performance (value-based purchasing) programs.

• Factor 8. The costs associated with a measure outweigh the benefit of its continued use in the 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.

3. Proposal to Adopt ASC–19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers (NQF #3357) for the ASCQR Program Measure Set

In the CY 2020 OPPS/ASC proposed rule (84 FR 39562 through 39567), we proposed one new quality measure for the ASCQR Program for the CY 2024 payment determination and subsequent years; ASC–19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers (NQF #3357).

a. Background

Ambulatory surgery in the outpatient setting is common in the United States. Nearly 70 percent of all surgeries in the United States are performed in an outpatient setting with an expanding number and variety of procedures being performed at stand-alone ASCs.[110] [111] General surgery procedures are commonly performed at ASCs. Based on an analysis of Medicare fee-for-service (FFS) claims for patients aged 65 years and older, from January 1, 2015 through December 31, 2015, 3,251 ASCs performed 149,468 general surgery procedures. These procedures include abdominal, alimentary tract, breast, skin/soft tissue, wound, and varicose vein stripping procedures. Of the 3,251 ASCs that performed general surgery procedures, 1,157 (35.5 percent) performed at least 25 such procedures during this time period. Because of the large number of general surgery procedures that occur in the ambulatory setting, we believe that adopting ASC–19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers in the ASCQR Program will provide beneficiaries with transparent quality data that can be utilized in choosing healthcare facilities.

While ambulatory surgery is considered low risk for complications, there are well-described and potentially preventable adverse events that can occur after ambulatory surgery leading to unplanned care at a hospital, such as emergency department (ED) visits, observation stays, or hospital admissions. These events include uncontrolled pain, urinary retention, infection, bleeding, and venous thromboembolism.[112] [113]

Hospital visits following same-day surgery are an important and broadly accepted patient-centered outcome reported in the literature.[114] [115] [116] [117] [118] [119] [120] [121] National estimates of hospital visit rates following outpatient surgery vary from 0.5 to 9.0 percent, based on the type of surgery, outcome measured (admissions alone or admissions and ED visits), and length of time between the surgery and the hospital visit.[122] [123] [124] [125] [126] [127] [128] [129] [130] The frequency of such events also varies among ASCs, suggesting variation in quality of pre-surgical assessment, surgical care, post-surgical care, and the care and support provided to patients post-discharge.[131] [132] [133] [134] [135] [136] [137] [138]

We calculated the national unadjusted rate of hospital visits (ED visits, observation stays, or hospital admissions) following any general surgery procedure at an ASC. In a Medicare FFS dataset of claims for services during CY 2015 (January 1, 2015–December 31, 2015), the distribution of unadjusted outcome rates was skewed, suggesting variation in quality of care. Among 1,153 ASCs with at least 25 qualifying general surgery cases in the Medicare FFS CY 2015 dataset, the unadjusted rate of unplanned hospital visits ranged from

[110] Cullen KA, Hall MJ, Golosinskiy A, Statistics NCfH. *Ambulatory surgery in the United States, 2006.* US Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics; 2009.

[111] Medicare Payment Advisory Committee. Report for the Congress: Medicare Payment Policy, March 2019. *http://medpac.gov/docs/default-source/reports/mar19_medpac_entirereport_sec.pdf?sfvrsn=0.* Accessed May 24, 2019.

[112] Coley KC, Williams BA, DaPos SV, Chen C, Smith RB. Retrospective evaluation of unanticipated admissions and readmissions after same day surgery and associated costs. *Journal of clinical anesthesia.* 2002;14(5):349–353.

[113] Bain J, Kelly H, Snadden D, Staines H. Day surgery in Scotland: Patient satisfaction and outcomes. *Quality in Health Care.* 1999;8(2):86–91.

[114] Majholm BB. Is day surgery safe? A Danish multicentre study of morbidity after 57,709 day surgery procedures. Acta anaesthesiologica Scandinavica. 2012;56(3):323–331.

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0.0 percent to 13.2 percent. These results suggest opportunity for ASCs to improve the quality of care for patients seeking general surgery procedures.

ASCs may be unaware of patients' subsequent unplanned hospital visits given that patients tend to present to the ED or to hospitals unaffiliated with the ASC. In addition, information on the rate of patients' subsequent unplanned hospital visits would provide transparent data to beneficiaries that could be utilized when choosing ambulatory surgery sites of care. Quality measurement of the number of unplanned hospital visits following general surgery procedures performed at ASCs, coupled with transparency through public reporting would make these outcomes more visible to both ASCs and beneficiaries. Therefore, we expect that this would encourage ASCs to incorporate quality improvement activities to reduce the number of unplanned hospital visits and track quality improvement over time.

Therefore, in the CY 2020 OPPS/ASC proposed rule (84 FR 39562 through 39567), we proposed to adopt ASC–19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers (NQF #3357) (hereafter referred to as the proposed ASC–19 measure) into the ASCQR Program for the CY 2024 payment determination and subsequent years.

The proposed ASC–19 measure was developed in conjunction with two other measures adopted for the ASCQR Program beginning with the CY 2022 payment determination as finalized in the CY 2018 OPPS/ASC final rule with comment period: ASC–17: Hospital Visits After Orthopedic Ambulatory Surgical Center Procedures (82 FR 59455) and ASC–18: Hospital Visits After Urology Ambulatory Surgical Center Procedures (82 FR 59463). All three measures assess the same patient outcome for care provided in the ASC setting and use the same risk-adjustment methodology. These three measures differ in surgical procedures considered (orthopedic, urological, or general surgery), specific risk variables included, and reporting of the outcome, unplanned hospital visits. The proposed ASC–19 measure reports the outcome as a risk-standardized ratio because the diverse mix of procedures included in the proposed ASC–19 measure can have varying levels of risk of unplanned hospital visits; while the ASC–17 and ASC–18 measures report a risk-standardized rate that reflects clinically specific cohorts with fairly comparable mixes of procedures. We refer readers to section XV.B.3.d. of this final rule with comment period for a full discussion on the measure outcome calculation.

b. Overview of Measure

The proposed ASC–19 measure is a risk-adjusted outcome measure of acute, unplanned hospital visits within 7 days of a general surgery procedure performed at an ASC among Medicare FFS patients aged 65 years and older. We define an unplanned hospital visit as including an ED visit, observation stay, or unplanned inpatient admission. The measure aligns with the Admissions and Readmissions to Hospitals and Preventable Healthcare Harm Meaningful Measure areas of our Meaningful Measures Initiative.[139] This measure was developed with input from a national Technical Expert Panel (TEP) consisting of patients, surgeons, methodologists, researchers, and providers. We also held a three-week public comment period soliciting stakeholder input on the measure methodology, and publicly posted a summary of the comments received as well as our responses (available in the Downloads section at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods.html*).

During the measure development public comment period, we received public comment recommending the removal of two specific procedures (CPT 29893 endoscopic plantar and CPT 69222 clean out mastoid cavity) deemed outside the scope of general surgery and to review the cohort procedure list with general surgeons to ensure appropriateness. In response to this feedback, we reviewed the cohort of procedures incorporating feedback from general surgeons and removed 15 individual skin/soft tissue and wound procedure codes from the measure that are outside the scope of general surgery practice. These procedures include those specifically suggested for removal (that is, endoscopic plantar and clean out mastoid cavity) as well as chemical peels, dermabrasions, and nerve procedures.

Section 1890A of the Act requires the Secretary to establish a pre-rulemaking process with respect to the selection of certain categories of quality and efficiency measures. Under section 1890A(a)(2) of the Act, the Secretary must make available to the public by December 1 of each year a list of quality and efficiency measures that the Secretary is considering. The ASC–19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers measure was included on a publicly available document entitled ''List of Measures under Consideration for December 1, 2017.'' [140] The Measures Applications Partnership (MAP) reviewed this measure (MUC17–233) and provided conditional support for rulemaking, pending NQF review and endorsement, with the recognition that this measure assesses an important outcome for patients receiving care at ASCs.[141] The MAP had some concerns about the attribution model of the measure, noting that hospital visits after ASC procedures are relatively rare events and could disproportionately affect low-income or rural ASCs and that the measure may need risk adjustment for social risk factors. At the time of the MAP's review, this measure was still undergoing field testing.

Since the MAP's conditional support,[142] we completed testing for the proposed ASC–19 measure by estimating risk-standardized scores using two full years of Medicare FFS claims data (CYs 2014 and 2015) containing 286,999 procedures. The results showed score variation across ASCs, from a minimum risk-standardized ratio of 0.42 to a maximum of 2.13; the median was 0.97 and the 25th and 75th percentiles were 0.90 and 1.10, respectively. After adjusting for case and procedure mixes of ASCs, these results suggest there are underlying differences in the quality of care and opportunities for quality improvement. The reliability testing found an intraclass correlation coefficient (ICC) score of 0.530, indicating moderate measure score reliability.[143] We considered the face validity of the measure score among TEP members. Among the 14 TEP members, 12 agreed that the measure scores are valid and useful measures of ASC quality of care for general surgery procedures and will provide ASCs with information that can be used to improve their quality of care. Detailed testing results are available in the technical report for this measure, located at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-*

[139] 83 FR 58820 through 58822.

[140] National Quality Forum. List of Measures under Consideration for December 1, 2017. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86526.*

[141] National Quality Forum. MAP 2018 Considerations for Implementing Measures: Hospitals—Final Report. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=87096.*

[142] Ibid.

[143] Landis JR, Koch GG. The Measurement of Observer Agreement for Categorical Data. *Biometrics.* 1977;33(1):159–174.

Instruments/HospitalQualityInits/Measure-Methodology.html.

On June 6, 2018, the NQF's Consensus Standards Approval Committee endorsed ASC–19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers (NQF #3357).[144] The proposed ASC–19 measure is consistent with the information submitted to the NQF and the MAP, supporting its scientific acceptability for use in quality reporting programs. We note that we have made minor annual coding updates to the measure to incorporate changes to the CPT and ICD–10 coding systems and to incorporate clinical input to remove select procedures outside the scope of general surgery as noted above, endoscopic plantar, clean out mastoid cavity, chemical peels, dermabrasions, and nerve procedures. For the current list of codes that define the proposed ASC–19 measure and a description of updates since development, we refer readers to the zip file labeled ''Version 1.0 Hospital Visits General Surgery ASC Procedures Measure Technical Report'' located at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

We believe this proposed measure reflects consensus among stakeholders because it was developed with stakeholder input from a TEP convened by a CMS contractor as well as from the measure development public comment period.[145] During the measure development processes and the MAP meeting, the majority of public commenters supported the measure's focus on assessing patient outcomes after general surgery procedures performed in ASC setting of care. Most commenters supported MAP's conditional support of the measure, noting it should be further developed and NQF-endorsed before implementation in the ASCQR Program. Importantly, the proposed ASC–19 measure addresses the MAP-identified priority measure area of addressing preventable healthcare harm, such as surgical complications, for the ASCQR Program.[146] Therefore, we believe it is appropriate to incorporate this proposed measure into the ASCQR Program measure set because collecting and publicly reporting these data would increase transparency, inform patients and ASCs, and foster quality improvement efforts.

c. Data Sources

The proposed ASC–19 measure is claims-based using Part A and Part B Medicare administrative claims and Medicare enrollment data to calculate the measure.

In the CY 2020 OPPS/ASC proposed rule (84 FR 39562 through 39567), we proposed that the data collection period for the proposed ASC–19 measure would be the 2 calendar years ending 2 years prior to the applicable payment determination year. For example, for the CY 2024 payment determination, the data collection period would be CYs 2021 to 2022. Because the measure data are collected via claims, ASCs will not need to submit any additional data directly to CMS. We refer readers to section XV.D.4. of this final rule with comment period for a more detailed discussion of the requirements for data submitted via claims.

d. Measure Calculation

The measure outcome is all-cause, unplanned hospital visits within 7 days of any general surgery procedure performed at an ASC. For the purposes of this measure, ''hospital visits'' include emergency department visits, observation stays, and unplanned inpatient admissions. The outcome of hospital visits is limited to 7 days since existing literature suggests that the vast majority of adverse events after outpatient surgery occur within the first 7 days following the surgery.[147] [148] When there are two or more qualifying surgical procedures within a 7-day period, the measure considers all procedures as index procedures; however, the timeframe for outcome assessment is defined as the interval between procedures (including the day of the next procedure) and then 7 days after the last procedure.

The facility-level score is a risk-standardized hospital visit ratio (RSHVR), an approach that accounts for the clustering of patients within ASCs and variation in sample size across ASCs. The proposed ASC–19 measure reports the outcome as a risk-standardized ratio because the diverse mix of procedures included in the proposed measure can have varying levels of risk of unplanned hospital visits. The RSHVR is calculated as the ratio of the predicted to the expected number of unplanned hospital visits among ASC patients. For each ASC, the numerator of the ratio is the number of hospital visits predicted for the ASC's patients accounting for its observed rate, the number of the general surgery procedures performed at the ASC, the case-mix, and the surgical complexity mix. The denominator of the ratio is the number of hospital visits expected nationally given the ASC's case-mix and surgical complexity mix. To calculate an ASC's predicted-to-expected (P/E) ratio, the measure uses a two-level hierarchical logistic regression model. The log-odds of the outcome for an index procedure is modeled as a function of the patient demographic, comorbidity, procedure characteristics, and a random ASC-specific intercept. A ratio of less than one indicates the ASC facility's patients were estimated as having fewer post-surgical visits than expected compared to ASCs with similar surgical complexity and patients; and a ratio of greater than one indicates the ASC facility's patients were estimated as having more visits than expected. This approach is analogous to an observed-to-expected ratio, but the method accounts for within-facility correlation of the observed outcome and sample size differences, accommodates the assumption that underlying differences in quality across ASCs lead to systematic differences in outcomes, and is tailored to and appropriate for a publicly reported outcome measure as articulated in published scientific guidelines.[149] [150] [151] For more

[144] National Quality Forum. Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers. Available at: *http://www.qualityforum.org/QPS/3357.*

[145] National Quality Forum. ''MAP 2018 Considerations for Implementing Measures in Federal Programs: Hospitals.'' Report. 2017. Available at: *http://www.qualityforum.org/map/* under ''Hospitals—Final Report.''

[146] The Centers for Medicare and Medicaid Services Center for Clinical Standards and Quality. ''2018 Measures under Consideration List: Program-Specific Measure Needs and Priorities''. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Downloads/2018-CMS-Measurement-Priorities-and-Needs.pdf.* Accessed February 28, 2019.

[147] Fleisher LA, Pasternak LR, Herbert R, Anderson GF. Inpatient hospital admission and death after outpatient surgery in elderly patients: importance of patient and system characteristics and location of care. *Arch Surg.* 2004;139(1):67–72.

[148] Mattila K, Toivonen J, Janhunen L, Rosenberg PH, Hynynen M. Postdischarge symptoms after ambulatory surgery: First-week incidence, intensity, and risk factors. *Anesthesia and analgesia.* 2005;101(6):1643–1650.

[149] Krumholz HM, Brindis RG, Brush JE, et al. Standards for Statistical Models Used for Public Reporting of Health Outcomes An American Heart Association Scientific Statement From the Quality of Care and Outcomes Research Interdisciplinary Writing Group: Cosponsored by the Council on Epidemiology and Prevention and the Stroke Council Endorsed by the American College of Cardiology Foundation. Circulation. 2006;113(3):456–462.

[150] Normand S-LT, Shahian DM. Statistical and clinical aspects of hospital outcomes profiling. Statistical Science. 2007;22(2):206–226.

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information on measure calculations, we refer readers to: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

e. Cohort

The patient cohort for the proposed ASC–19 measure includes all Medicare beneficiaries ages 65 and older undergoing outpatient general surgery procedures at an ASC who have 12 prior months of Medicare FFS (Medicare Parts A and B) enrollment. The target group of procedures includes those that: (1) Are routinely performed at ASCs; (2) involve some increased risk of post-surgery hospital visits; and (3) are within the scope of general surgery training. These include the following types of procedures: Abdominal (for example, hernia repair), alimentary tract (for example, hemorrhoid procedures), breast (for example, mastectomies), skin/soft tissue (for example, skin grafting), wound (for example, incision and drainage of skin and subcutaneous tissue), and varicose vein stripping. The proposed ASC–19 measure does not include gastrointestinal endoscopy, endocrine, or vascular procedures, other than varicose vein procedures, because for these procedures, reasons for hospital visits are typically related to patients' underlying comorbidities.

The scope of general surgery overlaps with that of other specialties (for example, vascular surgery and plastic surgery). For this measure, we targeted surgeries that general surgeons are trained to perform with the understanding that other subspecialists may also be performing many of these surgeries at ASCs. Since the type of surgeon performing a particular procedure may vary across ASCs in ways that affect quality, the measure is neutral to surgeons' specialty training.

Procedures included in the measure cohort are on CMS' list of covered ASC procedures.[152] We developed this list to identify surgeries that have a low-to-moderate risk profile. Surgeries on the ASC list of covered procedures do not involve or require major or prolonged invasion of body cavities, extensive blood loss, major blood vessels, or care that is either urgent or life threatening. We annually review and update this list, which includes a transparent public comment submission and review process for addition and/or removal of procedures codes.[153] The current list is accessible in the Downloads section at: *https://www.cms.gov/medicare/medicare-fee-for-service-payment/ascpayment/11_addenda_updates.html.*

In addition, the measure includes only ''major'' and ''minor'' procedures, as indicated by the Medicare Physician Fee Schedule global surgery indicator (GSI) values of 090 and 010, respectively, to focus the measure only on the subset of surgeries on CMS' list of covered ASC procedures that impose a meaningful risk of post-procedure hospital visits. This list of GSI values is publicly available for CY 2015 at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1612-FC.html* (download PFS Addenda, Addendum B). Moreover, to identify the subset of ASC procedures within the scope of general surgery, we used the Clinical Classifications Software (CCS) developed by the Agency for Healthcare Research and Quality (AHRQ).[154] We identified and included CCS categories within the scope of general surgery, and only included individual procedures within the CCS categories at the procedure (CPT code) level if they were within the scope of general surgery practice. For more cohort details, we refer readers to the measure technical report located at: *https://www.cms.gov/medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

To ensure that all patients included under this measure have full data available for outcome assessment, the measure excludes patients who survived at least 7 days following general surgery procedures at an ASC, but were not continuously enrolled in Medicare FFS (Medicare Parts A and B) during the 7 days after surgery. There are no additional patient inclusion or exclusion criteria for the proposed ASC–19 measure. Additional methodology and measure development details are available at: *https://www.cms.gov/medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

f. Risk Adjustment

The statistical risk-adjustment model includes clinically relevant risk-adjustment variables that are strongly associated with risk of hospital visits within 7 days following ASC general surgery procedures. Accordingly, only comorbidities that convey information about the patient at that time or in the 12 months prior, and not complications that arise during the course of the index procedure, are included in the risk adjustment. The measure risk adjusts for age, 18 comorbidities, procedure type (abdomen vs. alimentary tract vs. breast vs. skin/soft tissue vs. wound vs. varicose vein), a variable for work Relative Value Units (RVUs) to adjust for surgical complexity, and an interaction term of procedure type and surgical complexity.[155]

To select the final set of variables for the risk-adjustment model, candidate risk variables were entered into logistic regression analyses[156] predicting the outcome of hospital visits within 7 days. To develop a parsimonious risk model, non-significant variables were iteratively removed from the model using a stepwise selection approach described by Hosmer and Lemeshow.[157] All variables significant at $p < 0.05$ were retained in the final model. We also tested interaction terms and retained those that were both significant at $p < 0.05$ and demonstrated a clinically plausible relationship to the outcome. Finally, after reviewing TEP and public comments, as well as the statistically selected variables for face validity, we settled upon the model variables. We retained one additional variable (opioid use) for the final risk model because experts advised it was an important risk predictor and expressed a strong preference for including it in the model even though it was not statistically selected. Additional details on risk model development and testing are available in the technical report at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

g. Public Reporting

We proposed that if the proposed ASC–19 measure is adopted, we would publicly report results only for facilities

[151] National Quality Forum. Measure Evaluation Criteria and Guidance for Evaluating Measures for Endorsement. 2015. Available at: *http://www.qualityforum.org/Measuring_Performance/Submitting_Standards/2015_Measure_Evaluation_Criteria.aspx.* Accessed July 26, 2016.

[152] Centers for Medicare and Medicaid Services. ''Ambulatory Surgical Center (ASC) Payment: Addenda Updates.'' Available at: *https://www.cms.gov/medicare/medicare-fee-for-service-payment/ascpayment/11_addenda_updates.html.*

[153] Ibid.

[154] Healthcare Cost and Utilization Project. *Clinical Classifications Software for Services and Procedures.* Available at: *https://www.hcup-us.ahrq.gov/toolssoftware/ccs_svcsproc/ccssvcproc.jsp.*

[155] S. Coberly. The Basics; Relative Value Units (RVUs). National Health Policy Forum. January 12, 2015. Available at: *http://www.nhpf.org/library/the-basics/Basics_RVUs_01-12-15.pdf.*

[156] Hosmer DW, Lemeshow S. Introduction to the logistic regression model. *Applied Logistic Regression, Second Edition.* 2000:1–30.

[157] Hosmer DW, Lemeshow S. Introduction to the logistic regression model. *Applied Logistic Regression, Second Edition.* 2000:1–30.

with sufficient case numbers to meet moderate reliability standards.[158] We would determine the case size cutoff for meeting moderate reliability standards by calculating reliability at different case sizes using the ratio of true variance to observed variance during the measure dry run (discussed below).[159] We would provide confidential performance data directly to all facilities including those which do not meet the criteria for sufficient case numbers for reliability considerations so that all facilities can benefit from seeing their measure results and individual patient-level outcomes. We believe that the measure will provide beneficiaries with information about the quality of care for general surgery procedures in the ASC setting. In addition, we believe that these performance data may help ASCs track their patient outcomes and provide information on their cases that facilities can use to improve quality of care.

h. Provision of Facility-Specific Information Prior to Public Reporting

If this proposed measure is finalized, we intend to conduct a dry run before the official data collection period or any public reporting. A dry run is a period of confidential reporting and feedback during which ASCs may review their dry run measure results, and in addition, further familiarize themselves with the measure methodology and ask questions. For the dry run, we intend to use the most current 2-year set of complete claims (usually 12 months prior to the start date) available at the time of dry run. For example, if the dry run began in June 2020, the most current 2-year set of data available would likely be July 2017 to June 2019. Because we use paid, final action Medicare claims, ASCs would not need to submit any additional data for the dry run. The dry run would generate confidential feedback reports for ASCs, including patient-level data indicating whether the patient had a hospital visit and, if so, the type of visit (emergency department visit, observation stay, or unplanned inpatient admission), the admitting facility, and the principal discharge diagnosis. Further, the dry run would enable ASCs to see their dry run measure results prior to the measure being implemented. General information about the dry run as well as confidential facility-specific reports would be made available for ASCs to review on their accounts at: *http://www.qualitynet.org.* We plan to continue to generate these reports for ASCs after we implement the proposed measure if it is finalized so ASCs can use the information to identify performance gaps and develop quality improvement strategies.

These confidential dry run results are not publicly reported and do not affect payment. We expect the dry run to take approximately 1 month to conduct, during which facilities would be provided the confidential report and the opportunity to review their performance and provide feedback to us. After the dry run, measure results would have a payment impact and would be publicly reported as discussed above beginning with the CY 2024 payment determination and for subsequent years.

We have provided a summary of the public comments and responses to those comments.

Comment: Several commenters supported the proposal to adopt ASC–19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers for the ASCQR Program beginning with the CY 2024 payment determination and for subsequent years. Some commenters noted that this measure will provide valuable information and does not add reporting burden.

Response: We thank the commenters for supporting the adoption of this measure for the ASCQR Program. We agree that measuring quality of care associated with procedures performed at ASCs within the scope of general surgery training will provide useful information for facilities as well as beneficiaries and other stakeholders while limiting facility burden.

Comment: One commenter recommended that we adopt the measure sooner than the CY 2024 payment determination. One commenter requested that dry run reports be provided as early as 2020 to allow sufficient time for ASCs to review their performance and ask questions. One commenter recommended that the dry run process include 2 months of data.

Response: We appreciate the commenters' input on the timing and data collection for the dry run and desires for earlier supply of their data, but we disagree that the measure should be adopted sooner. We note that the timeline proposed for implementation of this measure was to allow adequate time to conduct a dry run with at least 2 years of data and to collect data with sufficient reliability prior to the measure being used toward payment determinations and believe that the CY 2024 payment determination best fits these needs.

Comment: A few commenters expressed concern that because the measure assesses mainly skin and soft tissue procedures, it assesses only a small subset of the procedures performed in ASCs. One commenter recommended that several exclusions be removed to enable the measure to reflect more procedures.

Response: We thank commenters for their thoughtful evaluation of the cohort specifications of ASC–19. The intent of ASC–19 is to assess the quality of care for surgical procedures that (1) are routinely performed at ASCs, (2) involve risk of post-surgery hospital visits, and (3) are within the scope of general surgery training. The measure cohort includes a set of procedures informed by a group of clinical consultants and a national TEP consisting of patients, clinicians, methodologists, researchers, and providers.[160] To identify eligible ASC general surgery procedures, we first identified a list of procedures from Medicare's 2014 and 2015 ASC lists of covered procedures. This list of surgical procedures is publicly available at: *https://www.cms.gov/medicare/medicare-fee-for-service-payment/ascpayment/11_addenda_updates.html.* Using an existing, defined list of surgeries, rather than defining surgeries de novo, is useful for long-term measure maintenance.

Ambulatory procedures include a heterogeneous mix of non-surgical procedures, minor surgeries, and more substantive surgeries. The measure is not intended to include very low-risk (minor) surgeries or non-surgical procedures, which typically have a high volume and a very low adverse outcome rate. To focus the measure only on the subset of surgeries on Medicare's list of covered ASC procedures that impose a meaningful risk of post-procedure hospital visits; the measure includes only ''major'' and ''minor'' procedures, as indicated by the Medicare Physician Fee Schedule GSI values of 090 and 010, respectively.[52] The GSI code reflects the number of post-operative days that are included in a given procedure's global surgical payment and identifies surgical procedures of greater complexity and follow-up care.[161] This list of GSI values

[158] Ibid.

[159] Snijders TA, Bosker RJ. *Multilevel Analysis: An introduction to basic and advanced multilevel modeling.* SAGE Publications. 2000. London.

[160] Centers for Medicare & Medicaid Services. (2017). *2017 Measure Technical Report: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers.* Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

[161] Medicare Learning Network. (2018) *Global Surgery Booklet: United States, 2017.* Retrieved

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is publicly available for CY 2014 at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1600-FC.html* and for CY 2015 at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1612-FC.html* (download PFS Addenda, Addendum B).

To identify the final subset of ASC general surgery procedures to be included in the measure, we reviewed with general surgeons and TEP members the CCS categories of procedures developed by the AHRQ. We identified and included CCS categories within the scope of general surgery, and only included individual procedures within the CCS categories at the procedure (CPT® code) level if they were within the scope of general surgery practice. We did not include in the measure calculations, gastrointestinal endoscopy, endocrine, or vascular procedures, other than varicose vein procedures, because reasons for hospital visits are typically related to patients' underlying comorbidities.

The sole patient characteristic measure exclusion criterion is ''Medicare coverage: beneficiaries who survived at least 7 days, but without continuous enrollment in Medicare FFS Parts A and B in the 7 days after surgery;'' these beneficiaries are excluded to ensure all patients have full data available for outcome assessment.

We will continue to evaluate whether there are additional procedures that are clinically appropriate for inclusion or exclusion in the cohort definition as part of measure reevaluation.

Comment: One commenter expressed concern that for certain procedure categories (such as ''Other therapeutic procedures, hemic and lymphatic system'' and ''Lumpectomy, quadrantectomy of breast and Mastectomy'' procedures), the top 10 primary diagnoses include diagnoses that reflect patients' underlying condition rather than the quality of care received. This commenter expressed concern that facilities will be held accountable for these outcomes and recommended that the measure specifications be updated to ensure that these diagnoses are not to be used as quality signals or included in the measure results.

Response: We appreciate the commenter's review of the top diagnoses associated with a hospital visit within 7 days of general surgery procedures. Although the top reasons for hospitals visits are likely due to complications of care, as the commenter points out, some hospital visits post procedure may be due to a patient's underlying condition. As discussed in section XV.B.3.f. of this final rule with comment period, the measure is adjusted to account for variation in patients' underlying risk of using the hospital within 7 days of a procedure. Therefore, the measure score is designed to reflect differences in quality rather than differences in pre-procedure patient risk and we believe the measure specifications account for such primary diagnoses that reflect patients' underlying conditions.

Further, the measure is designed to include only unplanned inpatient admissions occurring after general surgery procedures performed at ASCs. For the purposes of this measure, a planned admission is defined as a non-acute admission for a scheduled procedure (for example, total hip replacement or cholecystectomy). Post-discharge admissions for an acute illness or for complications of care are never considered planned. In contrast, ''planned'' admissions are those scheduled in advance for anticipated medical treatment or procedures that must be provided in the inpatient setting. To identify admissions as planned or unplanned, we applied an algorithm previously developed for CMS's hospital readmission measures, the CMS Planned Readmission Algorithm Version 4.0.[162] In brief, the algorithm uses the procedure codes and principal discharge diagnosis codes on each hospital claim to identify admissions that are typically planned.[54] A few specific, limited types of care are always considered planned (for example, major organ transplant, rehabilitation, or maintenance chemotherapy).

For more information on the measure calculation in regard to planned versus unplanned admissions, we refer readers to: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

Comment: One commenter expressed concern that the reliability of the measure, which has an ICC of 0.530, is not adequate, due to the number of low-volume ASCs. The commenter stated that the reliability of a measure intended for public reporting should be at least ''substantial'' (ICC between 0.61 and 0.80). This commenter recommended that the minimum number of qualifying procedures be increased to improve reliability.

Response: We thank the commenter for their comment regarding reliability of the measure. We tested the reliability of the measure score by calculating the ICC. The ICC evaluates the agreement between the risk-standardized hospital visit ratios (RSHVRs) calculated in two randomly selected patient samples. Since we measured the underlying quality of general surgery procedures performed at the ASC using patient outcomes, we anticipated that two independent, random samples of patients from an ASC would generate scores that are similar. We calculated measure score reliability for a 2-year reporting period and found that the agreement between the two RSHVR values for each ASC was calculated for 2 years to be ICC [2,1] = 0.526, indicating moderate measure score reliability. Thus, we do not believe that it is necessary increase the minimum number of qualifying procedures for reliability purposes as we view the measure as having a sufficient level of reliability for adoption by the ASCQR Program.

In addition, the results of reliability testing for this measure are consistent with current ASCQR Program claims-based measures of hospital visits post-specified procedures in the ASC setting as well as with similar outcome measures endorsed by NQF; this measure was endorsed by NQF in June 2018. The measure evaluation criteria of NQF committees are considered to be rigorous and these committees typically require moderate or high reliability to achieve endorsement.

Comment: One commenter expressed concern that the risk adjusted outcome rates show little variability between ASCs and that as a result there is little opportunity for ASCs to use the data for quality improvement or for patients to discern differences in quality. The commenter expressed concern that the measure would be considered topped-out. Some commenters expressed concern that many ASCs will not meet the minimum volume threshold for the measure, because it covers such a specific range of procedures. A few commenters expressed concern that measure results will not be shared with ASCs until months after patient visits, which will limit the usefulness of the information.

from Centers for Medicare & Medicaid Services website: *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/GloballSurgery-ICN907166.pdf.*

[162] Horwitz, L.I., Grady, J.N., Cohen, D.B., Lin, Z., Volpe, M., Ngo, C.K., . . . Bernheim, S.M. (2015). Development and Validation of an Algorithm to Identify Planned Readmissions From Claims Data. *Journal of hospital medicine, 10*(10), 670–677. doi:10.1002/jhm.2416.

Response: We understand the commenters' concerns about the ability of ASC–19 to discern differences in quality of care; however, we believe the distribution of the estimates of the measure rates for individual facilities convey meaningful variation for discerning differences between facilities and for use in quality improvement efforts. As presented in the measure technical report using Medicare FFS CYs 2014 and 2015 data, we found that the facility RSHVR ranged from 0.42 to 2.13, with a median RSHVR of 0.97 (the 25th and 75th percentiles were 0.90 and 1.10, respectively) (measure technical report available in the Downloads section at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospital QualityInits/Measure-Methodology.html*).

As the commenter pointed out, the descriptive approach categorized few facilities as outliers; in our measure development calculations, we identified 15 ASCs that had better than the national average and 16 ASCs that performed worse than the national average. We believe this indicates few facilities are outliers, evidencing very high or very low measure rates. The approach to categorizing facility outliers is very conservative using 95 percent confidence interval estimates (indicating a 95 percent certainty that the range of values determined by the measure calculation contains the true mean of the population of facilities) to identify outliers so as to limit erroneously designating facilities as having extreme measure rates.

Regarding the specific range of procedures for this measure, as discussed previously in this section, we focused the measure only on the subset of surgeries on Medicare's list of covered ASC procedures that impose a meaningful risk of post-procedure hospital visits.

Regarding the concern that many small-volume ASCs will not meet the minimum criteria threshold for reporting; we have sought to include as many procedures on Medicare's list of covered ASC procedures that impose a meaningful risk of post-procedure hospital visits in the measure as possible that fit within the scope of general surgery practice. In a national Medicare FFS claims dataset for CY 2014 and 2015 that included 286,999 procedures,[52] 1,642 ASCs were found to be performing at least 25 procedures during the data collection time period; these 1,642 ASCs had facility measure scores ranging from 0.42 to 2.13, with a median RSHVR of 0.97 (the 25th and 75th percentiles were 0.90 and 1.10, respectively). Thus, we believe that the measure as specified utilizing 2 years of claims data provides sufficient numbers of ASCs meeting the minimum volume threshold.

These findings also show that based upon the variation in the measure, while measure rates could be considered high, they are not sufficiently unvarying to not distinguish between facilities and, thus, would not be considered ''topped out''. During measure development testing using a very conservative approach of a 95 percent confidence level, ASC–19 measure calculations identified 31 outliers and sufficient variation in the RSHVRs to distinguish facilities.

Irrespective of claim volumes, all facilities will receive reports with any detected cases with patient-level information to inform quality improvement activities. To support continuous improvement across the full distribution of performance scores, we typically provide measure scores and patient-level reports to facilities that indicate whether their patients had a hospital visit within 7 days, and the diagnoses and locations of visits, and intend to provide these reports to ASCs once ASC–19 is implemented. Facilities can use these data to reduce hospital visits for important procedure-related outcomes that may be preventable, including urinary retention, pain, nausea, vomiting, syncope, and other surgery-related complications.

We will continue to monitor the data used for measure score calculation prior to and during any implementation of the measure. We will continue our multiyear assessment to weigh the tradeoffs between having an adequate number of cases for the greatest number of facilities and ensure that data are timely and actionable.

Regarding the availability of data for ASC–19, our goal is to provide ASCs with the timeliest claims data available. The expedience of the Medicare claims submission and processing timelines provide constraints to the timeliness of measure production. We continue to investigate the timeliness of claims data in efforts to increase timeliness of measure production without compromising accuracy.

Comment: One commenter recommended that additional analyses be performed on high and low performing ASCs to determine if risk adjustment washes out differences and to determine what diagnoses were associated with ASCs that showed poor performance.

Response: We thank the commenter for their attention to risk adjustment for the measure. We agree that risk adjustment obscuring differences can be a concern. However, we believe the current approach to risk adjustment for the ASC–19 measure is appropriate. As part of our standard process for measure reevaluation, we will continue to monitor measure calculations as additional years of data become available.

Comment: Some commenters believed that the title of the measure, which refers to General Surgery Procedures, will mislead beneficiaries by suggesting that the score reflects the practice of general surgery. One commenter recommended clarifying the name of the measure to specify ''abdominal, alimentary tract, breast, skin/soft tissue, wound, and varicose vein stripping procedures''. A few commenters expressed concern that the measure name, Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers, inaccurately suggests that it is assessing hospital visits that are 7 days in duration. Commenters recommended that the name be clarified.

Response: We appreciate the commenters' thoughtful recommendations for the measure title. We agree that it is important for the measure title to accurately reflect the focus of the measure. The scope of the measure was defined by the scope of practice of general surgeons, which includes abdominal, alimentary tract, breast, skin/soft tissue, wound, and varicose vein stripping procedures. In response to stakeholder input received during the public comment period in 2017 (available in the Downloads section at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods.html*), we revised the measure's title from ''Hospital Visits after General Surgery Ambulatory Surgical Center Procedures'' to, ''Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers'' to clarify the scope of the procedures included in the measure's cohort.

We have chosen not to further revise the measure title as ''7-Day'' represents the duration of hospital visits that define the outcome, and the title format is consistent with other CMS outcome measure titles (for example, ''Hospital 30-day all-cause risk-standardized readmission rate following acute myocardial infarction hospitalization'').

Comment: One commenter expressed concern that the measure may harm patients by discouraging necessary care, for example in a situation where an unforeseen clinical issue is discovered

during a procedure and sound clinical judgement calls for a provider to recommend hospitalization or observation.

Response: We appreciate the commenter's considerations of potential unintended consequences of implementing ASC–19. We believe that adverse impact on clinical decisions will be minimal due to risk adjustment. Risk adjustment ensures that ASCs are given credit for providing care for more complex patients who are at greater risk of hospital visits. A team of clinical consultants and the national TEP provided input on the measure risk-adjustment model at multiple points during development,[52] and the measure passed the NQF surgery committee's scientific acceptability criteria.[163]

After consideration of the public comments, we are finalizing our proposal to adopt ASC–19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers (NQF #3357) for the CY 2024 payment determination and subsequent years as proposed.

[163] National Quality Forum. (2017). *Surgery, Fall 2017 Cycle: CDP Report, 2017.* Retrieved from *https://www.qualityforum.org/Publications/2018/08/Surgery_Final_Report_-_Fall_2017_Cycle.aspx.*

4. Summary of ASCQR Program Quality Measure Set Finalized for the CY 2024 Payment Determination and for Subsequent Years

As discussed above, we are finalizing our proposal to add one measure beginning with the CY 2024 payment determination and for subsequent years to the ASCQR Program. We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59129 through 59132) for previously finalized ASCQR Program measure sets.

Table 63 summarizes the finalized ASCQR Program measure set for the CY 2024 payment determination and subsequent years (including previously adopted measures).

TABLE 63. 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).

5. ASCQR Program Measures and Topics for Future Consideration

In the CY 2020 OPPS/ASC proposed rule (84 FR 39567 through 39568), we considered one topic for future implementation: Updates to the submission method for ASC–1: Patient Burn, ASC–2: Patient Fall, ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant, and ASC–4: All-Cause Hospital Transfer/Admission measures.

ASC–1, ASC–2, ASC–3, and ASC–4 were adopted into the ASCQR Program in the CY 2012 OPPS/ASC final rule with comment period beginning with the CY 2014 payment determination (76 FR 74496 through 74500). These measures were developed by the ASC Quality Collaboration (ASC QC). The ASC QC is a cooperative effort of organizations and companies formed in 2006 with a common interest in ensuring that ASC quality data is measured and reported in a meaningful way.[164] Stakeholders in the ASC QC include ASC corporations, ASC associations, professional societies and accrediting bodies that focus on ASC quality and safety.[165] The ASC QC initiated a process of standardizing ASC quality measure development through evaluation of existing nationally endorsed quality measures to determine which could be directly applied to the outpatient surgery facility setting.[166]

The ASC QC developed and pilot-tested ASC–1, ASC–2, ASC–3, and ASC–4 at the facility-level for feasibility and usability (76 FR 74496). These measures are calculated via quality data

[164] ASC Quality Collaboration. ASC Quality Measures Implementation Guide Version 6.1 March 2019. Available at: *http://ascquality.org/documents/ASC-QC-Implementation-Guide-6.1-March-2019.pdf.*

[165] Ibid.

[166] Ibid.

codes (QDCs), as described in section XV.D.1. of this final rule with comment period. ASCs were formerly required to submit the appropriate QDCs on individual Medicare FFS claims billed by the facility (78 FR 75135). In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53640 through 53641), we finalized our policy that the minimum threshold for successful reporting be that at least 50 percent of claims meeting measure specifications contain QDCs. At that time, we believed that 50 percent was a reasonable minimum threshold for the initial implementation years of the ASCQR Program, because ASCs were not yet familiar with how to report quality data under the ASCQR Program and because many ASCs are relatively small and may have needed more time to set up reporting systems (77 FR 53641). We stated in that final rule that we intended to propose to increase this percentage for subsequent years' payment determinations as ASCs become more familiar with reporting requirements for the ASCQR Program. We have assessed this reporting threshold annually and have found that over 78 percent of reporting ASCs report data for at least 90 percent of eligible claims.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59117 through 59123), we expressed concern that the data submission method for these measures may impact the completeness and accuracy of the data due to the inability of ASCs to correct errors in submitted QDCs that are used to calculate these measures. An ASC that identifies an erroneous or missing QDC is unable to correct or add a QDC if the claim has already been submitted to Medicare and been processed. We also stated that we believe that revising the data submission method for the measures, such as via QualityNet, would address this issue and allow ASCs to correct any data submissions errors, resulting in more complete and accurate data. In that final rule with comment period, we explained that we agree it is important to continue to monitor the types of events included in these measures considering the potential negative impacts to patients' morbidity and mortality, in order to continue to prevent their occurrence and ensure that they remain rare. We acknowledged that these measures provide critical data to beneficiaries and further transparency for care provided in the ASC setting that would be useful in choosing an ASC for care, and that these measures are valuable to the ASC community.

As such, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59117 through 59123; 59134 through 59135), we retained these measures in the ASCQR Program, but suspended their data submission until further action in rulemaking with the goal of updating their data submission method.

In the CY 2020 OPPS/ASC proposed rule (84 FR 39567 through 39568), we requested comment about potential future updates to the data submission method for ASC–1: Patient Burn, ASC–2: Patient Fall, ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant, and ASC–4: All-Cause Hospital Transfer/Admission. Specifically, we have considered updating the data submission method to 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 QualityNet website (*https://www.qualitynet.org*) as our CMS online data submission tool.

To submit measures via an online data submission tool to the QualityNet website, ASCs and any agents submitting data on an ASC's behalf would have to maintain a QualityNet account (§ 416.310(c)(1)). A QualityNet security administrator would be necessary to set up such an account for the purpose of submitting this information (§ 416.310(c)(1)). We believe that using a CMS online data collection tool would address our concern about the ability of ASCs to correct data submission errors because ASCs would simply report their data via the online tool. If data for these measures were submitted via QualityNet, ASCs would still submit claims for reimbursement to CMS, but would not be required to include QDCs. As specified at § 416.310(c)(ii), the data collection time period for quality measures for which data are submitted via a CMS online data submission tool is for services furnished during the calendar year 2 years prior to the payment determination year. ASCs would then submit their data for ASC–1, ASC–2, ASC–3, and ASC–4 via QualityNet during the data submission period, January 1 through May 15 in the year prior to the payment determination year. ASCs would be able to submit and modify their data throughout the data submission period and could correct any errors during this period. We are seeking comments on whether updating the data submission method for ASC–1, ASC–2, ASC–3, and ASC–4 to a CMS online data submission tool would be appropriate for these measures in the future.

We are committed to work with stakeholders to ensure the ASCQR Program measure set does not place an inappropriate amount of burden on facilities while addressing and providing information about these types of patient safety, adverse, rare events to patients and other consumers. We recognize that updating the data submission method to a CMS online data submission tool would add some burden to the ASCQR Program due to the additional time for submitting any of these four measures via QualityNet for each payment determination year. Thus, we are also seeking comment about the burden associated with potentially updating the data submission method for ASC–1, ASC–2, ASC–3, and ASC–4 to a CMS online data submission tool (for example, the QualityNet website) in future years.

The comments and our responses to the comments regarding the ASCQR Program Measures and Topics for Future Consideration are set forth below.

Comment: Several commenters supported the inclusion of these measures in the ASCQR Program. Commenters also specifically supported the potential future updates to the data collection method for ASC–1: Patient Fall, ASC–2: Patient Burn, ASC–3: Wrong Site, Wrong Side, Wrong Procedure, Wrong Implant, and ASC–4: All-Cause Hospital Transfers/Admissions and noted that the measure steward has noted that the measures are suitable for submission through the QualityNet site. Commenters noted that the change would reduce cost and burden and limit the delay that results from QDC reporting.

Several commenters supported the inclusion of these four patient safety measures in both the ASCQR and HOQR Programs; these commenters cited supporting reasons, stating that these measures are outcome measures important to beneficiaries and the Medicare program and that their inclusion in both of these quality reporting programs would facilitate meaningful comparisons between ASCs and HOPDs.

Response: We thank the commenters for their support of the inclusion of the ASC–1, ASC–2, ASC–3, and ASC–4 measures in the ASCQR Program and for their support for submission of data for these measures through the QualityNet site.

Comment: Some commenters did not support the inclusion of the ASC–1 to ASC–4 measures in the ASCQR Program. These commenters cited: That

the measures lacked NQF endorsement, stating concerns about the usefulness of measuring rare events or being ''topped out''; that there could be data submission systems issues; and concerns about burden. A few commenters recommended that we continue the suspension of these measures rather than revise the data collection method. One commenter noted that CMS should not change the data collection method for these measures if it would increase burden or require manual data abstraction. One commenter suggested we work with HOPDs and ASCs to identify current forums or internal hospital portals where these safety issues are documented, discussed and remedied.

Response: We thank the commenters for their views, expressing their concerns and suggesting alternatives regarding the inclusion of the ASC–1 to ASC–4 measures in the ASCQR Program. We will take them into consideration as we determine future updates to ASC–1, ASC–2, ASC–3, and ASC–4 in the ASCQR Program.

6. Maintenance of Technical Specifications for Quality Measures

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74513 through 74514), where we finalized our proposal to follow the same process for updating the ASCQR Program measures that we adopted for the Hospital OQR Program measures, including the subregulatory process for updating adopted measures. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68496 through 68497), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75131), and the CY 2015 OPPS/ASC final rule with comment period (79 FR 66981), we provided additional clarification regarding the ASCQR Program policy in the context of the previously finalized Hospital OQR Program policy, including the processes for addressing nonsubstantive and substantive changes to adopted measures. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70531), we provided clarification regarding our decision to not display the technical specifications for the ASCQR Program on a CMS website, but stated that we will continue to display the technical specifications for the ASCQR Program on the QualityNet website. In addition, our policies regarding the maintenance of technical specifications for the ASCQR Program are codified at 42 CFR 416.325. In the CY 2020 OPPS/ASC proposed rule (84 FR 39568 through 39569), we did not propose any changes to our policies regarding the maintenance of technical specifications for the ASCQR Program.

7. Public Reporting of ASCQR Program Data

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74514 through 74515), we finalized a policy to make data that an ASC submitted for the ASCQR Program publicly available on a CMS website after providing an ASC an opportunity to review the data to be made public. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70531 through 70533), we finalized our policy to publicly display data by the National Provider Identifier (NPI) when the data are submitted by the NPI and to publicly display data by the CCN when the data are submitted by the CCN. In addition, we codified our policies regarding the public reporting of ASCQR Program data at 42 CFR 416.315 (80 FR 70533). In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79819 through 79820), we formalized our current public display practices regarding timing of public display and the preview period by finalizing our proposals to: Publicly display data on the Hospital Compare website, or other CMS website as soon as practicable after measure data have been submitted to CMS; to generally provide ASCs with approximately 30 days to review their data before publicly reporting the data; and to announce the timeframes for each preview period starting with the CY 2018 payment determination on a CMS website and/or on our applicable listservs. In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59455 through 59470), we discussed specific public reporting policies associated with two measures beginning with the CY 2022 payment determination: ASC–17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures, and ASC–18: Hospital Visits after Urology Ambulatory Surgical Center Procedures. In the CY 2020 OPPS/ASC Proposed Rule (84 FR 39569), we did not propose any changes to our public reporting policies.

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 maintenance of a QualityNet account and security administrator for the ASCQR Program at § 416.310(c)(1)(i). In the CY 2020 OPPS/ASC proposed rule (84 FR 39569), we did not propose any changes to these policies.

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. In the CY 2020 OPPS/ASC proposed rule (84 FR 39569), we did not propose any changes to these policies.

D. Form, Manner, and Timing of Data Submitted for the ASCQR Program

1. 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).

In the CY 2020 OPPS/ASC proposed rule (84 FR 39569) we did not propose any changes to these requirements. We note that data submission for the following claims-based measures using QDCs was suspended in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59117 through 59123; 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.

We also note that we are requesting comment on updating the submission method for the above measures in

section XV.B.5. of this final rule with comment period.

These data processing and collection period requirements will remain in the ASCQR Program for application to any future claims-based measures using QDCs adopted by the ASCQR Program.

2. 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. In the CY 2020 OPPS/ASC proposed rule (84 FR 39569), we did not propose any changes to these policies.

3. Requirements for Data Submitted via an Online Data Submission Tool

We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59472) (and the previous rulemakings cited therein) and 42 CFR 416.310(c) for our previously finalized policies for data submitted via an online data submission tool. For more information on data submission using QualityNet, we refer readers to: *https://www.qualitynet.org.*

a. 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 (that is, the CDC NHSN website). We codified our existing policies regarding the data collection time 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. In the CY 2020 OPPS/ASC proposed rule (84 FR 39569 through 39570), 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.

b. 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 § 416.310(c)(1) for our requirements regarding data submitted via a CMS online data submission tool. We are currently using the QualityNet website 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 to the § 416.310(c)(1)(i).

In the CY 2020 OPPS/ASC proposed rule (84 FR 39570), we did not propose any changes to this policy. 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

4. Requirements for Non-QDC Based, Claims-Based Measure Data

We did not propose any changes to our requirements for non-QDC based, claims-based measures in the CY 2020 OPPS/ASC proposed rule (84 FR 39570). We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59136 through 59138, where we established a 3-year reporting period for the previously adopted measure, ASC–12: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy. In that final rule with comment period (83 FR 59106 through 59107), we established a similar policy under the Hospital OQR Program.

We also note that we are finalizing our proposal to adopt ASC–19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers (NQF #3357) in section XV.B.3. of this final rule with comment period to which these requirements for non-QDC based, claims-based measures apply.

5. 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 ASC–15a–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. In the CY 2020 OPPS/ASC proposed rule (84 FR 39570), we did not propose any changes to this policy.

6. 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 also clarified that we will strive to complete our review of each request within 90 days of receipt. In the CY 2020 OPPS/ASC proposed rule (84 FR 39570), we did not propose any changes to these policies.

7. 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. In the CY 2020 OPPS/ASC proposed rule (84 FR 39570), we did not propose any changes to this policy.

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 2020, 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).

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, CY 2016, CY 2017, CY 2018, and CY 2019 OPPS/ASC final rules with comment period (79 FR 66981 through 66982; 80 FR 70537 through 70538; 81 FR 79825 through 79826; 82 FR 59475 through 59476; and

83 FR 59138 through 59139, respectively), we did not make any other changes to these policies. We did not propose any changes to these policies for CY 2020 in the CY 2020 OPPS/ASC proposed rule (84 FR 39570 through 39571), did not receive any public comments on these policies, and are finalizing the continuation of these policies for CY 2020.

XVI. Requirements for Hospitals To Make Public a List of Their Standard Charges and Request for Information (RFI): Quality Measurement Relating to Price Transparency for Improving Beneficiary Access to Provider and Supplier Charge Information

In the CY 2020 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule (84 FR 39398), we proposed requirements for hospitals to make public a list of their standard charges pursuant to 2718(e) of the Public Health Service (PHS) Act. We received over 1,400 comments on our proposed requirements for hospitals to make public their standard charges. We intend to summarize and respond to public comments on the proposed policies in a forthcoming final rule.

In addition, to inform our future efforts to develop policies related to transparency in health care charges, we published a Request for Information that sought stakeholder input on a number of related quality of health care issues. We received over 63 comments. We appreciate the feedback we received and will take it into account as we further consider our future policies.

XVII. Organ Procurement Organizations (OPOs) Conditions for Coverage (CfCs): Proposed Revision of the Definition of ''Expected Donation Rate''

A. Revision of the Definition of ''Expected Donation Rate''

To be an OPO, an entity must meet the applicable requirements of both the Act and the Public Health Service Act (the PHS Act). Section 1138(b) of the Act provides the statutory qualifications and requirements that an OPO must meet in order for organ procurement costs to be paid under the Medicare program or the Medicaid program. Section 1138(b)(1)(A) of the Act specifies that an OPO must operate under a grant made under section 371(a) of the PHS Act or must be certified or recertified by the Secretary as meeting the standards to be a qualified OPO within a certain time period. Congress has provided that payment may be made for organ procurement cost ''only if'' the OPO meets the performance-related standards prescribed by the Secretary. To receive payment under the Medicare program or the Medicaid program for organ procurement costs, the entity must have an agreement with, or be designated by, the Secretary (section 1138(b)(1)(F) of the Act and 42 CFR 486.304).

Pursuant to section 371(b)(1)(D)(ii)(II) of the PHS Act, the Secretary is required to establish outcome and process performance measures for OPOs to meet based on empirical evidence, obtained through reasonable efforts, of organ donor potential and other related factors in each service area of the qualified OPO. An OPO also must be a member of and abide by the rules and requirements of the OPTN that have been approved by the Secretary (section 1138(b)(1)(D) of the Act). We established Conditions for Coverage (CfCs) for OPOs to be able to receive payments from the Medicare and Medicaid programs at 42 CFR part 486, subpart G, to implement the statutory requirements. These regulations set forth the certification and recertification processes, outcome requirements, and process performance measures for OPOs and were effective on July 31, 2006 (71 FR 30982).

We proposed to harmonize the CMS definition of ''expected donation rate'' with the Scientific Registry for Transplant Recipient's (SRTR) definition of the term. The SRTR operates under contract from the Health Resources and Services Administration (HRSA) and is responsible for providing statistical and other analytic support to the Organ Procurement and Transplantation Network (OPTN) for purposes including the formulation and evaluation of organ allocation and other OPTN policies.[167] As we noted in the proposed rule (84 FR 39596), in 2009 the SRTR determined that a more precise method to calculate an OPO's expected donation rate would be to base it on the national experience for OPOs serving similar eligible donor populations and donation service areas (DSAs) and then adjust for patient characteristics, that is age, sex, race, and cause of death among eligible deaths. We agree with the SRTR's assessment for this specific measure and we proposed to revise such definition to state that the expected donation rate per 100 eligible deaths would be the rate expected for an OPO based on the national experience for OPOs serving similar eligible donor populations and DSAs. We proposed that this rate would be adjusted for the distributions of age, sex, race, and cause of death among eligible deaths.

We noted that if we finalize this proposal, this change would take effect on the effective date of the final rule with comment period, which would occur during the 2022 recertification cycle. Because the final regulation change would be prospective from the final rules' effective date in order to give OPOs adequate time to comply with the change to the definition for ''expected donation rate,'' we also proposed to change the time period for the observed donation rate for the second outcome measure for the 2022 recertification cycle only. As a result, we proposed to revise § 486.318(a)(2), (b)(2), and (c)(1) to reduce the time period for this outcome measure. We proposed to calculate the expected donation rate using 12 of the 24 months of data following the effective date of the final rule with comment period (using data from January 1, 2020 through December 31, 2021). After the 2022 recertification cycle, and if there were no other changes to the OPO outcome measures, we would return to assess OPO performance based on 36 months of data.

Comment: We received public comments from a wide range of individuals, OPOs, national associations and coalitions, and the Organ Procurement and Transplantation Network/United Network for Organ Sharing (OPTN/UNOS). The vast majority of comments were supportive of the proposed change to the definition of ''expected donation rate''.

Response: We appreciate the commenters' support for our proposal and we thank them for their feedback. Our proposal to align our definition of ''expected donation rate'' with the SRTR's definition will enable us to continue to enforce our second outcome measure, eliminate provider confusion, and provide consistency between the CMS requirements and the SRTR's data. We therefore are finalizing our proposal to revise the definition of ''expected donation rate'' to align with the SRTR's definition, without modification. Specifically, the revised definition will state that the expected donation rate per 100 eligible deaths is the rate expected for an OPO based on the national experience for OPOs serving similar eligible donor populations and DSAs. This rate would be adjusted for the distributions of age, sex, race, and cause of death among eligible deaths.

Comment: Many commenters disagreed with the proposed change to the timeframe, which would reduce the time period for this outcome measure for the 2022 recertification cycle only.

[167] *https://www.srtr.org/about-srtr/mission-vision-and-values/.*

The commenters stated that reducing the time period may have unintended consequences and distort, in a positive or negative way, an OPO's performance. Some also stated that this proposal would affect OPOs with smaller volumes, and those that may be sensitive to random variability over short periods of time. In summary, the commenters stated that this change would not provide adequate time period for a statistically meaningful set of data and may incorrectly identify OPOs as failing the metric due to normal random fluctuation in activity, rather than underlying performance concerns. The commenters requested that the new definition of ''expected donation rate'' therefore apply to the next recertification cycle, after the completion of the current cycle.

Response: We understand commenters' concerns regarding the proposed change to the time period for this second outcome measure and we are sensitive as to how such a change might negatively impact OPOs. We note that it was not our intention to unfairly penalize OPOs or undermine our goals of accurately measuring OPO performance. Rather, given the fact that the finalization of the CY 2020 OPPS/ASC proposed rule would occur during the 2022 recertification cycle, we attempted to mitigate any timing issues with regards to the use of data for purposes of determining the second outcome measure by applying the same standard to all OPOs for the identical time period once the rule was effective. We believed that a 12-month period of the 24 months of data following the effective date of the final rule with comment period would be sufficient to determine an OPO's performance on this measure. However, we agree that using 12 out of the 24 months of data may have unintended consequences on OPOs and the recertification process, and therefore we are not finalizing this proposal.

In order to ensure fairness for OPOs and in order to finalize our change to the definition of ''expected donation rate'' after the effective date of the final rule, we are finalizing a policy that would not require all OPOs to meet the standards of the second outcome measure for the 2022 recertification cycle only. We are requiring OPOs to meet one of the two other outcome measures in order to be recertified (the OPO's donation rate measure and aggregate donor yield measure) for the 2022 recertification cycle only. By deferring the use of the new standard, we would ensure that no OPOs would be prejudiced by the limited time period and OPOs that may not be able to meet the second measure due to limitations of the data or other variables as described by the commenters would not be decertified based only on the changed regulation. If no subsequent changes are made to the outcome measure requirements via rulemaking, the new definition of ''expected donation rate'' will apply after the 2022 recertification cycle. OPOs must continue to comply with the other CfCs and continue their quality improvement efforts through their Quality Assurance and Performance Improvement (QAPI) program, as required by our rules at § 486.348.

B. Request for Information Regarding Potential Changes to the Organ Procurement Organization and Transplant Center Regulations

In the proposed rule (84 FR 39597), we stated that we were considering a comprehensive proposal to update the CfCs for OPOs and possibly the CoPs for transplant centers, and that we were therefore seeking public input regarding what revisions may be appropriate for the current CfCs for OPOs, set forth at 42 CFR 486.301 through 486.360, and the current CoPs for transplant centers, set forth at 42 CFR 482.68 through 482.104.

We also solicited comments on whether the following two potential OPO outcome measures would be valid measures and would be consistent with statutory requirements. We noted that we were especially interested in public comments about the validity and reliability of these possible measures.

The first potential measure would be the actual deceased donors as a percentage of inpatient deaths among patients 75 years of age or younger with a cause of death consistent with organ donation. The data on inpatient deaths, including additional related demographic data, would be derived from the Center for Disease Control (CDC) Detailed Mortality File and the National Center for Health Statistic's National Vital Statistics Report.

The second potential measure is the actual organs transplanted as a percentage of inpatient deaths among patients 75 years of age or younger with a cause of death consistent with organ donation.

Comment: We received a wide range of comments on the RFI. Most commenters supported changing the OPO and transplant center CfCs and CoPs, and offered specific suggestions on potential changes to these requirements. Some of those suggestions included, but were not limited to: Recommendations that CMS work with the Health Resources and Services Administration (HRSA) and the OPTN to develop combined OPO and transplant center metrics; support for the development of best practices regarding donation after cardiac death (DCD) and regulations to require support for DCD; support for a cause, age, and, location consistent (CALC) deaths metric, recommendations to develop metrics that include donor hospitals and transplant centers; recommendations that referral and notifications of imminent death and potential donors be improved; support for addressing issues that OPOs in non-contiguous states and territories face; requests to improve reimbursement for transplant centers and OPOs; and suggestions to better align definitions and terminology.

Additional suggestions included: A recommendation that CMS not use the observed versus expected measure to evaluate OPOs and that the yield measure should ultimately be replaced or supplemented with a combined OPO and transplant center metric that measures how they interact to maximize organ transplants; a recommendation that CMS take into consideration an OPO's work and commitment to research and development, deceased donor research, and participation in such projects/practices as the HOPE Project, Donor Hypothermia Study and Stanford Donor Heart Study; a recommendation that an in-patient assessment of ICU deaths be conducted; a recommendation that CMS eliminate or revise the transplant center outcomes and that the SRTR star ratings or denominator for metrics or adjustments be eliminated; that CMS should prioritize national databases for regulatory purposes; and a recommendation that CMS, HRSA, OPTN, SRTR and the Centers for Disease Control (CDC) form a taskforce to examine publically available data sources that would evaluate sources and identify the practicality of identifying ventilated patient who die in hospitals/emergency departments.

Response: We thank the commenters for their responses to our RFI. We will continue to review the public comments on the RFI for future rulemaking and potential revisions to the CfCs for OPOs and the CoPs for transplant centers.

C. Miscellaneous Comments

Although not specifically discussed in the CY 2020 OPPS/ASC proposed rule, we wanted to address the multiple commenters who urged us to finalize our proposal on the transplant center CoPs. We note that, in response to public comments that we received on the CY 2020 OPPS/ASC proposed rule,

we finalized our proposals to remove the Medicare re-approval requirements for transplant centers. We refer readers to the Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care final rule (84 FR 51732) for more information.

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 we explained in the CY 2020 OPPS/ASC proposed rule (84 FR 39599), 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), (b)(3), or (b)(5) (an additional exception finalized in the CY 2018 OPPS/ASC final rule with comment period that we describe later in this section), 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), (b)(3), or (b)(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 recent 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; 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 conditionally package most CDLTs and only pay separately for a laboratory test 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, 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, which we describe below. 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 are separately payable and are listed on the CLFS are paid at the CLFS payment rates outside 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 Food and Drug Administration.

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) for the hospital outpatient setting 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.

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.*

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 applies 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 through communications with representatives of providers and suppliers affected by the policy that there are still many entities who will not be able to implement the laboratory DOS exception and will need additional time to come into compliance. The enforcement discretion period is currently in effect until January 2, 2020. The latest 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.*

As we explained in the CY 2020 OPPS/ASC proposed rule (84 FR 39600), during this time of enforcement discretion, we have continued to gage the industry's readiness to implement the laboratory DOS exception at § 414.510(b)(5). Stakeholders, including representatives of hospitals, have informed us that hospitals, in particular, are having difficulty with developing the systems changes necessary to provide the performing laboratory with the patient's hospital outpatient status, beneficiary demographic information, and insurance information, such as whether the beneficiary is enrolled in original fee-for-service Medicare or a specific Medicare Advantage plan. According to stakeholders, the performing laboratory requires this information so that it can bill Medicare directly for the test instead of seeking payment from the hospital.

In addition, stakeholders, including representatives of laboratories, have noted 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. According to these stakeholders, blood banks and blood centers that are not currently enrolled in the Medicare program would need to establish a billing mechanism so that they can bill Medicare directly when the requirements of § 414.510(b)(5) are met. Stakeholders have asserted that establishing a billing mechanism is labor intensive and that blood banks and blood centers currently lack the financial resources and expertise to take on this task.

We also noted in the CY 2020 OPPS/ASC proposed rule that protein-based Multianalyte Assays with Algorithmic Analysis (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, are also conditionally

packaged under the OPPS at this time. Several stakeholders have suggested that they believe that the pattern of clinical use of some of these protein-based MAAAs make them relatively unconnected to the primary hospital outpatient service, though they do not currently qualify for the DOS exception at § 414.510(b)(5) solely because they are MAAAs. We stated 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), and we intend to consider policies regarding MAAAs for future rulemaking.

F. Potential Revisions to Laboratory DOS Policy and Request for Public Comments

In the CY 2020 OPPS/ASC proposed rule (84 FR 39601), we stated that in response to the implementation concerns raised by stakeholders, we were considering making additional changes to the laboratory DOS policy.

We reiterated that, under the exception that we finalized at § 414.510(b)(5), for 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: (i) The test was performed following a hospital outpatient's discharge from the hospital outpatient department; (ii) the specimen was collected from a hospital outpatient during an encounter (as both are defined in 42 CFR 410.2); (iii) it was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter; (iv) the results of the test do not guide treatment provided during the hospital outpatient encounter; and (v) the test was reasonable and medically necessary for the treatment of an illness. When all conditions under the laboratory DOS exception at § 414.510(b)(5) are met, the DOS is the date of test performance, instead of the date of specimen collection, which effectively unbundles the test from the hospital outpatient encounter. As such, the test is not considered a hospital outpatient service for which the hospital must bill Medicare and for which the performing laboratory must seek payment from the hospital, but rather a laboratory test under the CLFS for which the performing laboratory must bill Medicare directly. In the CY 2020 OPPS/ASC proposed rule we considered three options for potential changes to the laboratory DOS exception at § 414.510(b)(5), and we requested comment on these changes. Specifically, we sought comment on:

- Changing the test results requirement at 42 CFR 414.510(b)(5)(iv);
- Limiting the laboratory DOS exception at 42 CFR 414.510(b)(5) to ADLTs; and/or
- Excluding blood banks and blood centers from the laboratory DOS exception at 42 CFR 414.510(b)(5).

These potential revisions are discussed below.

1. Changing the Test Results Requirement at 42 CFR 414.510(b)(5)(iv)

We explained in the CY 2020 OPPS/ASC proposed rule that, since finalizing the laboratory DOS exception at § 414.510(b)(5), we have continued to review and analyze the factors we use to determine whether a molecular pathology test or Criterion (A) ADLT is unrelated to the hospital treatment and used to determine posthospital care, and therefore should have a DOS that is the date of performance rather than the date of specimen collection. One such factor, in § 414.510(b)(5)(iv), is that the results of the test must not guide treatment provided during the hospital outpatient encounter—meaning, the encounter in which the specimen was collected. We stated in the proposed rule that we were no longer convinced that the determination as to whether a molecular pathology test or ADLT is separable from a hospital service should be based on whether the test results guide treatment during the specific hospital outpatient encounter in which the specimen was collected. We suggested that a molecular pathology test or an ADLT that is performed on a specimen collected during a hospital outpatient encounter, in which the results of the test are intended to guide treatment during a future hospital outpatient encounter, is a hospital service, and therefore should be billed by the hospital that collected the specimen under arrangements, just like if the test does not meet one of the other prongs of § 414.510(b)(5). In contrast, if the results of the test are not intended to guide treatment during a hospital outpatient encounter, and if all other requirements in § 414.510(b)(5) are met, the test is separable from a hospital service and therefore, should be considered a laboratory service and the performing laboratory should bill for the test.

We noted that a test's relationship to a hospital outpatient encounter depends on many factors, including the patient's current diagnosis (or lack of a current diagnosis), the procedure(s) being considered for the patient, the patient's current and previous medical history, and other factors and that the ordering physician would be aware of these beneficiary characteristics. As such, we indicated that it should be the role of the ordering physician to determine whether the results of a molecular pathology test or ADLT are or are not intended to guide treatment during a hospital outpatient encounter.

Therefore, we considered a revision to our current laboratory DOS policy at § 414.510(b)(5)(iv) to specify that the ordering physician would determine whether the results of the ADLT or molecular pathology test are intended to guide treatment provided during a hospital outpatient encounter, if the other four requirements under § 414.510(b)(5) are met. We noted that, under this approach, the test would be considered a hospital service unless the ordering physician determines that the test does not guide treatment during a hospital outpatient encounter. If the ordering physician determines that the test results are not intended to guide treatment during the hospital outpatient encounter from which the specimen was collected or during a future hospital outpatient encounter, for purposes of the laboratory DOS exception at § 414.510(b)(5), the DOS service of the test would be the date of test performance. In this situation, we stated, the test would not be considered a hospital service and the performing laboratory would be required to bill for the test.

We noted that, conversely, if the other four requirements under § 414.510(b)(5) are met but the ordering physician determines that the results of the laboratory test are intended to guide treatment during a hospital outpatient encounter, the DOS would be the date of specimen collection. As a result, the hospital that collected the specimen would bill for the laboratory test under arrangements and the laboratory would seek payment from the hospital for the test. We stated that this potential revision to the laboratory DOS exception at § 414.510(b)(5) would be consistent with our belief that a molecular pathology test or a Criterion (A) ADLT is a hospital service when the results of the test are intended to guide treatment during a hospital outpatient encounter.

We requested comments from hospitals, laboratories, physicians and non-physician practitioners, and other interested stakeholders regarding this potential revision to the laboratory DOS exception at § 414.510(b)(5). In particular we sought comments regarding our view that when the results of molecular pathology testing and Criterion (A) ADLTs are intended to

guide treatment during a future hospital outpatient encounter, the test is a hospital service. We also requested public comments regarding the administrative aspects of requiring the ordering physician to determine when the test results are not intended to guide the treatment during a hospital outpatient encounter, as well as the process for the ordering physician to document this decision and provide notification to the hospital that collected the specimen for billing purposes. We noted that we would consider finalizing this potential revision to the laboratory DOS policy as a result of our review of the comments received on this topic.

We also noted that we were only soliciting comments on potential changes to the laboratory DOS exception at § 414.510(b)(5), and not the 14-day rule DOS exception at § 414.510(b)(2) or the chemotherapy sensitivity test DOS exception at § 414.510(b)(3). We stated that these exceptions would continue to include the requirement that the results of the test do not guide treatment provided during the hospital stay, meaning the hospital stay in which the specimen was collected. Although we recognized that the considerations about how a hospital service is determined under § 414.510(b)(5) discussed previously may also be applicable to the 14-day rule DOS exception and chemotherapy sensitivity test DOS exception, we explained that we were only considering revisions to the laboratory DOS exception at § 414.510(b)(5) at that time. Because of the administrative issues raised by stakeholders regarding the implementation of the laboratory DOS exception at § 414.510(b)(5), we stated that we believed a cautious and incremental approach to making changes to laboratory DOS policy is warranted. As such, any potential changes to the 14-day rule DOS exception at § 414.510(b)(2) and the chemotherapy sensitivity test DOS exception at § 414.510(b)(3) would be addressed in future rulemaking.

A summary of the public comments received on this potential revision and our responses are provided below.

Comment: Many commenters stated that the current laboratory DOS exception at § 414.510(b)(5) has improved beneficiary access to precision testing like molecular pathology testing and ADLTs and urged us not to make any changes that would jeopardize beneficiary access to such testing. They asserted that this exception to laboratory DOS policy has limited delays in ordering precision diagnostic tests for patients seeking care during a hospital outpatient encounter and has afforded physicians more consistent and timely access to precision diagnostic information to guide clinical decision-making. A few commenters also submitted a summary analysis of Medicare Part B claims data comparing the utilization of molecular pathology testing in CY 2018, which reflects the first year of the laboratory DOS exception, to CY 2017, which was the last year before that exception became effective. The analysis found that the total number of molecular pathology test claims following a hospital outpatient encounter increased from 43,012 claims in 2017 to 66,637 claims in 2018, which represents an increase of about 55 percent. The commenters noted that despite the CMS announcement of enforcement discretion with respect to the laboratory DOS exception at § 414.510(b)(5), even in its first year this exception for the hospital outpatient setting has improved beneficiary access to timely diagnostic information and more effective targeted therapy and/or clinical management. As such, they urged us not to make any changes to the current laboratory DOS exception at § 414.510(b)(5), except for the change that would exclude blood banks and centers.

Response: We appreciate these comments and the claims analysis supporting the commenters' statements about increased beneficiary access to molecular pathology testing since the laboratory DOS exception at § 414.510(b)(5) became effective. As discussed later in this section, because of the concerns and objections raised by commenters, we are not finalizing the potential change to the test results requirement at § 414.510(b)(5)(iv) or the potential revision that would limit § 414.510(b)(5) to ADLTs approved under Criterion (A).

Comment: The overwhelming majority of commenters urged us not to finalize the potential change to the test results requirement at § 414.510(b)(5)(iv) because doing so would be inconsistent with current clinical practice and administratively burdensome, and may lead to beneficiary access issues. A few stakeholders also contended that this potential change to the laboratory DOS exception would be inconsistent with longstanding policy related to services performed outside the hospital outpatient setting. We discuss these comments in more detail below.

Many stakeholders stated that requiring the ordering physician to determine whether the test results are intended to guide treatment during a future hospital encounter is unworkable because it would be inconsistent with current clinical practice. They noted that the very reason why the physician is ordering the test is to determine the next clinical intervention steps for the patient. However, the ordering physician cannot be expected to reasonably predict how he or she will use the test results because the physician lacks the information to make that prediction at the time of ordering. They also noted that the physician ordering the testing may not be the only physician who treats the patient based on the test results. For example, patients with complex or chronic conditions, like cancer, often have multidisciplinary care teams that coordinate various aspects of the patients' treatment plan. In addition, the patient, and the patient's family are frequently involved in the treatment decision, which is informed by the results of the test. Therefore, commenters expressed that it is impossible for the ordering physician to predict the treatment preferences and/or site of treatment of the entire care team, as well as the preferences of the patient and the patient's family.

Many stakeholders also pointed out the administrative complexities associated with requiring the ordering physician to predict the future use of the test results, which would also require documentation in the beneficiary's medical record and coordination with the hospital and performing laboratory to ensure that the correct entity bills for the test. They contended that this potential policy change would result in a significant amount of ongoing administrative burden. For example, the hospital would need to develop a mechanism to ensure that the ordering physician actually makes a determination as to whether the test results guide treatment during a hospital outpatient encounter for each molecular pathology test and ADLT that meets the requirements of laboratory DOS exception at § 414.510(b)(5). The hospital would then need to extract that determination from the beneficiary's medical record and reflect it in the hospital's billing system, and make certain not to bill for a test that is not intended to guide treatment during the current hospital outpatient encounter or a future hospital outpatient encounter. In turn, the hospital would need to add this data element to the other data elements that it already must convey to the performing laboratory (for example, beneficiary demographic and insurance information) so that the performing laboratory can bill Medicare directly for the test.

Additionally, many commenters asserted that changing the test results requirement may lead to delayed

beneficiary access to molecular pathology testing and ADLTs. For instance, several commenters noted that the performing laboratory would be permitted to bill and be paid directly by Medicare only when the ordering physician determines that the test results do not guide treatment during any hospital outpatient encounter. They noted that if the ordering physician cannot make a prediction about the future use of the test results, which as discussed above, they believed is likely to be the case, the default date of service would be the date of specimen collection and the hospital would be required to bill for the test. Therefore, they suggested test orders would most likely be delayed until at least 14 days following the patient's discharge from the hospital outpatient department to allow the performing laboratory to bill Medicare directly for the test. As a result, they contended that changing the test results requirement would once again lead to the same beneficiary access issues that prompted us to establish the laboratory DOS exception under § 414.510(b)(5) in the first place.

Finally, a few commenters stated that the potential change to the test results requirement would be inconsistent with longstanding policy related to services performed outside the hospital outpatient setting. For example, they noted that in the final rule with comment period entitled, ''Office of Inspector General; Medicare Program; Prospective Payment System for Hospital Outpatient Services, Final Rule'' published in the **Federal Register** on April 7, 2000 (65 FR 18440 through 18441), the agency stated that ''[a] free-standing entity, that is, one that is not provider-based, may bill for services furnished to beneficiaries who do not meet the definition of a hospital outpatient at the time the service is furnished''. . . and that ''[o]ur bundling requirements apply to services furnished to a 'hospital outpatient,' as defined in § 410.2, during an 'encounter,' also defined in § 410.2.'' As such, they suggested the potential revision to the test results requirement would not be consistent with this longstanding policy position because it could require the hospital to bill for testing furnished days, and sometimes weeks, after the patient's hospital outpatient encounter. Therefore, they urged us not to finalize the change to the test results requirement discussed in the CY 2020 OPP/ASC proposed rule.

Response: We appreciate the stakeholder feedback regarding the various problems that could arise if we were to finalize the potential revision to the test results requirement under the laboratory DOS exception at § 414.510(b)(5)(iv) that we discussed in the CY 2020 OPP/ASC proposed rule. Based on the comments received on this potential revision, we agree that requiring the ordering physician to predict whether the results of the test will guide treatment during a future hospital outpatient encounter may be overly burdensome and inconsistent with clinical practice. As noted by the commenters, the results of the test are unknown at the time the test is ordered and, therefore, the ordering physician cannot be expected to reasonably predict how he or she will use those test results. In addition, we understand that the ordering physician typically will consult with other physicians and practitioners of the patient's care team, as well as the patient, to determine the future treatment of a patient and/or the site of service for that treatment. As such, we understand from commenters that it would be difficult for the ordering physician alone to determine whether the test results will or will not guide treatment during a future hospital outpatient encounter. We also agree that changing the test results requirement at § 414.510(b)(5)(iv) as discussed in the CY 2020 OPPS/ASC proposed rule may be administratively burdensome for the ordering physician, hospital, and performing laboratory and may lead to beneficiary access concerns. As the commenters pointed out, if the ordering physician does not make a determination as to whether the test results guide treatment during the current hospital outpatient encounter or a future hospital outpatient encounter, the default laboratory DOS would be the date of specimen collection and the hospital would be required to bill Medicare directly for the test. We agree with commenters that these circumstances could once again lead to delayed test ordering which may result in similar beneficiary access issues that existed prior to the implementation of the laboratory DOS exception at § 414.510(b(5). We also acknowledge the concerns about the potential change to the test results requirement being inconsistent with longstanding CMS policy. For these reasons, after considering the many concerns and objections raised by commenters, we are not finalizing the change to the test results requirement at § 414.510(b)(5)(iv).

2. Limiting the Laboratory DOS Exception at 42 CFR 414.510(b)(5) to ADLTs

As discussed previously in this section, we established the laboratory DOS exception at § 414.510(b)(5), in part, because of stakeholder concerns that the laboratory DOS policy in effect prior to CY 2018 created beneficiary access issues 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. In the CY 2018 OPPS/ASC proposed rule (82 FR 33653), we considered revising the DOS rule to create an exception only for ADLTs that meet the criteria in section 1834A(d)(5)(A) of the Act because ADLTs are offered and furnished only by a single laboratory (as defined in 42 CFR 414.502). We noted that a hospital, or another laboratory that is not the single laboratory (as defined in 42 CFR 414.502), cannot furnish the ADLT, and there may be additional beneficiary concerns for these ADLTs that may not apply to the molecular pathology tests. For example, a hospital may not have an arrangement with the single laboratory that furnishes a particular ADLT, which could lead the hospital to delay the order for the ADLT until 14 days after the patient's discharge to avoid financial risk and thus potentially delay medically necessary care for the beneficiary. We solicited comments as to whether molecular pathology tests present the same concerns of delayed access to medically necessary care as ADLTs, noting that molecular pathology tests are not required to be furnished by a single laboratory and that there may be ''kits'' for certain molecular pathology tests that a hospital can purchase, allowing the hospital to perform the test. In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59399) we agreed with commenters that limiting the new laboratory DOS exception to include only ADLTs (and not molecular pathology tests) would be inconsistent with the OPPS packaging policy and that relatively few laboratories may perform certain molecular pathology testing. We also acknowledged that hospitals may not currently have the technical expertise or certification requirements necessary to perform molecular pathology testing and therefore must rely on independent laboratories to perform the test. Therefore, we concluded that similar beneficiary access concerns that apply to ADLTs may also apply to molecular pathology tests, and we decided not to limit the exception at 42 CFR 414.510(b)(5) to ADLTs only.

However, in the CY 2020 OPPS/ASC proposed rule, we stated that after further review of this issue, we no longer believed the same beneficiary access concerns that apply to ADLTs also apply to molecular pathology tests.

In particular, unlike ADLTs, molecular pathology tests are not required by statute to be furnished by a single laboratory, so hospital laboratories and independent laboratories are not prevented from performing molecular pathology testing. In addition, we stated that we understood a number of kits have recently been developed and approved by FDA that would allow a hospital to more easily perform some of these molecular pathology tests. As such, we were no longer convinced that molecular pathology tests present the same concerns of delayed access to medically necessary care as ADLTs, which must be performed by a single laboratory. We noted that we believed a hospital's laboratory can develop the expertise to perform a molecular pathology test or establish an arrangement with an independent laboratory to perform the test. Therefore, we believed that any incentives that may exist to delay ordering until at least 14 days following a patient's discharge from the hospital outpatient department do not apply to molecular pathology tests.

We also recognized in the CY 2020 OPPS/ASC proposed rule that limiting the laboratory DOS exception to ADLTs is not consistent with OPPS packaging policy. As discussed previously in this section of the final rule, we exclude all molecular pathology laboratory tests from OPPS packaging 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 (80 FR 70348 through 70350). However, we stated in the proposed rule that consistency with the OPPS packaging policy only formed part of the basis for the laboratory DOS exception at § 414.510(b)(5). We noted that beneficiary access concerns were the primary reason for establishing this laboratory DOS exception and we no longer believed the access concerns are sufficiently compelling for the molecular pathology tests. In light of the billing and enrollment concerns raised by the blood banks and blood centers and administrative issues raised by other stakeholders, we expressed that the policy reasons for removing these tests from the laboratory DOS exception at § 414.510(b)(5) outweigh the difference it creates with the OPPS packaging policy.

Therefore, as discussed in the proposed rule, we considered a potential revision that would limit the laboratory DOS provisions of § 414.510(b)(5) to tests designated by CMS as an ADLT under paragraph (1) of the definition of an ADLT in § 414.502. Molecular pathology tests would be removed from the provisions of § 414.510(b)(5). However, we noted that molecular pathology tests would still be subject to the laboratory DOS provisions of § 414.510(b)(2) and (3).

We requested comments on potentially limiting the laboratory DOS exception policy at § 414.510(b)(5) to laboratory tests that have been granted Criterion (A) ADLT status by CMS. We also noted that we would consider finalizing this approach as a result of the public comments received.

A summary of the public comments received on this potential revision and our response is provided below.

Comment: Many stakeholders objected to this potential change to the laboratory DOS exception because molecular pathology tests continue to have similar beneficiary access issues as ADLTs. For example, they asserted that many molecular pathology tests that do not meet the clinical requirements of an ADLT under Criterion (A), are performed by a single laboratory (or very few laboratories) for specific clinical indications and that very few ''kits'' have been approved by the FDA. They noted that the vast majority of molecular pathology tests are performed by the laboratories that developed and validated them and therefore, hospitals rarely perform molecular pathology tests. A few commenters explained that about 50 test kits are available for purchase, but that many of them are redundant and test for the same analyte, leaving no more than 15–20 unique kits available for molecular testing that might be used by a hospital laboratory. In addition, these commenters stated that many hospitals would not have the capability to perform such specialized testing and the cost of bringing this specialized testing capability in-house may be prohibitive for many hospitals, particularly if the volume of testing is expected to be low, as would be the case for smaller and rural hospitals.

Several stakeholders pointed out that molecular pathology tests approved for ADLT status under Criterion (B), which requires FDA clearance or approval, are also statutorily required to be performed by a single laboratory and therefore have similar beneficiary access issues as Criterion (A) ADLTs. They contended that there is no reason why a sole-source molecular pathology test that is FDA cleared or approved should be excluded from the laboratory DOS exception, while sole-source testing approved as an ADLT under Criterion (A) are included. They noted that if the laboratory DOS exception at § 414.510(b)(5) was limited to tests granted ADLT status under Criterion (A), the performing laboratory would not be permitted to bill Medicare directly for any other molecular pathology testing performed on specimens collected during a hospital outpatient encounter, including those sole source tests approved as an ADLT under Criterion (B), unless the test meets the 14-day rule requirements under § 414.510(b)(2)(i). Therefore, these commenters maintained that limiting the laboratory DOS policy exception at § 414.510(b)(5) to ADLTs approved by CMS under Criterion (A) would once again lead to delayed test orders and timely beneficiary access concerns.

Response: We appreciate stakeholder feedback on the beneficiary access concerns related to molecular pathology testing that are not Criterion (A) ADLTs. As noted previously in this section of this final rule with comment period, we considered limiting the laboratory DOS exception at § 414.510(b)(5) to Criterion (A) ADLTs based on our belief that the beneficiary access concerns were no longer the same for molecular pathology testing, largely because they are not statutorily required to be performed by a single laboratory and we believed more kits are now available for hospitals to perform these tests. In addition, we noted this change could help address the billing and enrollment concerns raised by the blood banks and centers and administrative issues raised by other stakeholders. However, after reviewing the comments received on this topic, we no longer believe that limiting the laboratory DOS exception at § 414.510(b)(5) to ADLTs would be appropriate at this time. Commenters have informed us that many molecular pathology tests are performed by very few laboratories (or even by a single laboratory) and therefore, have similar beneficiary access concerns as ADLTs. In addition, based on the comments received, we understand that very few unique molecular pathology test kits are available for hospitals to use for molecular testing. We also acknowledge the comments that molecular pathology tests approved as ADLTs under Criterion (B) are also required by law to be performed by a single laboratory, and therefore, have similar beneficiary access issues as tests granted ADLT status under Criterion (A). As discussed later in this section of this final rule with comment period, we are finalizing the exclusion of molecular pathology testing performed by blood banks or centers from the laboratory DOS exception at § 414.510(b)(5). As such, we are no longer considering limiting

the exception to ADLTs as a mechanism for addressing the billing and enrollment concerns raised by the blood bank and center industry. In summary, because of the concerns raised by commenters, we are not finalizing this potential revision to limit the laboratory DOS policy exception at § 414.510(b)(5) to laboratory tests that have been granted Criterion (A) ADLT status by CMS.

Comment: Several stakeholders contended that limiting the laboratory DOS exception at § 414.510(b)(5) to Criterion (A) ADLTs would result in additional administrative burden for hospitals, laboratories and CMS. For example, they noted that because many molecular pathology tests are sole-source tests, we would receive a large number of requests for ADLT status under Criterion (A) so that the performing laboratory may bill for the test directly when performed on a specimen collected during a hospital outpatient encounter. As a result, they asserted that hospitals and laboratories may be required to reverse their billing policies multiple times over the course of a few years, or even a few months. For example, if the laboratory DOS exception at § 414.510(b)(5) were limited to ADLTs, the performing laboratory would no longer be permitted to bill for molecular pathology tests that are not currently Criterion (A) ADLTs, and therefore, the hospital and laboratory would be required to reverse its current billing practices so that the hospital bills Medicare directly for the test, instead of the performing laboratory. Stakeholders explained that for those molecular pathology tests that eventually receive approval as a Criterion (A) ADLT, the performing laboratory and hospital would again be required to reverse their billing policies and perhaps reverse those billing policies another time if the molecular pathology test ever loses its Criterion (A) ADLT status. They contended that this potential fluctuation in billing requirements would be administratively burdensome for hospitals and laboratories and urged us not to finalize this change to the laboratory DOS policy.

Response: We agree that if we were to finalize this change, potential fluctuation in billing may occur as a result of molecular pathology testing being granted Criterion (A) ADLT status in the future, and this could result in additional burden on hospitals and performing laboratories. As noted previously, because of the concerns raised by commenters, we are not finalizing the potential revision to limit the laboratory DOS policy exception at § 414.510(b)(5) to laboratory tests that have been granted Criterion (A) ADLT status by CMS.

Comment: A few commenters supported the revision that would limit the laboratory DOS exception at § 414.510(b)(5) to Criterion (A) ADLTs as discussed in the proposed rule. They contended that removing molecular pathology tests from the exception would greatly reduce the administrative burden associated with ensuring that the appropriate entity bill Medicare directly and would therefore allow work to be devoted to actual beneficiary care.

Response: As discussed previously in this section, as a result of our review of public comments on this topic, we believe that limiting the laboratory DOS exception to ADLTs could lead to a delay in test ordering and therefore, result in similar beneficiary access issues that prompted us to establish the laboratory DOS exception at § 414.510(b)(5). For this and other reasons discussed previously, we are not finalizing this change.

3. Excluding Blood Banks and Blood Centers From the Laboratory DOS Exception at 42 CFR 414.510(b)(5)

As we discussed in the CY 2020 OPPS/ASC proposed rule (84 FR 39603), following publication of the CY 2018 OPPS/ASC final rule with comment period, stakeholders informed us that blood banks and blood centers perform some of the molecular pathology test codes that are subject to the laboratory DOS exception at § 414.510(b)(5). We noted that, based on information from stakeholders, it was our understanding that blood banks and centers are entities whose primary function is the collection, storage and dissemination of blood products and are typically accredited by the AABB (formally known as the American Association of Blood Banks). We explained that representatives of blood banks and centers contend that while these entities may perform the same molecular pathology tests that are performed and billed by other laboratories that are not blood banks and centers, the blood banks and centers perform these tests for different reasons. Specifically, they assert that the blood banks and centers perform molecular pathology testing primarily to identify the most compatible blood product for a patient, whereas other laboratories typically provide molecular pathology testing for diagnostic purposes. We stated that, according to these stakeholders, the patient has already been diagnosed with a specific disease or condition before the blood sample is provided to the blood bank or center, which are then tasked with providing compatible blood products and assessing risks of incompatibility for hospitals. In other words, 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. We provided examples of molecular pathology testing performed by blood banks and centers, including red blood cell phenotyping, as described by HCPCS code 81403, red blood cell antigen testing as described by HCPCS code 0001U, and platelet antigen testing as described by HCPCS code 81105.

As discussed previously, when a test meets all of the conditions in the current laboratory DOS exception at § 414.510(b)(5), the DOS of the test must be the date the test was performed, and the laboratory that performed the test must bill Medicare directly for the test. This would include circumstances when a laboratory that is a blood bank or blood center performs the test. However, given the different purpose of molecular pathology testing performed by the blood banks and centers, that is, blood compatibility testing, in the CY 2020 OPPS/ASC proposed rule, 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. We stated in the CY 2020 OPPS/ASC proposed rule that based on our concern and the comments we had received from stakeholders, we were considering a regulatory change that would exclude blood banks and centers from the laboratory DOS exception at § 414.510(b)(5). Under this potential revision, the DOS for molecular pathology testing performed by blood banks and centers on specimens collected from a hospital outpatient during a hospital outpatient encounter would be the date of specimen collection unless another exception to the DOS policy applies. As a result, the hospital would bill for the molecular pathology test under arrangements and the blood bank or center performing the test would seek payment from the hospital. In addition, we noted that for purposes of excluding blood banks and centers from the provisions of § 414.510(b)(5), we would define a blood bank and center as an entity

whose primary function is the collection, storage and dissemination of blood products. We stated that we believed this potential definition of a blood bank and center describes the primary responsibility of all blood banks and centers, which distinguishes these entities from other laboratory types. We further noted that in developing a definition of blood banks and centers we were distinguishing blood banks and blood centers from non-blood bank and blood center laboratories that perform the same molecular pathology test codes but for different reasons, that is, for diagnostic purposes rather than for blood compatibility testing. We requested comments from hospitals, blood banks and centers, and other interested stakeholders regarding a potential revision to laboratory DOS policy that would exclude blood banks and centers from the laboratory DOS exception at § 414.510(b)(5). We also requested specific comments as to how a blood bank and blood center may be defined in the context of this provision, and particularly how to distinguish blood banks and centers from other clinical laboratories. We noted that we would consider finalizing a revision to the laboratory DOS policy that excludes blood banks and centers from the provisions of § 414.510(b)(5) as a result of comments received on this topic.

A summary of the public comments received on this potential revision and our responses are provided below.

Comment: Many stakeholders strongly supported the potential revision to exclude blood banks and centers from the laboratory DOS exception at § 414.510(b)(5) because this change would ensure beneficiary access to timely specialized molecular testing performed by blood banks and centers. They concurred with our reasoning that blood banks and centers typically perform molecular pathology testing to identify the most compatible blood product for the patient, which enables hospitals to prevent adverse conditions associated with blood transfusions and is inherently tied to a hospital service. They also noted that excluding blood banks and centers makes sense from a policy perspective because blood banks and centers are typically not Medicare enrolled entities, and therefore cannot bill Medicare directly. Therefore, the commenters stated that requiring blood banks and centers to comply with the laboratory DOS exception at § 414.510(b)(5) would create considerable burden and has the potential to cause delays in testing for blood compatibility and jeopardize Medicare beneficiaries' access to care. As such, stakeholders overwhelmingly supported the exclusion of blood banks and centers from the laboratory DOS exception at § 414.510(b)(5) so that the hospital is required to bill for molecular pathology testing performed by blood banks and centers.

In addition, a few commenters asserted that the potential definition of a blood bank and center, as discussed in the proposed rule, that is, ''an entity whose primary function is the collection, storage and dissemination of blood products'' omits ''processing'' and ''testing'' which are two critical, unique functions performed by blood banks and centers. Therefore, they recommended revisions to the potential definition of blood bank and blood center so that it clearly defines the role of blood banks and blood centers and better distinguishes these entities from other types of laboratories. Specifically, these commenters suggested that we define a blood bank and center 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.'' They noted that the suggested revisions are consistent with the definition used by the AABB, which accredits the activities conducted by blood centers and blood banks.

Response: For the reasons discussed in the CY 2020 OPPS/ASC proposed rule, and based on the support received from stakeholders, we are finalizing the revision to exclude blood banks and centers from the laboratory DOS exception at § 414.510(b)(5). In addition, we agree with commenters that their suggested revised definition of blood banks and centers clearly defines the primary role of blood banks and centers and better distinguishes blood banks and centers from other types of laboratories. To effectuate this policy change, we are revising § 414.510(b)(5) to exclude molecular pathology tests when performed by a laboratory that is a blood bank or center. We are defining the term ''blood bank or center'' instead of ''blood bank and center'' to reflect that a molecular pathology test is excluded when performed by either a blood bank or blood center. We are also defining ''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.

Comment: A few commenters urged us to clarify that all molecular testing performed by blood banks and blood centers, including molecular testing for red blood cells, white blood cells and platelets, is excluded from the laboratory DOS exception at § 414.510(b)(5). They noted that most blood banks and centers do not currently bill Medicare directly as laboratories and lack the infrastructure, resources and expertise to engage in direct billing. They also reiterated that requiring blood banks and centers to comply with the laboratory DOS exception would create considerable administrative burden on the blood bank and blood center industry. One stakeholder stated that requiring hospitals to ''tease out'' different purposes for molecular pathology tests performed by blood banks or centers would add even more complexity to the laboratory DOS policy exception. However, a few commenters that supported excluding blood banks and centers from the laboratory DOS exception at § 414.510(b)(5) believe that only molecular pathology testing performed for blood compatibility purposes should be excluded from the laboratory DOS exception; otherwise, blood banks or centers should be required to bill Medicare directly.

Response: We clarify that this policy change categorically excludes molecular pathology testing performed by laboratories that are blood banks or blood centers from the laboratory DOS exception at § 414.510(b)(5). Under our final policy, molecular pathology testing performed by blood banks or centers on a specimen collected during a hospital outpatient encounter is never subject to the laboratory DOS exception at § 414.510(b)(5). We believe that the burden on hospitals will be mitigated with the policy we are finalizing.

Comment: One commenter contended that excluding molecular pathology testing from the laboratory DOS exception at § 414.510(b)(5) would be consistent with existing CMS policy. The commenter noted that the Medicare Claims Processing Manual, chapter 16, section 100.2, already states that ''codes for procedures, services, blood products[,] auto- transfusions . . . codes such as whole blood, various red blood cell products, platelets, plasma, and cryoprecipitate,'' along with ''[o]ther codes for tests primarily associated with the provision of blood products'' are ''not clinical laboratory tests and are therefore never subject to [clinical laboratory] fee schedule limitations.'' The commenter noted that this is because ''[s]uch tests identify various characteristics of blood products, but are not diagnostic in nature.'' The commenter suggested that this Manual

guidance already excludes molecular pathology tests performed by blood banks and centers from the laboratory DOS policy exception at § 414.510(b)(5), because paragraph (b)(5), like the rest of § 414.510, applies to the date of service for ''a clinical laboratory test.'' However, the commenter stated that it would be appropriate to clarify that molecular pathology testing performed by blood banks and centers must be billed by the hospital.

Response: The Medicare Claims Processing Manual, chapter 16, section 100.2, describes laboratory test codes that are never subject to the CLFS because they are not clinical laboratory tests. They include test codes for procedures, services, blood products and auto-transfusions, and other test codes primarily associated with the provision of blood products. However, as discussed previously in this section, blood banks and centers also perform some of the same molecular pathology test codes that are performed and billed by other laboratories that are not blood banks or centers, and these molecular pathology test codes are subject to the laboratory DOS exception at § 414.510(b)(5). These molecular pathology test codes are not addressed in the manual guidance discussed by the commenter. Since blood banks and centers perform some of the same molecular pathology test codes as other laboratories that are not blood banks or centers, we believe that a regulatory revision is necessary to exclude these entities from the laboratory DOS exception at § 414.510(b)(5).

4. Additional Comments

Comment: One commenter submitted two alternative policy proposals. The first alternative policy proposal involves allowing hospitals the flexibility to negotiate with independent laboratories to determine which entity is responsible for billing Medicare for tests that are subject to the laboratory DOS exception at § 414.510(b)(5). Under this approach, the laboratory DOS exception at § 414.510(b)(5) would only apply if the hospital and the performing laboratory have not agreed that the hospital will bill for the test. For instance, the hospital and laboratory would affirm their agreement that the hospital will always bill for a molecular pathology test or ADLT performed on a specimen collected during a hospital outpatient encounter. If the hospital and a specific performing laboratory do not agree to this condition, the DOS would be the date of test performance and the performing laboratory would bill Medicare directly for the test. However, only one bill for the molecular pathology test or ADLT would be permitted. That is, under no circumstances would both the hospital and performing laboratory be permitted to bill for the same test for the same beneficiary with the same date of service. The same commenter suggested another alternative policy approach that would involve amending the referring laboratory billing for referred laboratory testing provision. The commenter stated that when a test does not guide treatment during a hospital outpatient encounter, the hospital laboratory is acting as a referring laboratory in accordance with section 1833(h)(5)(A) of the Act. Under this statutory provision, a referring laboratory may bill for a referred laboratory test subject to certain conditions. The commenter asserted that it would be reasonable for CMS to amend its current policy, which only permits independent clinical laboratories to bill claims for referred laboratory services, to also include the hospital laboratory when the requirements of the laboratory DOS policy exception at § 414.510(b)(5) are met.

The commenter asserted that these alternative policies would serve as a permanent solution that would address the many operational difficulties experienced by some hospitals and performing laboratories with respect to the DOS policy. The commenter urged us to finalize these suggested policy approaches effective January 1, 2020. Or in the alternative, the commenter requested that we extend the current enforcement discretion through CY 2020. The commenter contended that the additional time of enforcement discretion would allow us to address this issue in the CY 2021 OPPS/ASC proposed rule so that we could solicit stakeholder input on another solution.

Response: We are not adopting these suggestions for CY 2020. However, we will consider the commenter's suggestions as we continue to review, evaluate and refine the laboratory DOS exception at § 414.510(b)(5).

Comment: Two commenters recommended us to articulate a final implementation date for the laboratory DOS policy exception at § 414.510(b)(5). They explained that some hospitals have incurred significant cost to implement this change, however, due to CMS's announcements of enforcement discretion, some performing laboratories have refused to implement the change, which has forced hospitals to have different billing practices depending on the performing laboratory. They requested that CMS implement the revised laboratory DOS policy exception at § 414.510(b)(5), which was effective January 1, 2018, so that hospitals and performing laboratories can proceed with implementing this change.

Response: We appreciate the commenter's feedback on this topic. However, we wish to clarify that we have implemented the laboratory DOS exception at § 414.510(b)(5). The laboratory DOS exception at § 414.510(b)(5) is currently in effect; however, we have announced that we will exercise enforcement discretion, which has allowed hospitals to continue to bill for tests that would otherwise be subject to the exception. As discussed previously in this final rule with comment period, we heard from stakeholders that many hospitals and laboratories were experiencing administrative difficulties implementing the laboratory DOS exception at § 414.510(b)(5). Therefore, we issued consecutive enforcement discretions to allow more time for hospitals and laboratories to make the necessary systems changes to enable the performing laboratory to bill Medicare directly.

Comment: One commenter requested that we apply the same laboratory DOS exception for ADLTs and molecular pathology laboratory tests in the hospital outpatient setting to tests ordered for hospital inpatients. The commenter stressed the importance of having consistent policies across all care settings and asserted that allowing the same laboratory DOS exception to apply in the inpatient setting would improve CMS' ability to track the provision of molecular pathology tests and ADLTs using HCPCS codes, which would be useful for analyzing how specific tests contribute to episode cost, outcomes, and survival rates.

Response: As discussed in the CY 2018 OPPS/ASC final rule (82 FR 59398) we believe that a similar laboratory DOS exception for ADLTs approved under Criterion (A) and molecular pathology tests performed on specimens collected from hospital inpatients would have broader policy implications for the IPPS that need to be carefully considered. We also note that we did not discuss revising the laboratory DOS policy for the inpatient setting or to improve CMS' ability to evaluate patient outcomes in the CY 2020 OPPS/ASC proposed rule. However, we intend to continue studying the laboratory DOS exception and, if warranted, consider changes to the laboratory DOS policy for laboratory tests performed on specimens collected during an inpatient hospital stay in future rulemaking.

Comment: Several stakeholders requested that we add the technical

component of physician pathology services, such as in situ hybridization (ISH), and flow cytometry, to the list of test codes subject to the laboratory DOS exception at § 414.510(b)(5) because, like molecular pathology tests and ADLTs, timely access to these services are essential to determine the best course of clinical care. They also requested that molecular tests furnished as technical components of physician pathology services be excluded from OPPS packaging policy and paid at the Medicare physician fee schedule rate.

Response: We will consider the suggestions raised by commenters as we continue to review, evaluate and refine OPPS packaging policy and the laboratory DOS policy exception at § 414.510(b)(5).

Comment: A few commenters requested that CMS clarify that the date of performance is the date of a laboratory's final report. They suggested this clarification would avoid any ambiguity regarding the date of performance of the test.

Response: We appreciate the commenters' suggestion. However, as discussed in the CY 2018 OPPS/ASC final rule (82 FR 59398 through 59399) we continue to have concerns with this approach because we believe there is no clear and consistent definition of ''final report'' that applies to all laboratories and all types of specimens collected; that is, liquid-based, cellular, or tissue samples. Therefore, we are not making this clarification.

XIX. Prior Authorization Process and Requirements for Certain Hospital Outpatient Department (OPD) Services

A. Background

As part of our responsibility to protect the Medicare Trust Funds, we routinely analyze 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 outpatient department (OPD).

In line with this responsibility, we noted in the CY 2020 OPPS/ASC proposed rule that we recently completed an analysis of the volume of covered OPD services provided and determined that CMS has experienced significant increases in the utilization volume of some covered OPD services. In conducting the analysis, we targeted services that represent procedures that are likely to be cosmetic surgical procedures and/or are directly related to cosmetic surgical procedures that are not covered by Medicare, but may be combined with or masquerading as therapeutic services.[168] We also recognized 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 Medicare allowed amounts. Our analysis included the review of over 1.1 billion claims related to OPD services during the 11-year period from 2007 through 2017 [169] and detailed that the overall rate of OPD claims submitted for payment to the Medicare program increased each year by an average rate of 3.2 percent. This equated to an increase from approximately 90 million OPD claims submitted for payment in 2007 to approximately 118 million claims submitted for payment in 2017. 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 8.2 percent. We found that the total Medicare allowed amount for the OPD services claims processed in 2007 was approximately $31 billion and increased to $65 billion in 2017, while during this same 11-year period, the average annual increase in the number of Medicare beneficiaries per year was only 1.1 percent. The 8.2 percent increase exceeded the average annual increase of 5.8 percent per year in overall health care spending during that same time period (2007–2017), according to the analysis of the U.S. Bureau of Labor and Statistics Consumer Price Index for medical care.[170]

Upon reviewing specific OPD categories of services in comparison to these figures, we found higher than expected volume increases for several services. Many of these services fell within the following five general categories of services: (1) Blepharoplasty; (2) botulinum toxin injections; (3) panniculectomy; (4) rhinoplasty; and (5) vein ablation.

As discussed in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59004 through 59015), and addressed again in section X.D. of the CY 2020 OPPS/ASC proposed rule, we have developed many payment policies with the goal in mind of managing the growth in Medicare spending for OPD services, and most recently, to control unnecessary increases in the volume of OPD services using our authority under section 1833(t)(2)(F) of the Act. Section 1833(t)(2)(F) of the Act authorizes CMS to develop a method for controlling unnecessary increases in the volume of covered OPD services. We believe the increases in volume associated with certain covered OPD services described earlier in this section are unnecessary because the data show that the volume of utilization of these services far exceeds what would be expected in light of the average rate-of-increase in the number of Medicare beneficiaries; these procedures are often considered cosmetic and, in those instances, would not be covered by Medicare; and we are unaware of other factors that might contribute to clinically valid increases in volume. Therefore, these above-average increases in volume suggest an increase in unnecessary utilization. As discussed in detail below, we proposed to use the authority under section 1833(t)(2)(F) of the Act to require prior authorization for certain covered OPD services as a condition of Medicare payment.

B. Prior Authorization Process for Certain OPD Services

We believe a prior authorization process for certain OPD services would ensure that Medicare beneficiaries continue to receive medically necessary care while protecting the Medicare Trust Funds from improper payments, and at the same time keeping the medical necessity documentation requirements unchanged for providers. We believe prior authorization for these services will be an effective method for controlling increases in the volume of these services because we expect that it will reduce the instances in which Medicare pays for these services when they are merely cosmetic and not medically necessary. As a method for controlling unnecessary increases in the volume of certain covered OPD services, we proposed to use our authority under

[168] Medicare Benefit Policy Manual. Internet Only. Publication 100–02, Chapter 16, § 120.

[169] 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.*

[170] The 5.8 percent average increase per year in overall health care spending was arrived at using data publicly available on the Bureau of Labor and Statistics web page, located at: *https://www.bls.gov/cpi/factsheets/medical-care.htm.*

section 1833(t)(2)(F) of the Act to establish a process through which providers would submit a prior authorization request for a provisional affirmation of coverage before a covered OPD service is furnished to the beneficiary and before the claim is submitted for processing. We proposed to establish a new subpart I under 42 CFR part 419 to codify the conditions and requirements for the proposed prior authorization for certain covered OPD services to help control unnecessary increases in the volume of covered OPD services. This subpart would establish the conditions of payment for OPD services that require prior authorization; establish the submission requirements for prior authorization requests, including methods for expedited review of prior authorization requests; and provide for suspension of the prior authorization process generally, or for particular services. In order to allow time for providers to better understand this proposed prior authorization process, for CMS to ensure sufficient time is allowed for outreach and education to affected stakeholders, and for contractor operational updates to be in place, we proposed that this requirement would begin for dates of service on or after July 1, 2020. We note that we proposed to pattern some of the provisions for prior authorization for covered OPD services after the prior authorization program that we have already established for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) under 42 CFR 414.234.

As we noted, CMS routinely analyzes data as part of its oversight of the Medicare program, and our analysis was used as a basis for the CY 2020 OPPS/ASC proposed rule. Moreover, the Medicare program is continuing to incorporate advancements in health information technology (health IT) into its program operations. This includes improvements in interoperability, the secure electronic transmission of clinical data, and the potential incorporation of artificial intelligence into the claims review process. As these advancements in health IT continue, we are committed to ensuring that these efficiencies and enhancements will be considered, whenever possible, to reduce the burden placed on providers.

As stated earlier, we proposed to establish a new subpart I under part 419 (containing §§ 419.80 through 419.89 (§§ 419.84 through 419.89 would be reserved)) to codify the following proposed policies for prior authorization for certain covered OPD services.

1. Basis, Scope, and Definitions for Proposed New Subpart I Under Part 419

We proposed to specify the basis and scope of the proposed subpart under proposed new § 419.80, using section 1833(t)(2)(F) of the Act as our authority to establish the prior authorization process and requirements.

We proposed to define key terms associated with the proposed prior authorization process for certain covered OPD services under proposed new § 419.81. We proposed to define ''prior authorization'' to mean a process through which a request for provisional affirmation of coverage is submitted to CMS or its contractors for review before the service is provided to the beneficiary and before the claim is submitted. We proposed to define ''provisional affirmation'' to mean a preliminary finding that a future claim for the service will meet Medicare's coverage, coding, and payment rules. As previously mentioned, we patterned these proposed definitions after the prior authorization process for certain DMEPOS under 42 CFR 414.234. Lastly, we proposed to define the ''list of hospital outpatient department services requiring prior authorization'' as the list of outpatient department services CMS publishes in accordance with proposed new § 419.83(a) that require prior authorization as a condition of payment.

2. Prior Authorization as a Method for Controlling Unnecessary Increases in the Volume of Covered Outpatient Services (Proposed New § 419.82)

In proposed new § 419.82(a), we proposed that, as a condition of Medicare payment, a provider must submit a prior authorization request for services on the list of hospital outpatient department services requiring prior authorization to CMS that meets the requirements of the proposed new § 419.82(c); namely, that the prior authorization request includes all documentation necessary to show that the service meets applicable Medicare coverage, coding, and payment rules, and that the request be submitted before the service is provided to the beneficiary and before the claim is submitted. We proposed that claims submitted for services that require prior authorization that have not received a provisional affirmation of coverage from CMS or its contractors would be denied, unless the provider is exempt under § 419.83(c) (proposed new in § 419.82(b)(1)). This would include the denial of any claims associated with the denial of a service listed in proposed § 419.83(a)(1), including services such as anesthesiology services, physician services, and/or facility services. Moreover, we proposed that even when a provisional affirmation has been received, a claim for services may be denied based on either technical requirements that can only be evaluated after the claim has been submitted for formal processing or information not available at the time the prior authorization request is received (proposed new § 419.82(b)(2)(i) and (ii)).

We proposed that a provider must submit a prior authorization request for any service on the list of outpatient department services requiring prior authorization that would be published by CMS (proposed new § 419.82(c)). As noted earlier, we proposed that, in submitting a prior authorization request, the provider must include all relevant documentation necessary to show that the service meets applicable Medicare coverage, coding, and payment rules and that the request be submitted before the service is provided to the beneficiary and before the claim is submitted (proposed new § 419.82(c)(1)(i) and (ii)). We also proposed that providers have an opportunity to submit prior authorization requests for expedited review when a delay could seriously jeopardize the beneficiary's life, health, or ability to regain maximum function (proposed new § 419.82(c)(2). Documentation that the beneficiary's life, health, or ability to regain maximum function is in serious jeopardy must be submitted with this request.

We proposed that CMS or its contractor will review a prior authorization request for compliance with applicable Medicare coverage, coding, and payment rules (proposed new § 419.82(d)). If the request meets the applicable Medicare coverage, coding, and payment rules, CMS or its contractor would issue a provisional affirmation to the requesting provider (proposed new § 419.82(d)(1)(i)). If the request does not meet the applicable Medicare coverage, coding, and payment rules, CMS or its contractor would issue a non-affirmation decision to the requesting provider (proposed new § 419.82(d)(1)(ii)). In proposed new § 419.82(d)(iii), we proposed that CMS or its contractor would issue a decision (affirmative or non-affirmative) within 10 business days.

We proposed that, if the provider receives a non-affirmation decision, we would allow the provider to resubmit a prior authorization request with any applicable additional relevant documentation. This would include the resubmission of requests for expedited

reviews (proposed new § 419.82(e)(1) and (2)).

We proposed that CMS or its contractor would initiate an expedited review of a prior authorization request when requested by a provider and where CMS or its contractor determines that a delay could seriously jeopardize the beneficiary's life, health or ability to regain maximum function (proposed new § 419.82(d)(2)). Upon making this determination, we proposed that CMS or its contractor would issue a provisional affirmation or non-affirmation in accordance with proposed new § 419.82(d)(1) using an expedited timeframe of two business days.

As part of the requirements for the DMEPOS prior authorization process,[171] under 42 CFR 405.926(t), we specified that a prior authorization request that is non-affirmed is not an initial determination on a claim for payment for services provided and, therefore, would not be appealable. We proposed to apply this same provision to the OPD services prior authorization process. Therefore, we proposed to revise § 405.926(t) so that OPD prior authorization requests that are determined non-affirmed also would not be considered an initial determination and, therefore, would not be appealable. However, the provider will still have the opportunity to resubmit a prior authorization request under proposed new § 419.82(e) provided the claim has not yet been submitted and denied.

If a claim is submitted for the services listed in proposed new § 419.83(a)(1) without a provisional affirmation, it will be denied. The claim denial is an initial determination and a redetermination request may be submitted in accordance with 42 CFR 405.940. Consistent with current medical review and claims processing guidance, we also proposed in proposed new § 419.82(b)(3) that any claims associated with or related to a service listed in proposed new § 419.83(a)(1) for which a claim denial is issued will be denied as well since these services would be unnecessary if the service listed in proposed new § 419.83(a)((1) had not been provided. These associated services include, but are not limited to, services such as anesthesiology services, physician services, and/or facility services. The associated claims would be denied whether a non-affirmation was received for a service listed in proposed new § 419.83(a)(1) or the provider did not request a prior authorization request. A contractor is not required to request medical documentation from the provider who billed the associated claims before making such a denial. We requested public comments on whether the requirement in proposed new § 419.82(b)(3) should remain in 42 CFR part 419 or be co-located with the regulatory provisions governing initial determinations located in 42 CFR part 405.

3. Proposed List of Outpatient Department Services That Would Require Prior Authorization (Proposed New § 419.83)

We proposed that the list of covered OPD services that would require prior authorization are those identified by the CPT codes in Table 38. For ease of review, we are only including the five categories of services within which these CPT codes fall in proposed new § 419.83(a)(1). The five categories of services would be: Blepharoplasty; botulinum toxin injections; panniculectomy; rhinoplasty; and vein ablation. In proposed new § 419.83(a)(2), we proposed that technical updates, such as corrections or conforming changes to the names of the services or CPT codes, may be made on the CMS web page.

Also, we proposed that CMS may elect to exempt a provider from the prior authorization process in proposed new § 419.82 upon a provider's demonstration of compliance with Medicare coverage, coding, and payment rules and that this exemption would remain in effect until CMS elects to withdraw the exemption (proposed new § 419.83(c)). We would exempt providers that achieve a prior authorization provisional affirmation threshold of at least 90 percent during a semiannual assessment. We anticipate that an exemption will take approximately 90 calendar days to effectuate. We believe that, by achieving this percentage of provisional affirmations, the provider would be demonstrating an understanding of the requirements for submitting accurate claims. We do not believe it is necessary for a provider to achieve 100 percent compliance to qualify for an exemption because innocent and sporadic errors could occur that are not deliberate or systematic attempts to submit claims that are not payable. In addition, we propose that we might withdraw an exemption if evidence becomes available based on a review of claims that the provider has begun to submit claims that are not payable based on Medicare's billing, coding, or payment requirements. If the rate of nonpayable claims submitted becomes higher than 10 percent during a semiannual assessment, we will consider withdrawing the exemption. We anticipate that withdrawing the exemption may also take approximately 90 calendar days to effectuate.

Moreover, we proposed that CMS may suspend the outpatient department services prior authorization process requirements generally or for a particular service(s) at any time by issuing notification on CMS' web page (proposed new § 419.83(d)). While we believe this is unlikely to occur, we nonetheless believe it is necessary for us to retain flexibility in the event of certain circumstances, such as where the cost of the prior authorization program exceeds the savings it generates.

C. List of Outpatient Department Services Requiring Prior Authorization

As mentioned earlier, we have identified a list of specific services (Table 38) that, based on review and analysis of claims data for the 11-year period from 2007 through 2017, show higher than expected, and therefore, we believe, unnecessary increases in the volume of service utilization. These services fall within the following five categories: Blepharoplasty; botulinum toxin injections; panniculectomy; rhinoplasty; and vein ablation. In making the decision to propose to include the specific services in the proposed list of hospital outpatient department services requiring prior authorization as shown in Table 38, we first considered that these services are most often considered cosmetic and, therefore, are only covered by Medicare in very rare circumstances. We then viewed the current volume of utilization of these services and determined that the utilization far exceeds what would be expected in light of the average rate-of-increase in the number of Medicare beneficiaries. In the CY 2020 OPPS/ASC proposed rule, we noted that we are unaware of other factors that might contribute to increases in volume of services that indicate that the services are increasingly medically necessary, such as clinical advancements or expanded coverage criteria that would have led to the increases. Below we describe what we believe are the unnecessary increases in volume of each of the categories of services for which we proposed to require prior authorization:

- *Botulinum Toxin Injections:* In reviewing CMS data available through the Integrated Data Repository (IDR), we determined that destruction of nerves to muscles of the face via botulinum toxin injections had an overall average annual increase in the number of unique claims of approximately 19.3 percent from

[171] 80 FR 81674 (December 30, 2015).

2007 through 2017, with an average annual increase in financial expense to the Medicare program as a result of allowed amounts in service costs and payments of approximately 27.8 percent and an average annual increase in the number of unique patients of approximately 17.9 percent. Based on analysis and comparisons of claims data, these increases in service utilization volume, financial expense, and the number of Medicare patients far exceed the typical baseline rates or trends we identified.

• *Panniculectomy:* Our analysis of IDR data showed that panniculectomy had an average annual increase in the number of unique claims of approximately 9.2 percent from 2007 through 2017, with an average annual increase in financial expense to the Medicare program as a result of allowed amounts in service costs and payments of approximately 13.9 percent and an average annual increase in the number of unique patients of approximately 9.2 percent. Based on analysis and comparisons of claims data, these increases in service utilization volume, financial expense to the Medicare program, and the number of Medicare patients also far exceed the typical baseline rates or trends we identified (that is, the 9.2 percent average annual increase in the rate of Medicare beneficiaries receiving a panniculectomy is significantly higher than the 1.1 percent average annual increase in the Medicare beneficiaries who received outpatient services over that 11-year period). Additionally, some panniculectomy services were reported on claims by providers in combination with procedures performed on the patient's chest region, in addition to abdominal procedures.

• *Vein Ablation:* In reviewing the available data from the IDR, vein ablation had an average annual increase in the number of unique claims of approximately 11.1 percent from 2007 through 2017, with an average annual increase in financial expense to the Medicare program as a result of allowed amounts in service costs and payments of approximately 11.5 percent and an average annual increase in the number of unique patients of approximately 9.5 percent. Based on analysis and comparisons of claims data, these increases in service utilization volume, financial expense to the Medicare program, and the number of Medicare patients also far exceed the typical baseline rates or trends we identified (that is, the 9.5 percent average annual increase in the rate of Medicare beneficiaries receiving vein ablation is significantly higher than the 1.1 percent average annual increase in the Medicare beneficiaries who received outpatient services over that 11-year period).

• *Rhinoplasty:* In reviewing available IDR data, rhinoplasty had an average annual increase in the number of unique patients of approximately 1.9 percent. This represents a 64.1 percent increase in comparison to the 1.1 percent rate of increase for unique patients for all OPPS services for that same time period. Even though this category of services includes some procedures that had annual increases in service utilization volume far exceeding what we would expect based on the typical rate, this was not true for all services within the category. One example that did exceed the expected rate was the number of unique claims for the procedure of widening of the nasal passage. This rate increased significantly more than the expected rate and was as much as 34.8 percent from 2016 through 2017.

• *Blepharoplasty:* In reviewing the IDR data, blepharoplasty, like rhinoplasty, had overall statistics that were similar to the rate increases expected for outpatient services. However, some procedures had annual increases in service utilization volume that far exceeded these expected rates. As an example, the number of unique claims for the procedure of repairing of the upper eyelid muscle to correct drooping or paralysis increased as high as 48.9 percent from 2011 through 2012, which far exceeds the rate we would expect for such a service.

Table 38 lists the specific procedures within the five categories of services that we proposed for the proposed list of hospital outpatient department services requiring prior authorization.

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TABLE 38.--PROPOSED LIST OF OUTPATIENT SERVICES THAT WOULD REQUIRE PRIOR AUTHORIZATION

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
J0587	Injection, rimabotulinumtoxinb, 100 units
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 (eg, 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
21235	Obtaining ear cartilage for grafting
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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4. Summary of the Public Comments and Responses to Comments on the Proposed Rule

The proposed rule, titled ''Medicare Program; Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Proposed Revisions of Organ Procurement Organizations Conditions of Coverage; Proposed Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Proposed Changes to Grandfathered Children's Hospitals-Within-Hospitals'' (84 FR 39398 through 39644), hereinafter referred to as the ''CY 2020 OPPS/ASC proposed rule,'' was published in the **Federal Register** on August 6, 2019, with a comment period that ended on September 27, 2019. In that rule, for prior authorization, we received 96 public comments on our proposals, including comments from healthcare providers, professional and trade organizations, drug manufacturers, beneficiary advocacy organizations, and health care systems. The following is a summary of the comments we received and our responses.

Comment: We received several comments in support of prior authorization, with some adding they were ''intrigued'' by the promise prior authorization has in Fee-For-Service Medicare. Others commented that CMS is underestimating the amount of time and education providers will require in learning the new process. Some commenters suggested that CMS delay implementation of prior authorization beyond July 1, 2020, while others suggested that CMS proceed cautiously and roll out prior authorization on a limited basis and then scale nationally, similar to how the DMEPOS prior authorization process was implemented.

Response: We thank the commenters for their comments. We appreciate the positive responses to our proposed prior authorization process. In assessing the

operational implementation schedule for prior authorization, we believe that the July 1, 2020 implementation date is reasonable and will allow enough time to educate and prepare stakeholders to be able to submit the necessary documentation for prior authorization for these services. No new documentation requirements are created as a result of this process. Instead, currently needed documents are submitted earlier in the process.

Comment: Some commenters questioned whether section 1833(t)(2)(F) of the Act grants CMS the authority to establish a prior authorization process and noted that when Congress intended to give CMS authority to implement a prior authorization process, it has done so explicitly. Still others suggested the development of the new process 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. Several commenters quoted a recent decision from the United States District Court for the District of Columbia,[172] in which the court invalidated the policy we adopted in the CY 2019 OPPS/ASC final rule with comment period to reduce payment for clinic visits furnished in excepted off-campus provider-based departments to a Physician Fee Schedule-equivalent amount as a method to control unnecessary increases in the volume of clinic visits furnished in these settings. In its decision the court stated with respect to this policy, which we also adopted under section 1833(t)(2)(F) of the Act, that ''Congress did not intend CMS to use an untethered 'method' to directly alter expenditures independent of other processes.'' These commenters quoted the court as going on to state that, ''. . . Congress directed any 'methods' developed under paragraph (t)(2)(F) be implemented through other provisions of the statute.'' The commenters contended that we cannot point to any other provision of the OPPS statute that would authorize a prior authorization requirement, which the commenters believed we must do following the court's decision. Still others compared CMS' attempts to establish a prior authorization process to the ''functional equivalence'' initiative that CMS previously undertook, which Congress later prohibited.

Response: We disagree with the commenters' contentions. 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 believe that where, as here, we have determined that there have been unnecessary increases in services that are often cosmetic, section 1833(t)(2)(F) of the Act gives us authority to utilize prior authorization as a method to control those unnecessary increases. 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 Fee-for-Service Medicare, and which we believe will be effective at controlling unnecessary increases for those procedures that are often cosmetic and for which we have identified unnecessary volume increases. We also believe that the description of our extensive data analysis in the CY 2020 OPPS/ASC proposed rule, comparing trends for the procedures discussed against 1.1 billion OPD claims over 11 years, demonstrated that there have been unnecessary increases for all services for which we proposed to require prior authorization and that there have not been other, legitimate reasons for the sustained increases.

We also disagree with the commenters who believe the District Court's decision in the clinic visit litigation decision forecloses our ability to adopt a method to control unnecessary increases in the volume of covered outpatient department services under section 1833(t)(2)(F) of the Act without tying that method to another provision of the OPPS statute. Rather, we believe that, unlike the clinic visit policy at issue in that decision, the prior authorization policy does not have an immediate impact on the amount of payment or the budget neutrality calculations for the OPPS, and therefore, we believe it is distinguishable from the clinic visit policy that the court invalidated and does not need to be adopted under separate authority in addition to section 1833(t)(2)(F) of the Act.

Comment: Several commenters questioned why ambulatory surgical centers (ASCs) and other provider types are exempt from this prior authorization process. The commenters believed the prior authorization process should not be implemented until CMS can also establish a prior authorization process for ASCs because they believe physicians will simply provide the affected services in ASCs instead of hospitals, thereby avoiding the OPPS prior authorization process altogether. Still others believed that physicians should be required to obtain prior authorization instead of hospitals, and that CMS should adopt regulations under the Physician Fee Schedule to require physicians to adhere to the documentation and related requirements for prior authorization.

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 departments. As such, we cannot extend the process to ASCs or other healthcare provider types, including physicians outside of the outpatient department setting, because these entities are paid under other payment systems. We thank the commenters for noting the potential to shift these services to ASCs and will monitor these data and may consider additional program integrity oversight if such shifts are realized.

Comment: Several commenters suggested that prior authorization is not an effective method for controlling fraud and that other tools, such as CMS' development of National Coverage Decisions (NCDs) and Local Coverage Determinations (LCDs), prepayment and post-payment reviews, provider outreach and education, and law enforcement actions are more effective methods to control unnecessary increases in volume. In fact, some commenters suggested that we place providers on 100 percent pre-payment review in lieu of establishing the new prior authorization process. Others commented that prior authorization is nothing more than a ''blunt instrument;'' is contrary to some LCDs which clearly convey certain services are not covered; and that CMS needs to ensure coverage criteria are more easily identifiable and searchable so that hospitals can more readily comply with the requirements. One commenter questioned how to give input on establishing medical necessity and how medical necessity criteria will be set and another commenter specifically lauded CMS' not-yet-completed development of the documentation requirements look-up service (DRLS).

Response: We note that we have a variety of tools that can be used in making reasonable and necessary determinations for several procedures on the list of outpatient department services requiring prior authorization. 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, per section 1862(a)(1)(A) of the Act. This prior authorization process does not make any changes to current documentation requirements. While we recognize the utility of NCDs and LCDs and the

[172] *AHA et al.* v. *Azar,* No. 18–CV–2841, at *25 (D.D.C. Sept. 17, 2019).

importance of conducting prepayment and post-payment reviews, 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. 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. We will continue to work toward enhancing our overall program integrity strategy in meaningful ways. We also appreciate the positive input regarding the DRLS, and we agree that, once available, it will facilitate overall transparency in coverage requirements, which should benefit all parties.

Comment: Several commenters stated that prior authorization processes add burden, can result in unnecessary delays in care, and interfere with the physician-patient care decision or otherwise negatively affect patient care. Some commenters specifically mentioned problems associated with prior authorization processes within Medicare Advantage Plans while others conveyed that prior authorization is contrary to CMS' Patients Over Paperwork initiative.

Response: The process we are establishing specifically relates to Medicare FFS, not Medicare Advantage, and we have had demonstrated success in implementing prior authorization processes in the Medicare FFS for DMEPOS. As with our other prior authorization processes, we believe that the OPD prior authorization process for certain discrete, often cosmetic procedures can be implemented without the referenced delays in patient care. This is because we are establishing 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 will just require the same documents that are currently required to be submitted earlier in the process. Resources should not need to be diverted 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 believe that some assurance of payment and some protection from future audits will ultimately reduce burdens associated with denied claims and appeals.

Comment: We received comments with general questions regarding the proposed process such as who will be responsible for obtaining the prior authorization, that is, the physician or the hospital, and whether all related claims will be denied if prior authorization is not obtained. Some commenters expressed concern that physicians could be denied payment for services rendered if a hospital fails to submit a prior authorization request or fails to notify the physician of a denial.

Response: As noted above, this prior authorization process is being adopted under section 1833(t)(2)(F) of the Act, which is specific to OPD services, which provides payment only to hospital outpatient departments. In light of the different arrangements that could exist in different hospitals, we determined that enabling either the physician or the hospital to submit the prior authorization request on behalf of the hospital outpatient department was the best approach, though the hospital ultimately remains responsible for ensuring this condition of payment is met. Physicians and the hospitals are in the best position to account for the various relationships and obligations that exist and should account for the prior authorization process. Part of that process should be communication of prior authorization decisions between entities, as a unique tracking number (UTN) corresponding to the prior authorization decision must be included on the OPD claim for these services. Consistent with all Medicare Fee-for-Service prior authorization and pre-claim review processes, when a prior authorization request is submitted, the request will be assigned a UTN. The UTN must be included on any claim submitted for the services listed, which will be used to verify compliance with the prior authorization process.

Additionally, we stated that any claims associated with or related to a service that requires prior authorization for which a claim denial is issued would also be denied. These associated services include, but are not limited to, services such as anesthesiology services, physician services, and/or facility services. Consistent with current medical review and claims processing guidance (for example, Program Integrity Manual (internet Only Manuals, No. 100–08 chapter 3, section 3.2.3 *et seq.* and chapter 7, section 7.2.2.2), and in accordance with new § 419.82(b)(3), these related claims would be denied if the service listed in § 419.83(a)(1) had also been denied. Claims for physicians' services outside of the OPD setting will not be affected if the hospital fails to submit a prior authorization request for the OPD service.

Comment: Some commenters expressed concern that even when a provisional affirmation is obtained, the claim could ultimately be denied and that the requirement should be changed so that no claim could be denied for which a provisional affirmation was obtained. Still others asked for clarification regarding whether all claims would be denied in situations where a provisional affirmation was received but the corresponding claim was later denied. Others expressed concern that no appeal rights exist for those instances where a non-affirmation is received and that CMS should determine the cost of care to beneficiaries who are negatively impacted by the receipt of a non-affirmation or who have care denied.

Response: Having a provisional affirmation shows that a claim likely meets Medicare's coverage and payment rules and is likely to be paid. Absent evidence of fraud or gaming, a provider can anticipate payment as long as other payment requirements are met. We anticipate that most, if not all, claims for which a provisional affirmation is obtained would not be denied on the basis of medical necessity. However, it is possible the claim could be denied because it did not meet a coding or billing requirement (examples include, but are not limited to, when there are duplicate claims submitted, when some element of the claim form is incorrectly completed, or if a modifier is placed on a claim that prevents it from processing appropriately). In addition, The Improper Payments Elimination and Recovery Improvement Act of 2012 (IPERIA) (Pub. L. 112–248), requires all federal agencies to evaluate their

programs for improper payments. The CMS Comprehensive Error Rate Testing (CERT) program reviews a stratified, random sample of claims annually to identify and measure improper payments. It is possible for a claim subject to prior authorization to fall within the sample. In this situation, the subject claim would not be protected from the CERT audit. In addition, the Office of Inspector General's (OIG) authority to audit claims is not impacted by the protection from future audits provided by the provisional affirmation prior authorization decision.

While we appreciate that there is concern over the lack of appeal rights for non-affirmations, we note that providers are not limited in the number of times they can resubmit requests that were previously non-affirmed, and that appeal rights still exist once a claim is actually denied. Lastly, with regard to the impact on care for those beneficiaries for which hospitals receive non-affirmations, we note that we specifically chose services that are often cosmetic and believe that it is appropriate to deny such services in the case of a non-affirmation, because a non-affirmation would indicate that Medicare's coverage, coding, and/or payment rules for the service are not being met. Consistent with current Medicare Fee-for-Service prior authorization and pre-claim review processes, the provider will receive a detailed explanation as to why the request was non-affirmed and will be afforded an unlimited number of request resubmissions. Our experience in our other prior authorization and pre-claim review processes has been that approximately 95 percent of submissions are affirmed within two requests, and that the impact of non-affirmation decisions has been minimal for necessary, covered services.

Comment: Some commenters recommended that CMS decrease the ten business day time frame for issuing provisional affirmations and non-affirmations, because the commenters believed there could be occasions where the decision ultimately takes 15 days in light of weekends and holidays being excluded from the ten business day calculation. Still others commented that providers should be exempt from having to complete the prior authorization process in emergency situations or that retroactive provisional affirmations should be issued in these circumstances; the expedited review process should be completed within 24 hours if urgent circumstances exist; and the need to submit a request for an expedited review be eliminated and instead the judgment of the physician should suffice in triggering the expedited processing time frame.

Response: We appreciate the comments in response to our proposed process. While we recognize the desire to obtain provisional affirmations as quickly as possible, given that these services are typically cosmetic and would be provided in the outpatient hospital department setting, we believe the identified time frames adequately balance program integrity, provider burden, and beneficiary concerns. In those circumstances where approval is needed more expeditiously, an expedited request can be requested and if granted, will result in a provisional affirmation or non-affirmation being issued within two business days of the expedited request, which we believe is sufficient where expedition is necessary. With respect to the OPD services selected for this program, we believe that requests for expedited review will be minimal, and note that this prior authorization process does not remove or alter the clinical judgment process in any way. We are only requesting currently required documentation earlier in the process. As the OPD is ultimately responsible for this condition of payment to be met through the prior authorization process, we respectfully disagree with the commenter's suggestion to allow the OPD to be waived from their requirement to submit the prior authorization request solely on a physician's recommendation. All requests for expedited reviews will be considered based upon the documentation submitted by the OPD, including any justification provided by physicians on behalf of the OPD, and the timeframes designed into the process are intended to ensure that beneficiaries receive necessary care for these services when appropriate.

Comment: One commenter suggested that certain provisions, including the exemption rate and the notice of exemption and/or withdrawal of an exemption, should be explicitly accounted for within the regulations located in Part 419. Still other commenters suggested that CMS determine the rate of compliance with the coverage requirements prior to the implementation of this prior authorization process so that certain providers could begin the new process with an exemption in place for attaining or exceeding the requisite 90 percent compliance rate. Alternatively, one commenter suggested that CMS use existing data to identify egregious providers to reduce burden on historically compliant providers. Finally, one commenter suggested exempting providers from prior authorization if the providers participate in standardized data collection and are willing to share their data.

Response: We thank the commenters for these suggestions. We believe we have accounted for the exemption rate in the preamble and intend to maintain the 90 percent rate. With regard to the notice of exemption and/or withdrawal of an exemption, we agree that the regulations should account for this process in more detail. We had initially stated in the CY 2020 OPPS/ASC proposed rule (84 FR 39606) that we anticipate that an exemption will take approximately 90 calendar days to effectuate. In the interest of helping ensure providers incur the least burden possible, we will formalize the ability to notify providers before our anticipated 90-day period (that is, at least 60 days). As such, we have revised § 419.83(c) to redesignate the last sentence of proposed paragraph (c)—''An exemption will remain in effect until CMS elects to withdraw the exemption'' —as new subparagraph (1). We are adding a new provision at new paragraph (c)(2), which will account for the notice of an exemption or withdrawal of an exemption being delivered at least 60 calendar days prior to the implementation date. Because we are unable to determine a compliance or non-compliance rate prior to the initiation of the process because most claims have not undergone full medical review and were likely paid or denied based upon the completeness of the elements on the face of the claim, we cannot exempt certain providers or only require prior authorization for certain providers in advance of implementing the new process. Lastly, we do not believe it is sufficient to exempt providers who provide data. Through the prior authorization process, we are best able to identify problems before they occur and control for unnecessary increases in the volume of these procedures, while ensuring that beneficiaries receive medically necessary services.

Comment: Some commenters suggested that MACs do not 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. Still other commenters related several principles of prior authorization with which they believed we should comply as we implement the new prior authorization process. These principles include selective application of prior authorization to only ''outliers,''

review/adjustment of prior authorization lists to remove services/drugs that represent low-value prior authorization; transparency of prior authorization requirements and their clinical basis to patients and physicians; protections of patient continuity of care; and automation to improve prior authorization and 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 are adopting aligns with the principles outlined by the commenters. Of note, we have included a process to exempt providers who consistently demonstrate compliance with Medicare rules through this prior authorization process. We also are focusing initially on procedures that are not urgent and likely cosmetic and of high value, and we have included an expedited process if circumstances warrant. Along with our contractors, we will continue to analyze the value of the services that we target for prior authorization to be sure that services are selected that are appropriate for this process. As the process matures and CMS implements new technologies, such as the DRLS or other industry standards, we will effectuate improvements to the prior authorization process and coverage requirements.

Comment: Some commenters asked for clarification regarding how CMS would carry out certain provisions of the CY 2020 OPPS/ASC proposed rule, such as establishing standardized prior authorization protocols, including timely resolution of clinical reviews and clearly articulated decision criteria and rationale in an effort to minimize case delays and encourage effective communication changes between providers and health plans. Other commenters requested that CMS adopt a required response period for initial and repeat prior authorization requests, noted CMS' lack of experience in using prior authorization in Medicare Fee-For-Service, and referenced a lack of administrative structure and guidelines as well as the need for a well-functioning portal through which prior authorization requests could be submitted.

Response: In developing this prior authorization process, we indicated that we were building upon our already established prior authorization program established for certain DMEPOS under 42 CFR 414.234, and included more detailed requirements, such as decision timeframes for both regular and expedited reviews, as well as the percentages needed to demonstrate continued compliance with Medicare coverage, coding and payment rules in order to be exempt from the prior authorization process. We have considerable experience in light of the DMEPOS prior authorization program and are leveraging this experience accordingly. As we indicated in our prior responses, we are making additional changes, including adding specific regulatory provisions, to ensure the program's administrative requirements are clear. Once finalized, CMS and our contractors will provide additional educational and outreach materials to all stakeholders.

Comments: Some commenters requested changes that are out of the scope of this rule related to Medicare Advantage plans.

Response: This prior authorization policy is specific to Medicare FFS, so we are not able to respond to comments that raise concerns regarding Medicare Advantage prior authorization programs.

Comments: One commenter pointed out that we had used U.S. Bureau of Labor and Statistics (BLS) data when attempting to compare overall health care costs against the OPD payments trending data when other spending data may be more appropriate.

Response: We thank this commenter and have evaluated U.S. Bureau of Economic Analysis (BEA) data, which we agree may be more appropriate. We had compared the 8.2 percent average annual increase for OPD services over the 11-year period of 2007 through 2017 to the 5.8 percent average annual spending calculated from the BLS data; however, after consulting with both bureaus, the BEA data better aligns with our analytic process (that is, comparing overall expenditures for OPPS services via CMS data against overall expenditures for health care services via BEA data to as opposed to comparing overall expenditures for OPPS services via CMS data against the cost of health care services for the typical consumer via BLS data). The BEA data reflected a 2.3 percent average annual increase per year in overall health care spending using data publicly available on the BEA web page, located at: *https://apps.bea.gov/iTable/iTable.cfm?reqid=51&step=2&isuri=1https.*

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 and that CMS should analyze readily available clinical information that would explain changes in utilization before the agency adopts broad-based interventions such as imposing prior authorization on outpatient hospitals. The same commenter suggested that the increases seen in CPT codes 64612 and 64615 are likely due to other factors such as FDA's approval of BOTOX® in 2010, increased support for BOTOX® as a migraine treatment, and the addition of chronic migraine to the list of covered indications for BOTOX® in Medicare contractor LCDs. This commenter also recommended that if CMS chooses to move forward with implementing this prior authorization process that CMS expand the prior authorization requirements to apply to all four FDA-approved botulinum toxin therapeutic products to include DYSPORT® (J0586) and XEOMIN® (J0588) in addition to BOTOX® and MYOBLOC® so as not to create distortion in the marketplace and incentivize providers to administer those botulinum toxin therapeutic products that are not subject to prior authorization. One commenter also expressed concern that the prior authorization process could impact women and veterans more significantly than other categories because these groups tend to experience migraines at higher rates than other categories and this could ultimately lead to an increase in opioid abuse within these groups. We received several comments asking whether a provisional affirmation for botulinum toxin injections would be per injection or for a specific course of treatment over a period of time, such as twelve months. We also received comments to add codes to the list for alternative treatment options for varicose veins, such as phlebectomy and sclerotherapy.

Response: We thank the commenters for their input. In determining the specific services to which this prior authorization process would apply, we considered all available data and believe that comparing the utilization rate to the baseline growth rate is an appropriate method for identifying potentially unnecessary increases in volume. By identifying trends over the 11-year period for OPD services, we are able to contrast and compare specific services as targets for increases in volume versus

our expectations. Moreover, in making our decision we did consider the impact of changes in the use of these items and available clinical information. Of note, we determined that the increased utilization of botulinum toxin injections was not solely attributable to the Food and Drug Administration's approval for the treatment of migraines. We conducted additional analysis of the additional botulinum toxin products suggested by the commenter and determined that these too had similar increases in volume. As noted in the preamble, our statistical analysis of the botulinum toxin injection codes originally proposed showed an overall average annual increase in the number of unique claims of approximately 19.3 percent from 2007 through 2017, an annual average increase in costs and payments of approximately 27.8 percent, and an average annual increase in the number of unique patients of approximately 17.9 percent. When adding these two additional codes to our statistical analyses, utilizing the same methodology, we have identified that the overall average annual increase in the number of unique claims is now approximately 19.4 percent from 2007 through 2017, the annual average increase in payments is now approximately 26.1 percent, and the average annual increase in the number of unique patients is approximately 18.0 percent. Moreover, although we did observe some increases of the original botulinum toxin codes after the 2010 FDA clearance for chronic migraines, we noted an average annual increase in claims volume of 16.6 percent for J0585, 23.6 percent for J0586, 12.2 percent for J0587, and 17.9 percent for J0588. These statistics are for the period 2010 through 2017 for all four codes except J0588, which only had data beginning 2012 (with data for interim years within the four codes reflecting increases as high as 65.9 percent). These sustained and persistent increases above expected volumes are not explained by the new FDA approval in 2010. So as not to create distortion in the marketplace and incentivize providers to administer those botulinum toxin therapeutic products that are not subject to prior authorization, as the commenter suggests, we are including the two additional botulinum toxin codes on the final list, since they also show similar unnecessary increases in volume.

We acknowledge that circumstances exist where a prior authorization could apply for a specific course of treatment for the botulinum toxin injection procedures, such as a number of treatments over a specific period of time, and will allow for such prior authorization requests.

We performed similar data analysis on vein treatments and saw several of the procedures had similar unnecessary increases in volume; however, these procedures account for a different approach in treatment for varicose veins than the vein ablation procedures we discussed in the proposed rule. Since these are procedures and not products, we do not have the same concern about marketplace distortion and are not adding them to the list at this time. We will continue to monitor these and other OPD procedures for unnecessary increases in volume and will propose additional procedures through rulemaking.

In sum, we are finalizing our proposed prior authorization policy as proposed, including our proposed regulation text, with the following modifications: We are adding additional language at § 419.83(c) regarding the notice of exemption or withdraw of an exemption. We are including in this process the two additional botulinum toxin injections codes, J0586 and J0588. See Table 64 below for the final list of outpatient department services requiring prior authorization.

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TABLE 64.--PROPOSED LIST OF OUTPATIENT SERVICES THAT WOULD REQUIRE PRIOR AUTHORIZATION

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
J0587	Injection, rimabotulinumtoxinb, 100 units
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 (eg, 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
21235	Obtaining ear cartilage for grafting

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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4. Summary of the Public Comments and Responses to Comments on the Proposed Rule

The proposed rule, titled ''Medicare Program; Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Proposed Revisions of Organ Procurement Organizations Conditions of Coverage; Proposed Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Proposed Changes to Grandfathered Children's Hospitals-Within-Hospitals'' (84 FR 39398 through 39644), hereinafter referred to as the ''CY 2020 OPPS/ASC proposed rule,'' was published in the **Federal Register** on August 6, 2019, with a comment period that ended on September 27, 2019. In that rule, for prior authorization, we received 96 public comments on our proposals, including comments from healthcare providers, professional and trade organizations, drug manufacturers, beneficiary advocacy organizations, and health care systems. The following is a summary of the comments we received and our responses.

Comment: We received several comments in support of prior authorization, with some adding they were ''intrigued'' by the promise prior authorization has in Fee-For-Service Medicare. Others commented that CMS is underestimating the amount of time and education providers will require in learning the new process. Some commenters suggested that CMS delay implementation of prior authorization beyond July 1, 2020, while others suggested that CMS proceed cautiously and roll out prior authorization on a limited basis and then scale nationally, similar to how the DMEPOS prior authorization process was implemented.

Response: We thank the commenters for their comments. We appreciate the positive responses to our proposed prior authorization process. In assessing the operational implementation schedule for prior authorization, we believe that the July 1, 2020 implementation date will reasonably allow enough time to educate and prepare stakeholders to be able to submit the necessary documentation for prior authorization for these services. No new documentation requirements are created as a result of this process. Instead, currently needed documents are submitted earlier in the process.

Comment: Some commenters questioned whether section 1833(t)(2)(F) of the Act grants CMS the authority to

establish a prior authorization process and noted that when Congress intended to give CMS authority to implement a prior authorization process, it has done so explicitly. Still others suggested the development of the new process 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. Several commenters quoted a recent decision from the United States District Court for the District of Columbia,[173] in which the court invalidated the policy we adopted in the CY 2019 OPPS/ASC final rule with comment period to reduce payment for clinic visits furnished in excepted off-campus provider-based departments to a Physician Fee Schedule-equivalent amount as a method to control unnecessary increases in the volume of clinic visits furnished in these settings. In its decision the court stated with respect to this policy, which we also adopted under section 1833(t)(2)(F) of the Act, that ''Congress did not intend CMS to use an untethered 'method' to directly alter expenditures independent of other processes.'' These commenters quoted the court as going on to state that, ''. . . Congress directed any 'methods' developed under paragraph (t)(2)(F) be implemented through other provisions of the statute.'' The commenters contended that we cannot point to any other provision of the OPPS statute that would authorize a prior authorization requirement, which the commenters believed we must do following the court's decision. Still others compared CMS' attempts to establish a prior authorization process to the ''functional equivalence'' initiative that CMS previously undertook, which Congress later prohibited.

Response: We disagree with the commenters' contentions. We believe section 1833(t)(2)(F) of the Act gives us significant discretion to determine the appropriate methods to control unnecessary increases in the volume of covered OPD services. We believe that where, as here, we have determined that there have been unnecessary increases in services that are often cosmetic, section 1833(t)(2)(F) of the Act gives us authority to utilize prior authorization as a method to control those unnecessary increases. 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 Fee-for-Service Medicare, and which we believe will be effective at controlling unnecessary increases for those procedures that are often cosmetic and for which we have identified unnecessary volume increases. We also believe that the description of our extensive data analysis in the CY 2020 OPPS/ASC proposed rule, comparing trends for the procedures discussed against 1.1 billion OPD claims over 11 years, demonstrated that there have been unnecessary increases for all services for which we proposed to require prior authorization and that there have not been other, legitimate reasons for the sustained increases.

We also disagree with the commenters who believe the District Court's decision in the clinic visit litigation decision forecloses our ability to adopt a method to control unnecessary increases in the volume of covered outpatient department services under section 1833(t)(2)(F) of the Act without tying that method to another provision of the OPPS statute. Rather, we believe that, unlike the clinic visit policy at issue in that decision, the prior authorization policy does not have an immediate impact on the amount of payment or the budget neutrality calculations for the OPPS, and therefore, we believe it is distinguishable from the clinic visit policy that the court invalidated and does not need to be adopted under separate authority in addition to section 1833(t)(2)(F) of the Act.

Comment: Several commenters questioned why ambulatory surgical centers (ASCs) and other provider types are exempt from this prior authorization process. The commenters believed the prior authorization process should not be implemented until CMS can also establish a prior authorization process for ASCs because they believe physicians will simply provide the affected services in ASCs instead of hospitals, thereby avoiding the OPPS prior authorization process altogether. Still others believed that physicians should be required to obtain prior authorization instead of hospitals, and that CMS should adopt regulations under the Physician Fee Schedule to require physicians to adhere to the documentation and related requirements for prior authorization.

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 departments. As such, we cannot extend the process to ASCs or other healthcare provider types, including physicians outside of the outpatient department setting, because these entities are paid under other payment systems. We thank the commenters for noting the potential to shift these services to ASCs and will monitor these data and may consider additional program integrity oversight if such shifts are realized.

Comment: Several commenters suggested that prior authorization is not an effective method for controlling fraud and that other tools, such as CMS' development of National Coverage Decisions (NCDs) and Local Coverage Determinations (LCDs), prepayment and post-payment reviews, provider outreach and education, and law enforcement actions are more effective methods to control unnecessary increases in volume. In fact, some commenters suggested that we place providers on 100 percent pre-payment review in lieu of establishing the new prior authorization process. Others commented that prior authorization is nothing more than a ''blunt instrument;'' is contrary to some LCDs which clearly convey certain services are not covered; and that CMS needs to ensure coverage criteria are more easily identifiable and searchable so that hospitals can more readily comply with the requirements. One commenter questioned how to give input on establishing medical necessity and how medical necessity criteria will be set and another commenter specifically lauded CMS' not-yet-completed development of the documentation requirements look-up service (DRLS).

Response: We note that we have a variety of tools that can be used in making reasonable and necessary determinations. for several procedures on the list of outpatient department services requiring prior authorization. For other 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, per section 1862(a)(1)(A) of the Act. This prior authorization process does not make any changes to current documentation requirements. While we recognize the utility of NCDs and LCDs and the importance of conducting of prepayment and post-payment reviews, 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. 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 twill

[173] *AHA et al.* v. *Azar,* No. 18–CV–2841, at *25 (D.D.C. Sept. 17, 2019). [Do we want to mention the motion to modify?]

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. We will continue to work toward enhancing our overall program integrity strategy in meaningful ways. We also appreciate the positive input regarding the DRLS, and we agree that, once available, it will facilitate overall transparency in coverage requirements, which should benefit all parties.

Comment: Several commenters stated that prior authorization processes add burden, can result in unnecessary delays in care, and interfere with the physician-patient care decision or otherwise negatively affect patient care. Some commenters specifically mentioned problems associated with prior authorization processes within Medicare Advantage Plans while others conveyed that prior authorization is contrary to CMS' Patients Over Paperwork initiative.

Response: The process we are establishing specifically relates to Medicare FFS, not Medicare Advantage, and we have had demonstrated success in implementing prior authorization processes in the Medicare FFS for DMEPOS. As with our other prior authorization processes, we believe that the OPD prior authorization process for certain discrete, often cosmetic procedures can be implemented without the referenced delays in patient care. This is because we are establishing 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 will just require the same documents that are currently required to be submitted earlier in the process. Resources should not need to be diverted 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 believe that some assurance of payment and some protection from future audits will ultimately reduce burdens associated with denied claims and appeals.

Comment: We received comments with general questions regarding the proposed process such as who will be responsible for obtaining the prior authorization, that is, the physician or the hospital, and whether all related claims will be denied if prior authorization is not obtained. Some commenters expressed concern that physicians could be denied payment for services rendered if a hospital fails to submit a prior authorization request or fails to notify the physician of a denial.

Response: As noted above, this prior authorization process is being adopted under section 1833(t)(2)(F) of the Act, which is specific to OPD services, which provides payment only to hospital outpatient departments. In light of the different arrangements that could exist with physicians in different hospitals, we determined that enabling either the physician or the hospital to submit the prior authorization on behalf of the hospital outpatient department was the best approach. Physicians and the hospitals are in the best position to account for the various relationships and obligations that exist and should account for the prior authorization process. Part of that process should be communication of prior authorization decisions between entities, as a unique tracking number (UTN) corresponding to the prior authorization decision must be included on the OPD claim for these services. Consistent with all Medicare Fee-for-Service prior authorization and pre-claim review processes, when a prior authorization request is submitted, the request will be assigned a UTN. The UTN must be included on any claim submitted for the services listed, which will be used to verify compliance with the prior authorization process.

Additionally, we stated that any claims associated with or related to a service that requires prior authorization for which a claim denial is issued would also be denied. These associated services include, but are not limited to, services such as anesthesiology services, physician services, and/or facility services. Consistent with current medical review and claims processing guidance (for example, Program Integrity Manual (internet Only Manuals, Pub. L. 100–08 chapter 3, section 3.2.3 *et sec* and chapter 7, section 7.2.2.2), and in accordance with new § 419.82(b)(3), these related claims would be denied as well if the service listed in § 419.83(a)(1) had also been denied. If the prior authorization is not submitted by the hospital and the physician submits a claim for the service, it cannot be processed as an OPD service as this program requires prior authorization of the OPD service as a condition of payment.

Comment: Some commenters expressed concern that even when a provisional affirmation is obtained, the claim could ultimately be denied and that the requirement should be changed so that no claim could be denied for which a provisional affirmation was obtained. Still others asked for clarification regarding whether all claims would be denied in situations where a provisional affirmation was received but the corresponding claim was later denied. Others expressed concern that no appeal rights exist for those instances where a non-affirmation is received and that CMS should determine the cost of care to beneficiaries who are negatively impacted by the receipt of a non-affirmation or who have care denied.

Response: Having a provisional affirmation shows that a claim likely meets Medicare's coverage and payment rules and is likely to be paid. Absent evidence of fraud or gaming, a provider can anticipate payment as long as other payment requirements are met. We anticipate that most, if not all, claims for which a provision affirmation is obtained would not be denied on the basis of medical necessity. However, it is possible the claim could be denied because it did not meet a coding or billing requirement (examples include, but are not limited to, when there are duplicate claims submitted, when some element of the claim form is incorrectly completed, or if a modifier is placed on a claim that prevents it from processing appropriately). In addition, The Improper Payments Elimination and Recovery Improvement Act of 2012 (IPERIA) (Pub. L. 112–248), requires all federal agencies to evaluate their programs for improper payments. The CMS Comprehensive Error Rate Testing (CERT) program reviews a stratified, random sample of claims annually to identify and measure improper payments. It is possible for a claim subject to prior authorization to fall within the sample. In this situation, the subject claim would not be protected from the CERT audit. In addition, the Office of Inspector General's (OIG) authority to audit claims is not impacted by the protection from future audits provided by the provisional affirmation prior authorization decision.

While we appreciate that there is concern over the lack of appeal rights for non-affirmations, we note that providers are not limited in the number of times they can resubmit requests that were previously non-affirmed, and that appeal rights still exist once a claim is actually denied. Lastly, with regard to the impact on care for those beneficiaries for which hospitals receive non-affirmations, we note that we specifically chose services that are often cosmetic and believe that it is appropriate to deny such services in the case of a non-affirmation, because a non-affirmation would indicate that Medicare's coverage, coding, and/or payment rules for the service are not being met. Consistent with current Medicare Fee-for-Service prior authorization and pre-claim review processes, the provider will receive a detailed explanation as to why the request was non-affirmed and will be afforded an unlimited number of request resubmissions. Our experience in our other prior authorization and pre-claim review processes has been that approximately 95 percent of submissions are affirmed within two requests, and that the impact of non-affirmation decisions has been minimal for necessary, covered services.

Comment: Some commenters recommended that CMS decrease the ten business day time frame for issuing provisional affirmations and non-affirmations, because the commenters believed there could be occasions where the decision ultimately takes 15 days in light of weekends and holidays being excluded from the ten business day calculation. Still others commented that providers should be exempt from having to complete the prior authorization process in emergency situations or that retroactive provisional affirmations should be issued in these circumstances; the expedited review process should be completed within 24 hours if urgent circumstances exist; and the need to submit a request for an expedited review be eliminated and instead the judgment of the physician should suffice in triggering the expedited processing time frame.

Response: We appreciate the comments in response to our proposed process. While we recognize the desire to obtain provisional affirmations as quickly as possible, given that these are services are typically cosmetic and would be provided in the outpatient hospital department setting, we believe the identified time frames adequately balance program integrity, provider burden, and beneficiary concerns. In those circumstances where approval is needed more expeditiously, an expedited request can be requested and if granted, will result in a in a provisional affirmation or non-affirmation being issued within two business days of the expedited request, which we believe is sufficient where expedition is necessary. With respect to clinical judgement, the prior authorization process does not remove or alter the clinical judgement process in any way. We are only requesting currently required documentation earlier in the process. Physicians remain fully capable and responsible to support the reasonableness and necessity of the proposed services.

Comment: One commenter suggested that certain provisions, including the exemption rate and the notice of exemption and/or withdrawal of an exemption, should be explicitly accounted for within the regulations located in Part 419. Still other commenters suggested that CMS determine the rate of compliance with the coverage requirements prior to the implementation of this prior authorization process so that certain providers could begin the new process with an exemption in place for attaining or exceeding the requisite 90 percent compliance rate. Alternatively, one commenter suggested that CMS use existing data to identify egregious providers to reduce burden on historically compliant providers. Finally, one commenter suggested exempting providers from prior authorization if the providers participate in standardized data collection and are willing to share their data.

Response: We thank the commenters for these suggestions. We believe we have accounted for the exemption rate in the preamble and intend to maintain the 90 percent rate. With regard to the notice of exemption and/or withdrawal of an exemption, we agree that the regulations should account for this process in more detail. We had initially stated in the CY 2020 OPPS/ASC proposed rule (84 FR 39606) that we anticipate that an exemption will take approximately 90 calendar days to effectuate. In the interest of helping ensure providers incur the least burden possible, we have offered to formalize the ability to notify providers before our anticipated 90-day period (that is, at least 60 days) if and when possible. As such, we have revised § 419.83(c) to redesignate the last sentence of proposed paragraph (c)—''An exemption will remain in effect until CMS elects to withdraw the exemption''—as new subparagraph (1). We are adding a new provision at new paragraph (c)(2), which will account for the notice of an exemption or withdrawal of an exemption being delivered at least 60 calendar days prior to the implementation date. Because we are unable to determine a compliance or non-compliance rate prior to the initiation of the process because most claims have not undergone full medical review and were likely paid or denied based upon the completeness of the elements on the face of the claim, we cannot exempt certain providers or only require prior authorization for certain providers in advance of implementing the new process. Lastly, we do not believe it is sufficient to exempt providers who provide data. Through the prior authorization process, we are best able to identify problems before they occur and control for unnecessary increases in the volume of these procedures, while ensuring that beneficiaries receive medically necessary services.

Comment: Some commenters suggested that MACs do not 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. Still other commenters related several principles of prior authorization with which they believed we should comply as we implement the new prior authorization process. These principles include selective application of prior authorization to only ''outliers,'' review/adjustment of prior authorization lists to remove services/drugs that represent low-value prior authorization; transparency of prior authorization requirements and their clinical basis to patients and physicians; protections of patient continuity of care; and automation to improve prior authorization and 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 are adopting aligns with the principles outlined by the commenters. Of note, we have included a process to exempt providers who consistently demonstrate compliance with Medicare rules through this prior authorization process. We also are focusing initially

on procedures that are not urgent and likely cosmetic and of high value, and we have included an expedited process if circumstances warrant. Along with our contractors, we will continue to analyze the value of the services that we target for prior authorization to be sure that services are selected that are appropriate for this process. As the process matures and CMS implements new technologies, such as the DRLS or other industry standards, we will effectuate improvements to the prior authorization process and coverage requirements.

Comment: Some commenters asked for clarification regarding how CMS would carry out certain provisions of the CY 2020 OPPS/ASC proposed rule, such as establishing standardized prior authorization protocols, including timely resolution of clinical reviews and clearly articulated decision criteria and rationale in an effort to minimize case delays and encourage effective communication changes between providers and health plans. Other commenters requested that CMS adopt a required response period for initial and repeat prior authorization requests, noted CMS' lack of experience in using prior authorization in Medicare Fee-For-Service, and referenced a lack of administrative structure and guidelines as well as the need for a well-functioning portal through which prior authorization requests could be submitted.

Response: In developing this prior authorization process, we indicated that we were building upon our already established prior authorization program established for certain DMEPOS under 42 CFR 414.234, and included more detailed requirements, such as decision timeframes for both regular and expedited reviews, as well as the percentages needed to demonstrate continued compliance with Medicare coverage, coding and payment rules in order to be exempt from the prior authorization process. We have considerable experience in light of the DMEPOS prior authorization program and are leveraging this experience accordingly. As we indicated in our prior responses, we are making additional changes, including adding specific regulatory provisions, to ensure the program's administrative requirements are clear. Once finalized, CMS and our contractors will provide additional educational and outreach materials to all stakeholders.

Comments: Some commenters requested changes that are out of the scope of this rule related to Medicare Advantage plans.

Response: This prior authorization policy is specific to Medicare FFS, so we are not able to respond to comments that raise concerns regarding Medicare Advantage prior authorization programs.

Comments: One commenter pointed out that we had used U.S. Bureau of Labor and Statistics data when attempting to compare overall health care costs against the OPD payments trending data when other spending data may be more appropriate.

Response: We thank this commenter and have evaluated U.S. Bureau of Economic Analysis (BEA) data, which we agree may be more appropriate. We had compared the 8.2 percent average annual increase for OPD services over the 11-year period of 2007 through 2017 to the 5.8 percent average annual spending calculated from the Bureau of Labor and Statistics data; however, after consulting with both bureaus, the BEA data better aligns with our analytic process, which reflected a 2.3 percent average annual increase per year in overall health care spending using data publicly available on the BEA web page, located at: *https://apps.bea.gov/iTable/iTable.cfm?reqid=51&step=2&isuri=1https.*

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 and that CMS should analyze readily available clinical information that would explain changes in utilization before the agency adopts broad-based interventions such as imposing prior authorization on outpatient hospitals. The same commenter suggested that the increases seen in CPT codes 64612 and 64615 are likely due to other factors such as FDA's approval of BOTOX in 2010, increased support for BOTOX as a migraine treatment, and the addition of chronic migraine to the list of covered indications for BOTOX in Medicare contractor LCDs. This commenter also recommended that if CMS chooses to move forward with implementing this prior authorization process that CMS expand the prior authorization requirements to apply to all four FDA-approved botulinum toxin therapeutic products to include DYSPORT® (J0586) and XEOMIN® (J0588) in addition to BOTOX and MYOBLOC so as not to create distortion in the marketplace and incentivize providers to administer those botulinum toxin therapeutic products that are not subject to prior authorization. One commenter also expressed concern that the prior authorization process could impact women and veterans more significantly than other categories because these groups tend to experience migraines at higher rates than other categories and this could ultimately lead to an increase in opioid abuse within these groups. We received several comments asking whether a provisional affirmation for botulinum toxin injections would be per injection or for a specific course of treatment over a period of time, such as twelve months. We also received comments to add codes to the list for alternative treatment options for varicose veins, such as phlebectomy and sclerotherapy.

Response: We thank the commenters for their input. In determining the specific services to which this prior authorization process would apply, we considered all available data and believe that comparing the utilization rate to the baseline growth rate is an appropriate method for identifying potentially unnecessary increases in volume. By identifying trends over the 11-year period for OPD services, we are able to contrast and compare specific services as targets for increases in volume versus our expectations. Moreover, in making our decision we did consider the impact of changes in the use of these items and available clinical information. Of note, we determined that the increased utilization of botulinum toxin injections was not solely attributable to the Food and Drug Administration's approval for the treatment of migraines. We conducted additional analysis of the additional botulinum toxin injections and determined that these too had similar increases in volume and are including the two additional botulinum toxin codes on the final list. We acknowledge that circumstances exist where a prior authorization could apply for a specific course of treatment for the botulinum toxin injection procedures, such as a number of treatments over a specific period of time, and will allow for such prior authorization requests.

We performed similar data analysis on vein treatments and saw several of the procedures had similar unnecessary increases in volume; however, these procedures account for a different approach in treatment for varicose veins than vein ablation procedures. Since these are procedures and not products, we do not have the same concern about marketplace distortion and are not adding them to the list at this time. We will continue to monitor these and other OPD procedures for unnecessary increases in volume and will propose additional procedures through rulemaking.

In sum, we are finalizing our proposed prior authorization policy as proposed, including our proposed regulation text, with the following modifications: We are adding additional language at § 419.83(c) regarding the notice of exemption or withdraw of an exemption. We are including in this process the two additional botulinum toxin injections codes, J0586 and J0588. See Table 65 below for the final list of outpatient department services requiring prior authorization. Further, we had offered examples from our statistical analysis of the botulinum toxin injection in the preamble that explained that we had seen an overall average annual increase in the number of unique claims of approximately 19.3 percent from 2007 through 2017, an annual average increase in costs and payments of approximately 27.8 percent, and an average annual increase in the number of unique patients of approximately 17.9 percent. When adding these two additional codes to our statistical analyses, utilizing the same methodology, we have identified that the overall average annual increase in the number of unique claims is now approximately 19.4 percent from 2007 through 2017, the annual average increase in payments is now approximately 26.1 percent, and the average annual increase in the number of unique patients of approximately 18.0 percent. Moreover, although we did observe some increases of the original botulinum toxin codes after the 2010 FDA clearance for chronic migraines, we noted an average annual increase in claims volume of 16.6 percent for J0585, 23.6 percent for J0586, 12.2 percent for J0587, and 17.9 percent for J0588. These statistics are for the period 2010 through 2017 for all four codes except J0588, which only had data beginning 2012 (with data for interim years within the four codes reflecting increases as high as 65.9 percent). These sustained and persistent increases above expected volumes are not explained by the new FDA approval in 2010, which is why these codes, coupled with the specific procedures, have been included in this program.

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TABLE 65.--PROPOSED LIST OF OUTPATIENT DEPARTMENT SERVICES THAT WOULD REQUIRE PRIOR AUTHORIZATION

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 (eg, 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
21235	Obtaining ear cartilage for grafting
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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XX. Comments Received in Response to Comment Solicitation on Cost Reporting, Maintenance of Hospital Chargemasters, and Related Medicare Payment Issues

In the CY 2020 OPPS/ASC proposed rule (84 FR 39609), we included a Request for Information (RFI) related to the relationship of hospital chargemasters to the Medicare cost report and its use in setting Medicare payment for hospital services. We received approximately 46 timely pieces of correspondence on this RFI. We appreciate the input provided by commenters.

XXI. Changes to Requirements for Grandfathered Children's Hospitals-Within-Hospitals (HwHs)

Existing regulations at § 412.22(e) define a hospital-within-a-hospital (HwH) as a hospital that occupies space in the same building as another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital. Existing § 412.22(f) provides for the grandfathering of HwHs that were in existence on or before September 30, 1995, so long as the HwH continues to operate under the same terms and conditions, including the number of beds. Sections 412.22(h) and 412.25(e), relating to satellites of hospitals and hospital units, respectively, excluded from the IPPS, define a satellite facility as a part of a hospital or unit that provides inpatient services in a building also used by another hospital, or in one or more entire buildings located on the

same campus as buildings used by another hospital. Sections 412.22(h)(3) and 412.25(e)(3) provide for the grandfathering of excluded hospitals and units that were structured as satellite facilities on September 30, 1999, to the extent that they operate under the same terms and conditions in effect on that date. While these rules initially only applied to LTCHs, in 1997, CMS expanded the scope of these rules to all hospitals excluded from the IPPS (including children's hospitals) because the underlying policy concern of hospitals creating new entities that were separate in name only (essentially operating as units of the hospital) in order to increase Medicare revenue was not unique to LTCHs. For example, we have expressed our concerns that an HwH's ''configuration could result in patient admission, treatment, and discharge patterns that are guided more by attempts to maximize Medicare payments than by patient welfare'' and that ''the unregulated linking of an IPPS hospital and a hospital excluded from the IPPS could lead to two Medicare payments for what was essentially one episode of patient care'' (69 FR 48916 and 49191). HwHs which are grandfathered are not required to comply with the separateness and control requirements applicable to other HwHs.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38292 through 38294), we finalized a change to our HwH regulations at § 412.22(e) to only require, as of October 1, 2017, that IPPS-excluded HwHs that are co-located with IPPS hospitals comply with the separateness and control requirements in those regulations. We adopted this change because we believe that the policy concerns that underlay the previous HwH regulations are sufficiently moderated in situations where IPPS-excluded hospitals are co-located with each other, in large part due to changes that have been made to the way most types of IPPS-excluded hospitals are paid under Medicare. (We note that non-grandfathered HwHs, whether children's hospitals or not, which are co-located with IPPS hospitals must comply with separateness and control requirements. For more information we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38292 through 38294)). As part of our ongoing efforts to reduce regulatory burdens, we have continued to examine areas in which the rules for co-located entities are no longer necessary. As a result of this examination, we believe that there is no Medicare payment policy rationale for prohibiting grandfathered children's HwHs from increasing their number of beds. Given the low number of Medicare claims submitted by these children's hospitals, which results in a minimal level of Medicare payment to them relative to the payments they receive from other payers, we believe that such a regulatory change would allow these hospitals to address changing community needs for services without any increased incentive for inappropriate patient shifting to maximize Medicare payments. Additionally, we do not believe that allowing grandfathered children's HwHs to increase their bed size would impart an economic advantage to these hospitals relative to other hospitals. However, in the CY 2020 OPPS/ASC proposed rule, we proposed to revise § 412.22(f)(1) and (2) to allow a grandfathered children's HwH to increase its number of beds without resulting in the loss of grandfathered status. Additionally, we solicited comments on whether the proposal could create unintended or inadvertent consequences.

Comment: We received several comments on our proposal, all of which supported it. Some commenters also agreed with our assessment that allowing grandfathered children's HwHs to increase their beds would not impart an economic advantage to these hospitals.

Response: We thank commenters for their support.

In light of the comments received, we are finalizing our proposal without modification.

XXII. Notice of Closure of Two Teaching Hospitals and Opportunity To Apply for Available Slots

a. Background

Section 5506 of the Affordable Care Act (Pub. L. 111–148) added subsection (vi) to section 1886(h)(4)(H) of the Act and modified language at section 1886(d)(5)(B)(v) of the Act, to instruct 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 Hahnemann University Hospital, Located in Philadelphia, PA, and the Application Process—Round 16

CMS has learned of the closure of Hahnemann University Hospital, located in Philadelphia, PA (CCN 390290). 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 16th round (''Round 16'') of the application and selection process. Table 66 below contains the identifying information and IME and DGME FTE resident caps for the closed teaching hospital, which are part of the Round 16 application process under section 5506 of the Affordable Care Act.

TABLE 66.--IME and DGME FTE RESIDENT CAPS FOR HAHNEMANN UNIVERSITY 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])
390290	Hahnemann University Hospital	Philadelphia, PA	37964	September 6, 2019	587.25 – 30.44 = 556.81[2]	603.96 – 29.14 = 574.82 [3]

[1] Section 422 of the MMA, Pub. L. 108-173, redistributed unused IME and DGME residency slots effective July 1, 2005.
[2] Hahnemann University Hospital's 1996 IME FTE resident cap is 587.25. Under section 422 of the MMA, the hospital received a reduction of 30.44 to its IME FTE resident cap: 587.25 – 30.44 = 556.81.
[3] Hahnemann University Hospital's 1996 DGME FTE resident cap is 603.96. Under section 422 of the MMA, the hospital received a reduction of 29.14 to its DGME FTE resident cap: 603.96– 29.14 = 574.82.

c. Notice of Closure of Ohio Valley Medical Center, Located in Wheeling, WV, and the Application Process—Round 17

CMS has learned of the closure of Ohio Valley Medical Center, located in Wheeling, WV (CCN 510039). 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 17th round (''Round 17'') of the application and selection process. Table 67 below contains the identifying information and IME and DGME FTE resident caps for the closed teaching hospital, which are part of the Round 17 application process under section 5506 of the Affordable Care Act.

TABLE 67--IME and DGME FTE RESIDENT CAPS FOR OHIO VALLEY 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])
510039	Ohio Valley Medical Center	Wheeling, WV	48540	September 20, 2019	24.37– 3.33[2] + 1.89[3] = 22.93	24.91 – 3.74[2] + 1.76[3] = 22.93

[1] Section 422 of the MMA, Pub. L. 108-173, redistributed unused IME and DGME residency slots effective July 1, 2005.
[2] Ohio Valley Medical Center's 1996 IME FTE resident cap is 24.37. Under section 422 of the MMA, the hospital received a reduction of 3.33 and an increase of 1.89 to its IME FTE resident cap: 24.37 – 3.33 + 1.89 = 22.93. 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] Ohio Valley Medical Center's 1996 DGME FTE resident cap is 24.91. Under section 422 of the MMA, the hospital received a reduction of 3.74 and an increase of 1.76 to its DGME FTE resident cap: 24.91 – 3.74 + 1.76 = 22.93. 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 Direct Graduate Medical Education (DGME) website as noted at the end of this section) directly to the CMS Central Office no later than January 30, 2020. 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 January 30, 2020 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 [16 or 17] due to the closure of [Hahnemann University Hospital or Ohio Valley 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 Direct Graduate Medical Education (DGME) website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/DGME.html* 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

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 2020, we are retaining these columns, updated to reflect the amount of the 2020 inpatient deductible.

To view the Addenda to this final rule with comment period pertaining to CY 2020 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 ''1717–FC'' from the list of regulations. All OPPS Addenda to this final rule with comment period are contained in the zipped folder entitled ''2020 NFRM OPPS Addenda'' at the bottom of the page. To view the Addenda to this final rule with comment period pertaining to CY 2020 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 ''1717–FC'' from the list of regulations. All ASC Addenda to this final rule with comment period are contained in a zipped folder entitled ''Addendum AA, BB, DD1, DD2, and EE.''

XXV. 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 public comment 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 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 2019 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; and 83 FR 59155 through 59156, respectively) for detailed discussions of Hospital OQR Program information collection requirements we have previously finalized. The information collection requirements associated with the Hospital OQR Program are currently approved under OMB control number 0938–1109 which expires on March 31, 2021. Below we discuss only the changes in burden that will result from the finalized policies in this final rule with comment period.

In section XIV.B.3.b. of this final rule with comment period, we are finalizing our proposal with modification to remove one measure from the Hospital OQR Program for the CY 2022 payment determination; OP–33: External Beam Radiotherapy for Bone Metastases. The reduction in burden associated with this measure removal is discussed below.

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, 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 for the Hospital OQR Program. In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59156), we utilized a median hourly wage of $18.29 per hour. Since then, more recent wage data have become available and we are updating the wage rate used in these calculations. The latest data (May 2018) from the BLS reflects a median hourly wage of $19.40 [174] per hour for a Medical Records and Health Information Technician professional. 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 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 and allows for a conservative estimate of hourly costs. This approach is consistent with our previously finalized burden calculation methodology (82 FR 59477). Accordingly, we calculate cost burden to facilities using a wage plus benefits estimate of $38.80 per hour throughout the discussion below for the Hospital OQR Program.

2. Finalized Removal of OP–33 for the CY 2022 Payment Determination and Subsequent Years

In section XIV.B.3.b. of this final rule with comment period, we are finalizing our proposal with modification to remove one measure submitted via a web-based tool beginning with the CY 2022 payment determination and for subsequent years: OP–33: External Beam Radiotherapy for Bone Metastases. In the CY 2020 OPPS/ASC proposed rule, we inadvertently stated that we were proposing to remove this measure beginning with October 2020 encounters for CY 2022 payment determination and subsequent years (84 FR 39554 through 39556). As discussed in section XXVI.B.2. of this final rule with comment period, we intended to remove this measure beginning with the CY 2022 payment determination and subsequent years, but starting with January 2020 encounters, not October.

Because we are finalizing removal of this measure beginning with the same CY 2022 payment determination, as was proposed, the estimated effects remain the same as discussed in the proposed rule. As we stated in the CY 2016 OPPS/

[174] Occupational Employment and Wages, May 2018. Available at: *https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm.* Accessed May 7, 2019.

ASC final rule with comment period (80 FR 70582), we estimate that hospitals spend approximately 10 minutes, or 0.167 hours, per measure to report web-based measures. Accordingly, we believe that the removal of OP–33 for the CY 2022 payment determination will reduce burden by 0.167 hours per hospital, resulting in a burden reduction of 551 hours (0.167 hours × 3,300 hospitals) and $21,379 (551 hours × $38.80) across 3,300 hospitals.

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, and CY 2019 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; and 83 FR 59156 through 59157, respectively) for detailed discussions of the ASCQR Program information collection requirements we have previously finalized. The information collection requirements associated with the ASCQR Program are currently approved under OMB control number 0938–1270 which expires on January 31, 2022. As discussed below, there are only nominal changes in burden that will result from the finalized policies in this final rule with comment period.

2. Adoption of ASC–19: Facility-Level 7–Day Hospital Visits After General Surgery Procedures Performed at Ambulatory Surgical Centers (NQF #3357)

In section XV.B.3. of this this final rule with comment period, we are finalizing our proposal, beginning with the CY 2024 payment determination and for subsequent years, to adopt one measure collected via Medicare claims: ASC–19: Facility-Level 7–Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers (NQF #3357). Data used to calculate scores for this measure are collected via Medicare Part A and Part B administrative claims and Medicare enrollment data; therefore, ASCs will not be required to report any additional data. Because this measure does not require ASCs to submit any additional data, we believe there will be only a nominal change in other costs experienced by ASCs associated with this measure adoption due to having to review and track confidential feedback and reports related to the finalized ASC–19 measure.

D. ICRs for Revision of the Definition of ''Expected Donation Rate'' for Organ Procurement Organizations

We are finalizing our proposal to revise the definition of ''expected donation rate'' in the OPO CfCs. This change would allow OPOs to receive payment for organ donor costs under the Medicare and Medicaid programs using a definition that is consistent with the definition used by the Scientific Registry of Transplant Recipients (SRTR). Because we will be using data from the OPTN and the SRTR in assessing whether OPOs have satisfied the outcome measures of 42 CFR 486.318(b), we are adopting the definition currently used by the OPTN and SRTR in their statistical evaluation of OPO performance. This revision would not change the data that are already collected by the OPTN and SRTR, and therefore it will not affect the information collection burden on OPOs.

E. ICR for Prior Authorization Process and Requirements for Certain Hospital Outpatient Department (OPD) Services

In section XX. of the proposed rule, we proposed to establish a prior authorization process for certain hospital outpatient services as a condition for Medicare payment. We proposed to use our authority under section 1833(t)(2)(F) of the Act, which authorizes CMS to develop a method for controlling unnecessary increases in the volume of covered OPD services, to establish the prior authorization process. We believe a prior authorization process for OPD services will ensure beneficiaries receive medically necessary care while minimizing the risk of improper payments without changing the documentation requirements for providers and, therefore, will protect the Medicare Trust fund.

We proposed that providers would be required to obtain prior authorization from CMS for five groups of services and their related services before the services are provided to Medicare beneficiaries and before the provider could submit claims for payment under Medicare for these services. The five groups of services proposed are: Blepharoplasty, Botulinum Toxin Injections, Panniculectomy, Rhinoplasty, and Vein Ablation. The ICRs associated with prior authorization requests for these covered outpatient department services would be the required documentation submitted by providers. We proposed that a prior authorization request must include all relevant documentation necessary to show that the service meets applicable Medicare coverage, coding, and payment rules and that the request be submitted before the service is provided to the beneficiary and before the claim is submitted for processing. The burden associated with this finalized process is 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 would be sent by means other than mail. However, we estimate a cost of $5 per request for mailing medical records. Due to a July start date, the first year of the prior authorization will only include 6 months. Based on calendar year (CY) 2018 data, we estimate that for those first 6 months at a minimum there will be 15,191 initial requests mailed during that timeframe. In addition, we estimate there will be 4,987 resubmissions of a request mailed following a non-affirmed decision. Therefore, the total mailing cost is estimated to be $100,890 (20,178 mailed requests × $5). Based on CY 2018 data, we estimate that annually at a minimum there will be 30,381 initial requests mailed during a year. In addition, we estimate there will be 9,971 resubmissions of a request mailed following a non-affirmed decision. Therefore, the total mailing cost is estimated to be $201,762 (40,352 mailed requests × $5). We also estimate that an additional 3 hours would be required for attending educational meetings and reviewing training documents. While there may be an associated burden on beneficiaries while they wait for the prior authorization decision, we are unable to quantify that burden.

The average labor costs (including 100 percent fringe benefits) used to estimate the costs were calculated using data available from the BLS. Based on the BLS information, we estimate an average hourly rate of $16.63 with a loaded rate of $33.26. The prior authorization program does not create any new documentation or

administrative requirements. Instead, it just requires the currently required documents to be submitted earlier in the claim process. Therefore, the estimate uses the clerical rate as we do not believe that clinical staff would need to spend more time on completing the documentation than would be needed in the absence of the demonstration. The hourly rate reflects the time needed for the additional clerical work of submitting the prior authorization request itself. Therefore, we estimate that the total burden for the first year (6 months), allotted across all providers, would be 50,826 hours (.5 hours × 67,260, submissions plus 3 hours × 5,732 providers for education). The burden cost for the first year (6 months) is $1,791,363 (50,826 hours × $33.26 plus $100,890 for mailing costs). In addition, we estimate that the total annual burden hours, allotted across all providers, would be 84,450 hours (.5 hours × 134,508 submissions plus 3 hours × 5,732 providers for education). The annual burden cost would be $3,010,569 (84,450 hours × $33.26 plus $201,762 for mailing costs). For the total burden and associated costs, we estimate the annualized burden to be 73,242 hours and $2,604,167 million. 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 information collection request is under development and will be submitted to OMB for approval.

F. Revision to Laboratory Date of Service (DOS) Policy

In section XIX. of this final rule with comment period, we discuss our comment solicitation regarding potential revisions to the laboratory date of service (DOS) provisions at § 414.510(b)(5) for a molecular pathology test or a test designated by CMS as an ADLT under paragraph (1) of the definition of an ''advanced diagnostic laboratory test'' in § 414.502. As a result of our evaluation of public comments, we are finalizing a revision to exclude blood banks or centers from the laboratory DOS policy exception at § 414.510(b)(5). This revision to our laboratory DOS policy does not impose any information collection requirements. Consequently, review by the Office of Management and Budget under the authority of the PRA is not required.

XXV. 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.

XXVI. Economic Analyses

A. Statement of Need

This final rule with comment period is necessary to make updates to the Medicare hospital OPPS rates. It is necessary to make changes to the payment policies and rates for outpatient services furnished by hospitals and CMHCs in CY 2020. 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, 2018, through and including December 31, 2018, and processed through June 30, 2019, and updated cost report information.

We note that we are completing the phase-in of our method, as described below, to control unnecessary increases in the volume of covered outpatient department services by paying for clinic visits furnished at off-campus PBDs at an amount equal to the site-specific PFS payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD (the PFS payment rate). The site-specific PFS payment rate for clinic visits furnished in excepted off-campus PBDs is the OPPS rate reduced to the amount paid for clinic visits furnished by nonexcepted off-campus PBDs under the PFS, which is 40 percent of the OPPS rate. In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59013 through 59014), we implemented this policy with a 2-year phase-in. In CY 2019, the payment reduction was transitioned by applying 50 percent of the total reduction in payment that would apply if these off-campus PBDs were paid the site-specific PFS payment rate for the clinic visit service. In other words, these excepted off-campus PBDs were paid 70 percent of the OPPS rate for the clinic visit service in CY 2019. In CY 2020, we are completing the transition of paying the PFS-equivalent amount for clinic visits furnished in excepted off-campus PBDs. In other words, these excepted off-campus PBDs will be paid the full reduced payment, or 40 percent of the OPPS rate for the clinic visit service in CY 2020. We acknowledge that the United States District Court for the District of Columbia vacated the volume control policy for CY 2019 and we are working to ensure affected 2019 claims for clinic visits are paid consistent with the court's order. We do not believe it is appropriate at this time to make a change to the second year of the two-year phase-in of the clinic visit policy. The government has appeal rights, and is still evaluating the rulings and considering, at the time of this writing, whether to appeal from the final judgment.

This final rule with comment period also is necessary to make updates to the ASC payment rates for CY 2020, enabling CMS to make changes to payment policies and payment rates for covered surgical procedures and covered ancillary services that are performed in an ASC in CY 2020. 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 for 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 2020.

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. In the CY 2020 OPPS/ASC proposed rule (84 FR 39398), 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 with comment period, as appropriate.

We estimate that the total increase in Federal Government expenditures under the OPPS for CY 2020, compared to CY 2019, due only to the changes to the OPPS in this final rule with comment period, will be approximately $1.21 billion. Taking into account our estimated changes in enrollment, utilization, and case-mix for CY 2020, we estimate that the OPPS expenditures, including beneficiary cost-sharing, for CY 2020 will be approximately $79.0 billion, which is approximately $6.3 billion higher than estimated OPPS expenditures in CY 2019. We note that these spending estimates include the CY 2020 completion of the phase-in, finalized in CY 2019, to control for unnecessary increases in the volume of covered outpatient department services by paying for clinic visits furnished at excepted off-campus PBDs in CY 2020 at a rate that will be 40 percent of the OPPS rate for a clinic visit service. 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 68 of this final rule with comment period displays the distributional impact of the CY 2020 changes in OPPS payment to various groups of hospitals and for CMHCs.

As noted in section V.B.5 of this final rule with comment period, we are finalizing our proposal for CY 2020 to pay for separately payable drugs and biological products that do not have pass-through payment status and are not acquired under the 340B program at WAC+3 percent instead of WAC+6 percent, if ASP data are unavailable for payment purposes. If WAC data are not available for a drug or biological product, we will continue our policy to pay separately payable drugs and biological products at 95 percent of the AWP. We note that under our CY 2020 policy, drugs and biologicals that are acquired under the 340B Program would continue to be paid at ASP minus 22.5 percent, WAC minus 22.5 percent, or 69.46 percent of AWP, as applicable.

We 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 in CY 2020 under the OPPS at ASP–22.5 percent.

We estimate that the update to the conversion factor and other adjustments (not including the effects of outlier payments, the pass-through payment estimates, the application of the frontier State wage adjustment for CY 2020, and the completion of the phase-in to control for unnecessary increases in the volume of covered outpatient department services described in section X.D. of this final rule with comment period) will increase total OPPS payments by 1.3 percent in CY 2020. 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 2019 and CY 2020, considering all budget neutral payment adjustments, changes in estimated total outlier payments, pass-through payments, the application of the frontier State wage adjustment, and the completion of the phase-in to control unnecessary increases in the volume of outpatient services as described in section X.D. of this final rule with comment period, 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 1.3 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 2020 compared to CY 2019, to be approximately $180 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 42 and 43 of this final rule with comment period display the redistributive impact of the CY 2020 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 2020 policy changes on various hospital groups. We post on the CMS website our hospital-specific estimated payments for CY 2020 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–1717–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 41. 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 and 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 CY 2020 Completion of Phase-in to Control for Unnecessary Increases in the Volume of Outpatient Services

In section X.D. of this final rule with comment period, we discuss the CY 2020 completion of the phase-in of our CY 2019 finalized method to control for unnecessary increases in the volume of outpatient department services by paying for clinic visits furnished at an off-campus PBD at an amount equal to the site-specific PFS payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD (the PFS payment rate). Specifically, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59013 through 59014), we finalized our proposal to pay for HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient) when billed with modifier ''PO'' at an amount equal to the site-specific PFS payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD (the PFS payment rate), with a 2-year transition period. For a discussion of the PFS payment amount for outpatient clinic visits furnished at nonexcepted off-campus PBDs, we refer readers to the CY 2018 PFS final rule with comment period discussion (82 FR 53023 through 53024), as well as the CY 2019 PFS final rule and the CY 2020 PFS proposed rule.

To develop an estimated impact of this policy, we began with CY 2018 outpatient claims data used in ratesetting for the CY 2020 OPPS. We then flagged all claim lines for HCPCS code G0463 that contained modifier ''PO'' because the presence of this modifier indicates that such claims were billed for services furnished by an off-campus department of a hospital paid under the OPPS. Next, we excluded those that were billed as a component of C–APC 8011 (Comprehensive Observation Services) or packaged into another C–APC because, in those instances, OPPS payment is made for a broader package of services. We then simulated payment for the remaining claim lines as if they were paid at the PFS-equivalent rate. An estimate of the policy that includes the effects of estimated changes in enrollment, utilization, and case-mix based on the FY 2020 Midsession Review approximates the estimated decrease in total payment under the OPPS at $800 million, with Medicare OPPS payments decreasing by $640 million and beneficiary copayments decreasing by $160 million. We note that the additional impact specifically as a result of completing the phase-in in CY 2020, is $400 million, with Medicare payments decreasing by $320 million and beneficiary copayments decreasing by $80 million. This estimate is utilized for the accounting statement displayed in Table 42 of this final rule with comment period because the impact of this CY 2020 policy, which is not budget neutral, is combined with the impact of the OPD update, which is also not budget neutral, to estimate changes in Medicare spending under the OPPS as a result of the changes in this final rule with comment period.

We note that our estimates may differ from the actual effect of the proposed policy due to offsetting factors, such as changes in provider behavior. We note that, by removing this payment differential that may influence site-of-service decision-making, we anticipate an associated decrease in the volume of clinic visits provided in the excepted off-campus PBD setting. In the proposed rule, we reminded readers that this estimate could change in the final rule with comment period based on factors such as the availability of updated data. Finally, we acknowledge that the United States District Court for the District of Columbia vacated the volume control policy for CY 2019 and we are working to ensure affected 2019 claims for clinic visits are paid consistent with the court's order. Our estimates may differ from the actual effect of this policy depending on the outcome of this litigation.

c. Estimated Effects of OPPS Changes on Hospitals

Table 41 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 41, 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 2020, we are finalizing our proposal to pay CMHCs for partial hospitalization services under APC 5853 (Partial Hospitalization for CMHCs), and finalizing our proposal 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 2020 is 3.0 percent. Section 1833(t)(3)(F)(i) of the Act reduces that 3.0 percent by the multifactor productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, which is 0.4 percentage point for FY 2020 (which is also the MFP adjustment for FY 2020 in the FY 2020 IPPS/LTCH PPS final rule (84 FR 19411)), resulting in the OPD fee schedule increase factor of 2.6 percent. We are using the OPD fee schedule increase factor of 2.6 percent in the calculation of the CY 2020 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 41 of this final rule with comment period.

To illustrate the impact of the CY 2020 changes, our analysis begins with

a baseline simulation model that uses the CY 2019 relative payment weights, the FY 2019 final IPPS wage indexes that include reclassifications, and the final CY 2019 conversion factor. Table 41 shows the estimated redistribution of the increase or decrease in payments for CY 2020 over CY 2019 payments to hospitals and CMHCs as a result of the following factors: the impact of the APC reconfiguration and recalibration changes between CY 2019 and CY 2020 (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 2.6 percent OPD fee schedule increase factor update to the conversion factor (Column 4); the finalized off-campus PBD clinic visits payment policy (Column 5), and the estimated impact taking into account all payments for CY 2020 relative to all payments for CY 2019, including the impact of changes in estimated outlier payments, and changes to the pass-through payment estimate (Column 6).

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 2020. 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 2020 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 2019 and CY 2020 by various groups of hospitals, which CMS cannot forecast.

Overall, we estimate that the rates for CY 2020 will increase Medicare OPPS payments by an estimated 1.3 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 1.3 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 41 shows the total number of facilities (3,732), including designated cancer and children's hospitals and CMHCs, for which we were able to use CY 2018 hospital outpatient and CMHC claims data to model CY 2019 and CY 2020 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 2019 or CY 2020 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 (3,625), 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 41 CMHCs at the bottom of the impact table (Table 41) 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 a 0.1 percent increase, with the impact ranging from a decrease of 0.1 percent to an increase of 0.4 depending on the number of beds. Rural hospitals will experience a decrease of up to 0.9 percent depending on the number of beds. Major teaching hospitals will experience no change.

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 2020 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 2019 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 proposed updated wage indexes, including the application of budget neutrality for the rural floor policy on a nationwide basis, as well as the CY 2020 proposed changes in wage index policy discussed in section II.C. of the CY 2020 OPPS/ASC proposed rule. 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 2020, as described in section II.E. of this final rule with comment period. We also modeled a budget neutrality adjustment for the cancer hospital payment adjustment because we are using a payment-to-cost ratio target for the cancer hospital payment adjustment in CY 2020 of .90, which is higher than the ratio that was reported for the CY 2019 OPPS/ASC final rule with comment period (83 FR 58873). 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 2020 scaled weights and a CY 2019 conversion factor that included a budget neutrality adjustment for the effect of the changes to the wage indexes between CY 2019 and CY 2020.

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 2.6 percent.

Overall, these changes will increase payments to urban hospitals by 2.7 percent and to rural hospitals by 2.8 percent. The increase for classes of rural hospitals will vary with sole community hospitals receiving a 2.8 percent increase and other rural hospitals receiving an increase of 2.7 percent.

Column 5: Off-Campus PBD Visits Payment Policy

Column 5 displays the estimated effect of our finalized CY 2020 volume control method, finalized in CY 2019, to pay for clinic visit HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient) when billed with modifier ''PO'' by an excepted off-campus PBD at a rate that will be 40 percent of the OPPS rate for a clinic visit service for CY 2020. We note that the numbers provided in this column isolate the estimated effect of this policy adjustment relative to the numerator of Column 4. Therefore, the numbers reported in Column 5 show how much of the difference between the estimates in Column 4 and the estimates in Column 6 are a result of the finalized off-campus PBD visits policy for CY 2020, as finalized in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59013 through 59014).

Column 6: All Changes for CY 2020

Column 6 depicts the full impact of the CY 2020 policies on each hospital group by including the effect of all changes for CY 2020 and comparing them to all estimated payments in CY 2019. Column 6 shows the combined budget neutral effects of Columns 2 through 3; the OPD fee schedule increase; the effect of the CY 2020 off-campus PBD visits policy finalized in CY 2019, 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 2019 update (and assumed, for modeling purposes, to be the same number for CY 2020), we included 24 hospitals in our model because they had both CY 2018 claims data and recent cost report data. We estimate that the cumulative effect of all changes for CY 2020 will increase payments to all facilities by 1.3 percent for CY 2020. We modeled the independent effect of all changes in Column 6 using the final relative payment weights for CY 2019 and the relative payment weights for CY 2020. We used the final conversion factor for CY 2019 of $79.490 and the final CY 2020 conversion factor of $80.784 discussed in section II.B. of this final rule with comment period.

Column 6 contains simulated outlier payments for each year. We used the 1-year charge inflation factor used in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42629) of 5.4 percent (1.05404) to increase individual costs on the CY 2018 claims, and we used the most recent overall CCR in the July 2019 Outpatient Provider-Specific File (OPSF) to estimate outlier payments for CY 2019. Using the CY 2018 claims and a 5.4 percent charge inflation factor, we currently estimate that outlier payments for CY 2019, using a multiple threshold of 1.75 and a fixed-dollar threshold of $4,825, will be approximately 1.0 percent of total payments. The estimated current outlier payments of 1.0 percent are incorporated in the comparison in Column 6. We used the same set of claims and a charge inflation factor of 11.1 percent (1.11100) and the CCRs in the July 2019 OPSF, with an adjustment of 0.97615, to reflect relative changes in cost and charge inflation between CY 2018 and CY 2020, 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 $5,075. The charge inflation and CCR inflation factors are discussed in detail in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 42629).

Overall, we estimate that facilities will experience an increase of 1.3 percent under this final rule with comment period in CY 2020 relative to total spending in CY 2019. This projected increase (shown in Column 6) of Table 68 reflects the 2.6 percent OPD fee schedule increase factor, minus 0.6 percent for the off-campus PBD visits policy, minus 0.74 percent for the change in the pass-through payment estimate between CY 2019 and CY 2020, plus no difference in estimated outlier payments between CY 2019 (1.00 percent) and CY 2020 (1.00 percent). We estimate that the combined effect of all final changes for CY 2020 will increase payments to urban hospitals by 1.3 percent. Overall, we estimate that rural hospitals will experience a 1.1 percent increase as a result of the combined effects of all the changes for CY 2020.

Among hospitals, by teaching status, we estimate that the impacts resulting from the combined effects of all changes will include an increase of 0.9 percent for major teaching hospitals and an increase of 1.5 percent for nonteaching hospitals. Minor teaching hospitals will experience an estimated increase of 1.3 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 1.1 percent, proprietary hospitals will experience an increase of 2.1 percent, and governmental hospitals will experience an increase of 1.3 percent.

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TABLE 68—ESTIMATED IMPACT OF THE CY 2020 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

		(1)	(2)	(3)	(4)	(5)	(6)
		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**	**Existing Off-Campus Provider-Based Department Visits Policy**	**All Changes**
ALL FACILITIES *		3,732	0.0	0.1	2.7	-0.6	1.3
ALL HOSPITALS		3,625	0.0	0.1	2.7	-0.6	1.3
(excludes hospitals permanently held harmless and CMHCs)							
URBAN HOSPITALS		2,849	0.1	0.0	2.7	-0.5	1.3
	LARGE URBAN	1,471	0.0	-0.2	2.4	-0.4	1.2
	(GT 1 MILL.)						
	OTHER URBAN	1,378	0.1	0.2	3.0	-0.6	1.4
	(LE 1 MILL.)						
RURAL HOSPITALS		776	-0.5	0.7	2.8	-0.6	1.1
	SOLE COMMUNITY	365	-0.5	0.7	2.8	-0.7	0.9
	OTHER RURAL	411	-0.6	0.7	2.7	-0.5	1.3

		(1)	(2)	(3)	(4)	(5)	(6)
		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**	**Existing Off-Campus Provider-Based Department Visits Policy**	**All Changes**
BEDS (URBAN)							
	0 - 99 BEDS	973	0.4	0.1	3.2	-0.4	1.9
	100-199 BEDS	822	-0.1	0.0	2.5	-0.5	1.1
	200-299 BEDS	444	0.0	0.0	2.6	-0.5	1.3
	300-499 BEDS	390	0.1	0.3	3.0	-0.5	1.5
	500 + BEDS	220	0.1	-0.1	2.6	-0.7	1.1
BEDS (RURAL)							
	0 - 49 BEDS	342	-0.9	1.2	2.9	-0.3	1.5
	50- 100 BEDS	267	-0.6	0.9	2.9	-0.7	0.9
	101- 149 BEDS	87	-0.6	0.9	2.9	-0.6	1.2
	150- 199 BEDS	43	-0.2	0.8	3.2	-0.9	1.3
	200 + BEDS	37	-0.1	-0.5	1.9	-0.6	0.6
REGION (URBAN)							
	NEW ENGLAND	134	-0.3	-2.0	0.3	-1.0	-1.4
	MIDDLE ATLANTIC	335	0.0	0.1	2.7	-0.4	1.5
	SOUTH ATLANTIC	461	0.1	-0.1	2.5	-0.5	1.2
	EAST NORTH CENT.	456	-0.1	-0.2	2.3	-0.7	0.8
	EAST SOUTH CENT.	165	0.2	0.8	3.6	-0.2	2.6
	WEST NORTH CENT.	179	0.3	1.2	4.1	-0.6	1.7
	WEST SOUTH CENT.	491	0.4	0.1	3.1	-0.5	1.9
	MOUNTAIN	208	0.0	-0.2	2.4	-0.5	0.7
	PACIFIC	373	0.3	0.5	3.4	-0.5	2.1
	PUERTO RICO	47	1.0	17.8	22.0	0.0	20.9
REGION (RURAL)							
	NEW ENGLAND	21	-0.5	-1.4	0.7	-1.9	-1.8
	MIDDLE ATLANTIC	53	-0.6	-0.1	1.9	-1.0	0.2

		(1)	(2)	(3)	(4)	(5)	(6)
		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**	**Existing Off-Campus Provider-Based Department Visits Policy**	**All Changes**
	SOUTH ATLANTIC	119	-0.8	0.9	2.7	-0.2	1.7
	EAST NORTH CENT.	120	-0.5	-0.2	1.9	-0.7	0.4
	EAST SOUTH CENT.	150	-0.5	1.2	3.3	-0.2	2.3
	WEST NORTH CENT.	96	-0.3	1.5	3.8	-0.8	1.1
	WEST SOUTH CENT.	145	-0.6	1.0	3.0	-0.3	2.0
	MOUNTAIN	49	-0.3	2.4	4.8	-0.3	1.1
	PACIFIC	23	-0.6	0.7	2.7	-1.0	1.0
TEACHING STATUS							
	NON-TEACHING	2,469	-0.1	0.3	2.8	-0.4	1.5
	MINOR	781	0.1	0.2	2.9	-0.6	1.3
	MAJOR	375	0.0	-0.2	2.4	-0.8	0.9
DSH PATIENT PERCENT							
	0	13	2.5	0.4	5.6	0.0	4.4
	GT 0 - 0.10	274	1.0	0.0	3.6	-0.3	2.3
	0.10 - 0.16	256	0.0	0.0	2.6	-0.5	1.2
	0.16 - 0.23	558	0.1	0.0	2.7	-0.4	1.4
	0.23 - 0.35	1,117	-0.1	0.2	2.8	-0.6	1.1
	GE 0.35	931	-0.1	0.1	2.6	-0.6	1.2
	DSH NOT AVAILABLE **	476	2.0	0.9	5.6	-0.4	4.7
URBAN TEACHING/DSH							
	TEACHING & DSH	1,038	0.1	0.0	2.7	-0.7	1.1
	NO TEACHING/DSH	1,344	0.1	0.1	2.8	-0.3	1.6
	NO TEACHING/NO DSH	12	2.5	0.5	5.7	0.0	4.8

		(1)	(2)	(3)	(4)	(5)	(6)
		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**	**Existing Off-Campus Provider-Based Department Visits Policy**	**All Changes**
	DSH NOT AVAILABLE**	455	1.8	0.8	5.3	-0.3	4.5
TYPE OF OWNERSHIP							
	VOLUNTARY	1,981	0.0	0.1	2.6	-0.6	1.1
	PROPRIETARY	1,182	0.4	0.2	3.2	-0.2	2.1
	GOVERNMENT	462	-0.1	0.3	2.8	-0.7	1.3
CMHCs		41	1.4	0.5	4.5	0.0	3.7

Column (1) shows total hospitals and/or CMHCs.

Column (2) includes all final CY 2020 OPPS policies and compares those to the CY 2019 OPPS.

Column (3) shows the budget neutral impact of updating the wage index by applying the FY 2020 hospital inpatient wage index and the non-budget neutral frontier adjustment. The rural SCH adjustment continues our policy of 7.1 percent so the budget neutrality factor is 1. The budget neutrality adjustment for the cancer hospital adjustment is 0.9999 because in CY 2020 the target payment-to-cost ratio is higher than CY 2019 PCR target (0.89).

Column (4) shows the impact of all budget neutrality adjustments and the addition of the 2.6 percent OPD fee schedule update factor (3.0 percent reduced by 0.4 percentage point for the productivity adjustment).

Column (5) shows the additional impact of the policy to pay clinic visits for nonexcepted providers under the otherwise applicable payment system. We note that we are completing the 2-year phase-in so the amount of the reduction will be the full difference in CY 2020 (or payment at 40 percent of the OPPS rate).

Column (6) 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 moved the frontier adjustment to Column 3 in this table.

* These 3,732 providers include children's and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs.

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d. Estimated Effects of OPPS Changes on CMHCs

The last line of Table 68 demonstrates the isolated impact on CMHCs, which furnish only partial hospitalization services under the OPPS. In CY 2019, 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 2018 claims used for ratesetting in the proposed 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 3.7 percent increase in payments from CY 2019 (shown in Column 6). We note that this includes the trimming methodology as well as the final CY 2020 floor on geometric mean costs used for developing the PHP payment rates described in section VIII.B. of this final rule. The CY 2020 proposal to establish a floor based on geometric mean costs, rather than based on a predetermined payment rate, makes the OPPS budget neutrality adjustments for both the weight scaler and the conversion factor applicable.

Column 3 shows that the estimated impact of adopting the final FY 2020 wage index values will result in an increase of 0.5 percent to CMHCs. Column 4 shows that combining this proposed OPD fee schedule increase factor, along with final changes in APC policy for CY 2020 and the final FY 2020 wage index updates, will result in an estimated increase of 4.5 percent. Column 5 shows that the off-campus PBD clinic visits payment policy has no estimated effect on CMHCs. Column 6 shows that adding the final changes in outlier and pass-through payments will result in a total 3.7 percent increase in payment for CMHCs. This reflects all final changes for CMHCs for CY 2020.

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 will 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 on the calculation of the national unadjusted copayments and minimum unadjusted copayments, we refer readers to section II.I. of the CY 2020 OPPS/ASC proposed rule. 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 will be 18.1 percent for all services paid under the OPPS in CY 2020. The estimated aggregate beneficiary coinsurance reflects general system adjustments, including the final CY 2020 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 $1.21 billion in program payments for OPPS services furnished in CY 2020. 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 final changes in the final rule will increase these Medicaid beneficiary payments by approximately $45 million in CY 2020. Currently, there are approximately 10 million dual-eligible beneficiaries, which represents approximately one third of Medicare Part B fee-for-service beneficiaries. The impact on Medicaid was determined by taking one-third 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 $80 million Medicaid increase, approximately $45 million will be from the Federal Government and $35 million will be from State governmenwe dis. Alternative OPPS Policies Considered

Alternatives to the OPPS changes we proposed and the reasons for our selected alternatives are discussed throughout the final rule.

• Alternatives Considered for the Methodology for Assigning Skin Substitutes to High or Low Cost Groups

We refer readers to section V.B.7. of the CY 2020 OPPS/ASC proposed rule for a discussion of our policy to assign any skin substitute product that was assigned to the high cost group in CY 2019 to the high cost group in CY 2020, regardless of whether the product's mean unit cost (MUC) or the product's per day cost (PDC) exceeds or falls below the overall CY 2020 MUC or PDC threshold. We will continue to assign products that exceed either the overall CY 2020 MUC or PDC threshold to the high cost group. We also considered, but are not proposing, reinstating our methodology from CY 2017 and assigning skin substitutes to the high cost group based on whether an individual product's MUC or PDC exceeded the overall CY 2020 MUC or PDC threshold based on calculations done for either the proposed rule or the final rule with comment period.

• Alternatives Considered for the Methodology for Payment for Non-Opioid Pain Management Treatments

We refer readers to sections II.A.3.b. and XIII.D.3. of the CY 2020 OPPS/ASC proposed rule (84 FR 39425 for a discussion of our packaging policy for certain drugs when administered in the ASC setting and policy of providing separate payment for non-opioid pain management drugs that function as a supply when used in a surgical procedure when the procedure is performed in an ASC. In those sections of the CY 2020 OPPS/ASC proposed rule, we discuss our proposal to continue paying 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 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, we discuss the comments we received on whether we should pay separately for various non-opioid treatments for pain under the OPPS and the ASC payment system and also finalize the policy for non-opioid pain management drugs that function as surgical supplies.

• Alternatives Considered for the Proposed Changes in the Level of Supervision of Outpatient Therapeutic Services in Hospitals and Critical Access Hospitals (CAHs)

We refer readers to section X.A. of the proposed rule for a discussion of our proposal to change the minimum required default level of supervision from direct supervision to general supervision for all hospital outpatient therapeutic services provided by all hospitals and CAHs. We also considered, but did not propose, reevaluation of the level of physician supervision for cardiac rehabilitation services to determine whether we should propose to change the supervision level from direct supervision to general supervision. Under this alternative, direct supervision would have remained the minimum required default level for most hospital outpatient therapeutic services with the exception of those services that have been evaluated by the HOP Panel and received a change in supervision level based on those recommendations.

2. Estimated Effects of CY 2020 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 2020 ASC relative payment weights by scaling the proposed CY 2020 OPPS relative payment weights by the proposed ASC scalar of 0.8550. The estimated effects of the proposed updated relative payment weights on payment rates are varied and are reflected in the estimated payments displayed in Tables 39 and 40 below.

Beginning in CY 2011, section 3401 of the Affordable Care Act requires that the annual update to the ASC payment system (which we proposed will be the hospital market basket for CY 2020) after application of any quality reporting reduction be reduced by a productivity adjustment. The Affordable Care 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, the CY 2020 payment determinations will be based on the application of a 2.0

percentage point reduction to the annual update factor, which we proposed will be the hospital market basket for CY 2020. We calculated the CY 2020 ASC conversion factor by adjusting the CY 2019 ASC conversion factor by 1.0001 to account for changes in the pre-floor and pre-reclassified hospital wage indexes between CY 2019 and CY 2020 and by applying the CY 2020 MFP-adjusted hospital market basket update factor of 2.6 percent (which is equal to the projected hospital market basket update of 3.0 percent minus an MFP adjustment of 0.4 percentage point). The proposed CY 2020 ASC conversion factor is $47.747 for ASCs that successfully meet the quality reporting requirements.

a. Limitations of Our Analysis

Presented here are the projected effects of the proposed changes for CY 2020 on Medicare payment to ASCs. A key limitation of our analysis is our inability to predict changes in ASC service-mix between CY 2018 and CY 2020 with precision. We believe the net effect on Medicare expenditures resulting from the proposed CY 2020 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 proposed update to the CY 2020 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 proposed CY 2020 updates to the ASC payment system on Medicare payments to ASCs, assuming the same mix of services, as reflected in our CY 2018 claims data. Table 70 depicts the estimated aggregate percent change in payment by surgical specialty or ancillary items and services group by comparing estimated CY 2019 payments to estimated proposed CY 2020 payments, and Table 69 shows a comparison of estimated CY 2019 payments to estimated proposed CY 2020 payments for procedures that we estimate will receive the most Medicare payment in CY 2019.

In Table 70, 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 70.

- 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 2019 ASC Payments were calculated using CY 2018 ASC utilization data (the most recent full year of ASC utilization) and CY 2019 ASC payment rates. The surgical specialty and ancillary items and services groups are displayed in descending order based on estimated CY 2019 ASC payments.
- Column 3—Estimated CY 2020 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 proposed updates to ASC payment rates for CY 2020 compared to CY 2019.

As shown in Table 69, for the six specialty groups that account for the most ASC utilization and spending, we estimate that the proposed update to ASC payment rates for CY 2020 will result in a 4-percent increase in aggregate payment amounts for eye and ocular adnexa procedures, a 3-percent increase in aggregate payment amounts for nervous system procedures, 1-percent increase in aggregate payment amounts for digestive system procedures, a 2-percent increase in aggregate payment amounts for musculoskeletal system procedures, a 2-percent increase in aggregate payment amounts for genitourinary system procedures, and a 5-percent increase in aggregate payment amounts for cardiovascular system procedures. We note that these changes can be a result of different factors, including updated data, payment weight changes, and proposed changes in policy. In general, spending in each of these categories of services is increasing due to the 2.6 percent proposed 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 2.6-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 proposed aggregate eye and ocular adnexa procedure payments due to an increase in hospital reported costs for the primary payment grouping for this category under the OPPS. This increases the payment weights for eye and ocular adnexa procedure payments and, overall, is further increased by the proposed 2.6 percent ASC rate update for these procedures. For estimated changes for selected procedures, we refer readers to Table 70 provided later in this section.

Also displayed in Table 69 is a separate estimate of Medicare ASC payments for the group of separately payable covered ancillary items and services. The payment estimates for the covered surgical procedures include the costs of packaged ancillary items and services. We estimate that aggregate payments for these items and services will decrease by 12 percent for CY 2020. This is largely attributed to the drug packaging policies adopted under the OPPS and ASC payment system.

TABLE 69.—ESTIMATED IMPACT OF THE FINAL CY 2020 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE CY 2020 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP

Surgical Specialty Group (1)	Estimated CY 2019 ASC Payments (in Millions) (2)	Estimated CY 2020 Percent Change (3)
Total	$5,044	3
Eye and ocular adnexa	$1,743	4
Nervous system	$1,106	3
Digestive system	$893	1
Musculoskeletal system	$608	2
Genitourinary system	$194	2
Cardiovascular system	$184	5
Ancillary items and services	$99	-12

Table 70 shows the estimated impact of the updates to the revised ASC payment system on aggregate ASC payments for selected surgical procedures during CY 2020. The table displays 30 of the procedures receiving the greatest estimated CY 2019 aggregate Medicare payments to ASCs. The HCPCS codes are sorted in descending order by estimated CY 2019 program payment.

- Column 1—CPT/HCPCS code.
- Column 2—Short Descriptor of the HCPCS code.
- Column 3—Estimated CY 2019 ASC Payments were calculated using CY 2018 ASC utilization (the most recent full year of ASC utilization) and the CY 2019 ASC payment rates. The estimated CY 2019 payments are expressed in millions of dollars.
- Column 4—Estimated CY 2020 Percent Change reflects the percent differences between the estimated ASC payment for CY 2019 and the estimated payment for CY 2020 based on the proposed update.

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TABLE 70.--ESTIMATED IMPACT OF THE FINAL CY 2020 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/HCPCS Code (1)	Short Descriptor (2)	Estimated CY 2019 ASC Payment (in millions) (3)	Estimated CY 2020 Percent Change (4)
66984	Xcapsl ctrc rmvl w/o ecp	$1,210	3
63685	Insrt/redo spine n generator	$259	4
45385	Colonoscopy w/lesion removal	$200	0
45380	Colonoscopy and biopsy	$184	0
63650	Implant neuroelectrodes	$183	1
43239	Egd biopsy single/multiple	$177	1
64483	Inj foramen epidural l/s	$114	4
0191T	Insert ant segment drain int	$96	1
66982	Xcapsl ctrc rmvl cplx wo ecp	$91	3
64635	Destroy lumb/sac facet jnt	$79	2
64493	Inj paravert f jnt l/s 1 lev	$73	4
66821	After cataract laser surgery	$69	0
62323	Njx interlaminar lmbr/sac	$55	2
G0105	Colorectal scrn; hi risk ind	$54	0
64590	Insrt/redo pn/gastr stimul	$53	2
29827	Arthroscop rotator cuff repr	$49	2

CPT/HCPCS Code (1)	Short Descriptor (2)	Estimated CY 2019 ASC Payment (in millions) (3)	Estimated CY 2020 Percent Change (4)
45378	Diagnostic colonoscopy	$45	0
G0121	Colon ca scrn not hi rsk ind	$44	0
C9740	Cysto impl 4 or more	$42	6
36902	Intro cath dialysis circuit	$42	7
22869	Insj stablj dev w/o dcmprn	$34	-22
15823	Revision of upper eyelid	$34	3
64721	Carpal tunnel surgery	$33	2
63655	Implant neuroelectrodes	$30	2
29881	Knee arthroscopy/surgery	$29	2
64561	Implant neuroelectrodes	$28	2
26055	Incise finger tendon sheath	$26	1
G0260	Inj for sacroiliac jt anesth	$26	2
67042	Vit for macular hole	$25	3
64490	Inj paravert f jnt c/t 1 lev	$25	4

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c. Estimated Effects of ASC Payment System Policies on Beneficiaries

We estimate that the proposed CY 2020 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 proposed to add to the ASC list of covered surgical procedures and for those we proposed to designate as office-based for CY 2020. For example, using 2018 utilization data and proposed CY 2020 OPPS and ASC payment rates, we estimate that if 5 percent of coronary intervention procedures migrate from the hospital outpatient setting to the ASC setting as a result of this proposed policy, Medicare payments will be reduced by approximately $20 million in CY 2020 and total beneficiary copayments will decline by approximately $5 million in CY 2020. 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. The statute requires that copayment amounts under the OPPS not exceed the hospital inpatient deductible.) 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 proposed to designate as office-based in CY 2020, 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).

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. The first accounting statement, Table 71, illustrates the classification of expenditures for the CY 2020 estimated hospital OPPS incurred benefit impacts associated with the proposed CY 2020 OPD fee schedule increase. This $1.21 billion in additional Medicare spending estimate includes the $1.53 billion in additional Medicare spending associated with updating the CY 2019 OPPS payment rates by the hospital market basket update for CY 2020, offset by the $320 million in Medicare savings associated with the CY 2020 completion of phase-in finalized in CY 2019 to pay for clinic visits furnished at off-campus PBDs at a PFS-equivalent rate. In addition, we estimate that these OPPS changes in the final rule will increase copayments that Medicaid may make on behalf of Medicaid recipients who are also Medicare beneficiaries by approximately $45 million in CY 2020. The second accounting statement, Table 72, illustrates the classification of expenditures associated with the 2.6 percent CY 2020 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 estimated costs of ICR Burden and Regulatory Familiarization are included in Table 73.

TABLE 71.--ACCOUNTING STATEMENT: CY 2020 ESTIMATED HOSPITAL OPPS TRANSFERS FROM CY 2019 TO CY 2020 ASSOCIATED WITH THE FINAL CY 2020 HOSPITAL OUTPATIENT OPD FEE SCHEDULE INCREASE

Category	Transfers
Annualized Monetized Transfers	$1,210 million
From Whom to Whom	Federal Government to outpatient hospitals and other providers who receive payment under the hospital OPPS
Total	$1,210 million

TABLE 72.--ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2019 TO CY 2020 AS A RESULT OF THE FINAL CY 2020 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 73.—ESTIMATED COSTS in CY 2020

CATEGORY	Costs
ICR Burden	$1.58 million*
Regulatory Familiarization	$3.37 million**

*The annual estimates are in 2018 year dollars which includes the impact of hospital outpatient QRP and prior authorization process and requirements for certain OPD services.
** Regulatory familiarization costs occur upfront only.

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 OQR Program for the CY 2018, CY 2019, and CY 2020 payment determinations. Of the approximately 3,300 hospitals that met eligibility requirements for the CY 2019 payment determination, we determined that 14 hospitals did not meet the requirements to receive the full OPD fee schedule increase factor. In the CY 2020 OPPS/ASC Proposed Rule (84 FR 39556), we did not propose to add any quality measures to the Hospital OQR Program measure set for the CY 2021 or CY 2022 payment determinations. However, we are finalizing our proposal to remove one measure from the program measure set, as discussed in section XIV.B.3.b. of this final rule with comment period. We do not believe that this finalized policy will increase the number of hospitals that do not receive a full annual payment update for the CY 2021 or CY 2022 payment determinations.

b. Estimated Effects of Finalized Removal of OP–33 for the CY 2022 Payment Determination and Subsequent Years

In section XIV.B.3.b. of this final rule with comment period, we are finalizing our proposal with modification to remove one measure submitted via a web-based tool beginning with the CY 2022 payment determination and for subsequent years: OP–33: External Beam Radiotherapy for Bone Metastases. In the CY 2020 OPPS/ASC proposed rule, we inadvertently stated that we were proposing to remove this measure beginning with October 2020 encounters for CY 2022 payment determination and subsequent years (84 FR 39554 through 39556). As discussed in section XXVI.B.2. of this final rule with comment period, we intended to remove this measure beginning with the CY 2022 payment determination and subsequent years, but starting with January 2020 encounters, not October. Because we are finalizing removal of this measure beginning with the same CY 2022 payment determination, as was proposed, the estimated impacts and burden reduction remain the same as discussed in the proposed rule. As discussed in section XXVI.B.2. of this final rule with comment period, we anticipate a burden reduction of 551 hours and $21,379 associated with the removal of OP–33 for the CY 2022 payment determination. In addition to burden associated with information collection, we also anticipate that hospitals will experience a general burden and cost reduction associated with this removal stemming from no longer having to implement, review, track, and maintain program requirements associated with this measure.

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 ASCQR Program. For the CY 2019 payment determination, of the 6,393 ASCs that met eligibility requirements for the ASCQR Program, 203 ASCs did not meet the requirements to receive the full annual payment update. In section XV.B.3. of this final rule with comment period, we are finalizing our proposal to adopt ASC–19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers to the ASCQR Program measure set for the CY 2024 payment determination and subsequent years. We do not believe that adoption of the finalized ASC–19 measure will cause any ASCs to fail to meet the ASCQR Program requirements. Therefore, we do not believe this measure adoption will increase the number of ASCs that do not receive a full annual payment update for the CY 2024 payment determination. Below we discuss only the effects that will result from the provisions finalized in this final rule with comment period.

b. Estimated Effects of Adoption of ASC–19: Facility-Level 7-Day Hospital Visits After General Surgery Procedures Performed at Ambulatory Surgical Centers (NQF #3357)

In section XV.B.3. of this final rule with comment period, we are finalizing our proposal, beginning with the CY 2024 payment determination and for subsequent years, to adopt one measure: ASC–19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers (NQF #3357). As discussed in section XXVI.C.2. of this final rule with comment period, data used to calculate scores for this finalized measure are collected via Medicare Part A and Part B administrative claims and Medicare enrollment data. Therefore, ASCs will not be required to report any additional data. Because this change does not affect ASCQR Program participation requirements or data reporting requirements, we do not expect this finalized measure to change the information collection burden; it will only nominally affect other costs experienced by ASCs due to having to review and track confidential feedback and reports related to the finalized ASC–19 measure.

XXVI. Economic Analyses

D. Effects of Prior Authorization Process and Requirements for Certain Hospital Outpatient Department (OPD) Services

1. Overall Impact

As discussed in section XX. CY 2020 OPPS/ASC proposed rule (84 FR 39556), we proposed developing a new prior authorization process and requirements for certain hospital outpatient department (OPD) services. This proposal will use our authority in section 1833(t)(2)(f) of the Act to require provisional affirmation of coverage as a condition of Medicare payment unless the provider is exempt. This new requirement for prior authorization of certain covered OPD services aims to reduce the unnecessary increases in volume of certain covered hospital outpatient department services.

We believe there are a number of factors that may contribute to the potential growth assumed in the estimate presented below. For example, as the provider community acclimates to using prior authorization as part of their billing practice, there may be greater systemic or other processing efficiencies to allow more extensive implementation.

The overall economic impact on the health care sector is dependent on the number of claims affected. Table 74, Overall Economic Impact to the Health Sector, lists an estimate for the overall economic impact to the health sector for the services combined. The values populating this table were obtained from the cost reflected in Table 48, Annual Private Sector Costs, and Table 76, Estimated Annual Medicare Costs. Together, Tables 75 and 76 combine to convey the overall economic impact to the health sector, which is illustrated in Table 74. It should be noted that due to a July start date, year one will include only 6 months of prior authorization requests.

Based on the estimate, the overall economic impact is approximately $5.7 million in the first year based on 6 months. The 5-year impact is approximately $46.5 million, and the 10-year impact is approximately $98.7 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 some savings. We believe there are likely to be other benefits and cost savings that result from the OPD service prior authorization requirement. However, many of those benefits are difficult to quantify. For instance, we expect to see savings in the form of reduced unnecessary utilization, fraud, waste, and abuse, including a reduction in improper Medicare fee-for-service payments (we note that not all improper payments are fraudulent).

TABLE 74.--OVERALL ECONOMIC IMPACT TO THE HEALTH SECTOR

	Year 1	5 Years	10 Years
Private Sector Costs	$1,791,363	$13,261,482	$28,314,327
Medicare Costs	$3,947,588	$33,252,077	$70,451,742
Total Economic Impact to Health Sector	$5,738,951	$46,513,559	$98,766,069

The rationale behind requiring prior authorization is to control unnecessary increases in the volume of certain covered OPD services that are often cosmetic. We believe that the purpose of the statute is to avoid unnecessary utilization of OPD services. Therefore, we do not view decreased revenues from OPD services 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 and payment rules and requirements. This policy will offer an additional protection to a provider's cash flow as the provider will know in advance if the Medicare requirements are met.

2. Anticipated Specific Cost Effects

a. Private Sector Costs

We do not believe that this finalized policy will significantly affect the number of legitimate claims submitted for these services. However, we do expect a decrease in the overall amount paid for OPD services resulting from a reduction in unnecessary utilization of the services requiring prior authorization.

As described previously in the CY 2020 OPPS/ASC proposed rule (84 FR 39556), we have identified a list of specific services that, based on review and analysis of claims data, show higher than expected, and therefore we believe unnecessary, increases in the volume of service utilization. In making the decision to include the specific services in the list of hospital outpatient department services requiring prior authorization, we first considered that these services are primarily cosmetic and, therefore, are only covered by Medicare in very rare circumstances. We then viewed the current volume of utilization of these services and determined that the utilization far exceeded what will be expected.

We have developed a list of potential OPD services categories for inclusion in the OPD services prior authorization process—blepharoplasty; botulinum toxin injections; panniculectomy; rhinoplasty; and vein ablation. The list includes services from each of five categories that have demonstrated unnecessary increases in volume and that are likely to be cosmetic surgical procedures and/or are directly related to cosmetic surgical procedures that are not covered by Medicare, but may be combined with or masquerading as therapeutic services.

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 is equivalent to that of submitting 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 75.--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	35,446	0.5	17,723	$589,465
Fax and Electronic Submitted Requests-Resubmissions	11,636	0.5	5,818	$193,508
Mailed in Requests-Initial Submissions	15,191	0.5	7,596	$252,628
Mailed in Requests-Resubmissions	4,987	0.5	2,493	$82,932
Mailing Costs	20,178	5		$100,890
Provider Demonstration-Education	5,732	3	17,196	$571,939
Total			50,826	$1,791,363

b. Medicare Costs

Medicare will incur additional costs associated with processing prior authorization requests. We use the range of potentially affected cases (submissions and resubmissions) and multiply it by $50, the estimated cost to review each request. The cost also includes other elements such as appeals, education and outreach, and system changes.

TABLE 76.--Year 1 (6 Month) ESTIMATED ANNUAL MEDICARE COSTS

Blepharoplasty	Panniculectomy	Vein Ablation	Rhinoplasty	Botulinum Toxin Injections	Combined
$787,427	$68,175	$531,897	$604,678	$1,505,411	$3,947,588

c. Estimated Beneficiary Costs

We expect a reduction in the utilization of Medicare OPD services 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 system 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.

3. Estimated Benefits

There will be quantifiable benefits because we expect a reduction in the unnecessary utilization of those Medicare OPD services subject to prior authorization. It is difficult to project the decrease in unnecessary utilization. However, for the first 6 months we estimate the savings to be $6,059,950 and the net savings as $2,112,362. Annually, the estimated savings are $12,119,899 and the net savings are $4,679,966. We will closely monitor utilization and billing practices. The expected benefits will include a changed billing practice that also enhances the coordination of care for the beneficiary. For example, requiring prior authorization for certain OPD

services ensures 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 evaluates the beneficiary to determine his or her condition and what services are needed and medically necessary. This requires 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 the 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, will likely be reduced by the requirement that a provider submit clinical documentation created by as part of its prior authorization request.

E. Effects of Requirements Relating to Changes in the Definition of Expected Donation Rate for Organ Procurement Organizations

We are finalizing our proposal to revise the definition of ''expected donation rate'' in the CfCs for OPOs. This change will allow OPOs to receive payment for organ donor costs under the Medicare and Medicaid programs using a definition that is consistent with the definition used by the Scientific Registry of Transplant Recipients (SRTR).

Due to comments received on the CY 2020 OPPS/ASC proposed rule (and discussed in section XVIII.A of this final rule with comment period), we are finalizing a policy that would not require all OPOs to meet the standards of the second outcome measure for the 2022 recertification cycle only. As a result, OPOs will only have to meet one of the remaining outcome measures, which may provide temporary relief for a small number of OPOs that, absent this waiver, might have faced de-certification and the appeal process due to only meeting one outcome measure.

For subsequent recertification cycles, all 58 OPOs will once again be required to meet two out of three outcome measures detailed in the CfCs for OPOs regulations at 42 CFR 486.318(a) and (b). The second outcome measure relies on the aforementioned ''expected donation rate'' definition, and therefore all OPOs will be affected by the finalized change. This revision will eliminate the potential for confusion in the OPO community due to different definitions of the same term; however, it will not affect data collection or reporting by OPTNs and SRTRs, nor their statistical evaluation of OPO performance, and therefore it will not result in any quantifiable impact.

F. Revisions to the Laboratory Date of Service Policy

In section XIX of this final rule with comment period, we discuss our comment solicitation on potential revisions to the laboratory date of service (DOS) exception at 42 CFR 414.510(b)(5) for molecular pathology tests and tests designated by CMS as an ADLT under paragraph (1) of the definition of advanced diagnostic laboratory test in § 414.502. As a result of our evaluation of public comments, we are finalizing a revision to exclude blood banks or centers from the laboratory DOS exception at § 414.510(b)(5). Because the molecular pathology tests performed by blood banks or centers are excluded from our packaging policy under the OPPS, and are paid at the applicable rate for the laboratory test under the CLFS, regardless of whether the hospital or the performing laboratory bills Medicare for the test, this revision will not result in net costs or savings to the Medicare program. Accordingly, the discussion in section XIX of this final rule with comment period is not reflected in Table 41 in the regulatory impact analysis under section XXVI.C.1. of this final rule with comment period.

G. Effect of Changes to Requirements for Grandfathered Children's Hospitals-Within-Hospitals (HwHs)

In section XXII. of this final rule, we are finalizing our proposal to revise § 412.22(f)(1) and (2) to allow grandfathered children's HwHs to increased beds while maintaining their grandfathered status. This policy change will allow providers to address changing community needs for services without any increased incentive for inappropriate patient shifting to maximize Medicare payments given the low Medicare utilization in children's hospitals. Based on the best available information, there are currently very few grandfathered children's HwHs (3 or less). For these reasons, we estimate any impact on Medicare expenditures as a result of this policy change will be negligible. On average there are approximately 50 Medicare discharges per year from children's hospitals at an average cost of approximately $33,000 per discharge. There are two possible sources for an increase, if any, in Medicare discharges at grandfathered children's hospitals as a result of our policy change—(1) either the discharges will have been treated at another children's hospital; or (2) the cases will have been treated at an IPPS hospital. In either case given the few number of Medicare discharges at children's hospitals, the impact of this policy change on Medicare spending is negligible

H. 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 the CY 2020 OPPS/ASC proposed rule (3,853) will be the number of reviewers of this final rule with comment period. We acknowledge that this assumption may understate or overstate the costs of reviewing this final rule with comment period. It is possible that not all commenters will review this final rule with comment period in detail, and it is also possible that some reviewers will choose not to comment on this final rule with comment period. Nonetheless, we believed that the number of commenters on the CY 2019 OPPS/ASC proposed rule would be a fair estimate of the number of reviewers of this final rule with comment period. In the CY 2020 OPPS/ASC proposed rule (84 FR 39637), we welcomed any comments on the approach in estimating the number of entities that will review the proposed rule. We also recognize that different types of entities are, in many cases, affected by mutually exclusive sections of the proposed rule and 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 2018 BLS for medical and health service managers (Code 11–9111), we estimated that the cost of reviewing this rule is $109.36 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 this final rule with comment period. For each facility that reviewed this final rule with comment period, the estimated cost is $874.88 (8 hours × $109.36). Therefore, we estimated that the total cost of reviewing this final rule with comment period is $3,370,913 ($874.88 × 3,853 reviewers).

I. 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 $41.0 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 less than 2 percent; therefore, it should not have a significant impact on approximately 609 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.

J. 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 $154 million. This final rule with comment period does not mandate any requirements for State, local, or tribal governments, or for the private sector.

K. 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 $2.5 million in annualized cost at a 7-percent discount rate, discounted relative to 2016, over a perpetual time horizon.

L. 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 2020. Table 68 demonstrates the estimated distributional impact of the OPPS budget neutrality requirements that will result in a 1.3 percent increase in payments for all services paid under the OPPS in CY 2020, 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, the finalized off-campus provider-based department clinic visits payment policy, 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 2020.

The updates to the ASC payment system for CY 2020 will affect each of the approximately 5,600 ASCs currently approved for participation in the Medicare program. The effect on an individual ASC will 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 69 demonstrates the estimated distributional impact among ASC surgical specialties of the MFP-adjusted hospital market basket update factor of 2.6 percent for CY 2020.

XXVII. 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 68 of this final rule with comment period, we estimate that OPPS payments to governmental hospitals (including State and local governmental hospitals) will increase by 1.3 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.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

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, Drugs, Health

facilities, Health professions, Diseases, 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 486

Definitions, Medicare, Organ procurement.

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 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405 continues to read as follows:

Authority: 42 U.S.C. 263a, 495(a), 1302, 1302b-12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k).

■ 2. Section 405.926 is amended by revising paragraph (t) to read as follows:

§ 405.926 Actions that are not initial determinations.

* * * * *

(t) A contractor's prior authorization determination with regard to—

(1) Durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS)); and

(2) Hospital outpatient department (OPD) services.

* * * * *

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 3. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

■ 4. Section 410.27 is amended by revising paragraph (a)(1)(iv) to read 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) Under the general supervision (or other level of supervision as specified by CMS for the particular service) of a physician or a nonphysician practitioner as specified in paragraph (g) of this section, subject to the following requirements:

(A) For services furnished in the hospital or CAH, or in an outpatient department of the hospital or CAH, both on and off-campus, as defined in § 413.65 of this chapter, general supervision means the definition specified at § 410.32(b)(3)(i).

(B) Certain therapeutic services and supplies may be assigned either direct supervision or personal supervision. 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. Personal supervision means the definition specified at § 410.32(b)(3)(iii);

* * * * *

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 412.22 is amended by revising paragraphs (f)(1) and (2) to read as follows:

§ 412.22 Excluded hospitals and hospital units: General rules.

* * * * *

(f) * * *

(1) Continues to operate under the same terms and conditions, including the number of beds, unless the hospital is a children's hospital as defined at § 412.23(d), and square footage considered to be part of the hospital for purposes of Medicare participation and payment in effect on September 30, 1995; or

(2) In the case of a hospital that changes the terms and conditions under which it operates after September 30, 1995, but before October 1, 2003, continues to operate under the same terms and conditions, including the number of beds, unless the hospital is a children's hospital as defined at § 412.23(d), and square footage considered to be part of the hospital for purposes of Medicare participation and payment in effect on September 30, 2003.

* * * * *

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 7. The authority citation for part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

■ 8. Section 414.502 is amended by adding a definition for ''Blood bank or center'' in alphabetical order to read as follows:

§ 414.502 Definitions.

* * * * *

Blood bank or center means 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.

* * * * *

■ 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, or a test designated by CMS as an ADLT under paragraph (1) of the definition of an advanced diagnostic laboratory test in § 414.502, 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. 273, 1302, 1320b-8, and 1395hh.

■ 11. Section 416.171 is amended by adding paragraph (b)(4) to read as follows:

§ 416.171 Determination of payment rates for ASC services.

* * * * *

(b) * * *

(4) Notwithstanding paragraph (b)(2) of this section, low volume device-intensive procedures where the otherwise applicable payment rate calculated based on the standard methodology for device intensive procedures described in this paragraph (b) would exceed the payment rate for the equivalent service set under the

payment system established under part 419 of this chapter, for which the payment rate will be set at an amount equal to the amount under that payment system.

* * * * *

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

■ 12. The authority citation for part 419 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395l(t), and 1395hh.

■ 13. Section 419.66 is amended by revising paragraph (c)(2) to read as follows:

§ 419.66 Transitional pass-through payments: Medical devices.

* * * * *

(c) * * *

(2) CMS determines either of the following:

(i) The 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 payment status will begin on or after January 1, 2020, as an alternative pathway to paragraph (c)(2)(i) of this section, the device has received FDA marketing authorization and is part of the FDA's Breakthrough Devices Program.

* * * * *

■ 14. Subpart I, consisting of §§ 419.80 through 419.89, is added to read as follows:

Subpart I—Prior Authorization for Outpatient Department Services

Sec.

419.80 Basis and scope of this subpart.
419.81 Definitions.
419.82 Prior authorization for certain covered hospital outpatient department services.
419.83 List of hospital outpatient department services requiring prior authorization.
419.84–419.89 [Reserved]

Subpart I—Prior Authorization for Outpatient Department Services

§ 419.80 Basis and scope of this subpart.

(a) *Basis.* The provisions in this subpart are issued under the authority of section 1833(t)(2)(F) of the Act, which authorizes the Secretary to develop a method for controlling unnecessary increases in the volume of covered hospital outpatient department services.

(b) *Scope.* This subpart specifies the process and requirements for prior authorization for certain hospital outpatient department services as a condition of Medicare payment.

§ 419.81 Definitions.

As used in this subpart, unless otherwise specified, the following definitions apply:

List of hospital outpatient department services requiring prior authorization means the list of hospital outpatient department services described in § 419.83(a) that CMS adopts in accordance with § 419.83(b) that require prior authorization as a condition of Medicare payment.

Prior authorization means the process through which a request for provisional affirmation of coverage is submitted to CMS or its contractors for review before the service is provided to the beneficiary and before the claim is submitted for processing.

Provisional affirmation means a preliminary finding that a future claim meets the Medicare coverage, coding, and payment rules in chapter IV of this title or in Title XVIII of the Social Security Act.

§ 419.82 Prior authorization for certain covered hospital outpatient department services.

(a) *Prior authorization as condition of payment.* As a condition of Medicare payment for the services in the categories of services on the list of hospital outpatient department services requiring prior authorization as specified in § 419.83(a), a provider must submit to CMS or its contractors a prior authorization request in accordance with the requirements of paragraph (c) of this section.

(b) *Denial of claim.* (1) CMS or its contractors will deny a claim for a service that requires prior authorization if the provider has not received a provisional affirmation of coverage on the claim from CMS or its contractor unless the provider is exempt under § 419.83(c).

(2) CMS or its contractor may deny a claim that has received a provisional affirmation based on either of the following:

(i) Technical requirements that can only be evaluated after the claim has been submitted for formal processing; or

(ii) Information not available at the time of a prior authorization request.

(3) CMS or its contractor may deny claims for services related to services on the list of hospital outpatient department services for which the provider has received a denial.

(c) *Submission of prior authorization request.* A provider must submit to CMS or its contractor a prior authorization request for any service on the list of outpatient department services requiring prior authorization.

(1) *Prior authorization request requirements.* A prior authorization request must—

(i) Include all documentation necessary to show that the service meets applicable Medicare coverage, coding, and payment rules in chapter IV of this title or in Title XVIII of the Social Security Act.

(ii) Be submitted before the service is provided to the beneficiary and before the claim is submitted.

(2) *Request for expedited review.* A provider may submit a request for expedited review of a prior authorization request. The request for expedited review must comply with the requirements in paragraphs (c)(1)(i) and (ii) of this section and include documentation showing that the processing of the prior authorization request must be expedited due to the beneficiary's life, health, or ability to regain maximum function being in serious jeopardy.

(d) *Reviews*—(1) *Review of prior authorization request.* Upon receipt of a prior authorization request, CMS or its contractor will review the request for compliance with applicable Medicare coverage, coding, and payment rules in chapter IV of this title or in Title XVIII of the Social Security Act.

(i) CMS or its contractor will issue a provisional affirmation to the provider if it is determined that applicable Medicare coverage, coding, and payment rules in chapter IV of this title or in Title XVIII of the Social Security Act are met.

(ii) CMS or its contractor will issue a non-affirmation to the provider if it is determined that applicable Medicare coverage, coding, and payment rules in chapter IV of this title or in Title XVIII of the Social Security Act are not met.

(iii) The provisional affirmation or non-affirmation will be issued within 10 business days of receipt of the prior authorization request.

(2) *Review of expedited review request.* Upon receipt of a request for expedited review, CMS or its contractor will complete an expedited review of the prior authorization request if it is determined that a delay could seriously jeopardize the beneficiary's life, health, or ability to regain maximum function, and issue a provisional affirmation or non-affirmation decision in accordance with paragraph (d)(1) of this section within 2 business days of the expedited review request.

(e) *Resubmission.* (1) A provider may resubmit a prior authorization request, upon receipt of a non-affirmation, consistent with the requirements in paragraph (c)(1) of this section.

(2) A provider may resubmit a request for expedited review consistent with the requirements in paragraph (c)(1) of this section.

§ 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:

(i) Blepharoplasty.

(ii) Botulinum toxin injections.

(iii) Panniculectomy.

(iv) Rhinoplasty.

(v) Vein ablation.

(2) 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.

(b) *Adoption of the list of services.* CMS will adopt the list of hospital outpatient department service categories requiring prior authorization and any updates or geographic restrictions through formal notice-and-comment rulemaking.

(c) *Exemptions.* CMS may elect to exempt a provider from the prior authorization process in § 419.82 upon a provider's demonstration of compliance with Medicare coverage, coding, and payment rules in chapter IV of this title or in Title XVIII of the Social Security Act through such prior authorization process.

(1) An exemption will remain in effect until CMS elects to withdraw the exemption.

(2) Notice of an exemption or withdraw of an exemption will be provided at least 60 days prior to the effective date.

(d) *Suspension of prior authorization process or services.* CMS may suspend the outpatient department services prior authorization process requirements generally or for a particular service(s) at any time by issuing notification on the CMS website.

PART 486—CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS

■ 15. The authority citation for part 486 is revised to read as follows:

Authority: 42 U.S.C. 273, 1302, 1320b–8, and 1395hh.

■ 16. Section 486.302 is amended by revising the definition of ''Expected donation rate'' to read as follows:

§ 486.302 Definitions.

* * * * *

Expected donation rate means the expected donation rate per 100 eligible deaths that is the rate expected for an OPO based on the national experience for OPOs serving similar eligible donor populations and donation service areas. This rate is adjusted for the distributions of age, sex, race, and cause of death among eligible deaths.

* * * * *

■ 17. Section 486.316 is amended by adding paragraph (a)(3) and revising paragraph (b) to read as follows:

§ 486.316 Re-certification and competition processes.

(a) * * *

(3) For the 2022 recertification cycle only, an OPO is recertified for an additional 4 years and its service area is not opened for competition when the OPO meets one out of the two outcome measure requirements described in § 486.318(a)(1) and (3) for OPOs not operating exclusively in the noncontiguous States, Commonwealths, Territories, or possessions; or § 486.318(b)(1) and (3) for OPOs operating exclusively in noncontiguous States, Commonwealths, Territories, and possessions. An OPO is not required to meet the second outcome measure described in § 486.318(a)(2) or (b)(2) for the 2022 recertification cycle.

(b) *De-certification and competition.* (1) If an OPO does not meet two out of the three outcome measures as described in paragraph (a)(1) of this section or the requirements described in paragraph (a)(2) of this section, the OPO is de-certified. If the OPO does not appeal or the OPO appeals and the reconsideration official and CMS hearing officer uphold the de-certification, the OPO's service area is opened for competition from other OPOs. The de-certified OPO is not permitted to compete for its open area or any other open area. An OPO competing for an open service area must submit information and data that describe the barriers in its service area, how they affected organ donation, what steps the OPO took to overcome them, and the results.

(2) For the 2022 recertification cycle only, if an OPO does not meet one of the outcome measures as described in paragraphs § 486.318(a)(1), (a)(3), (b)(1), or (b)(3), or the requirements described in paragraph (a)(2) of this section, the OPO is de-certified. If the OPO does not appeal or the OPO appeals and the reconsideration official and CMS hearing officer uphold the de-certification, the OPO's service area is opened for competition from other OPOs. The de-certified OPO is not permitted to compete for its open area or any other open area. An OPO competing for an open service area must submit information and data that describe the barriers in its service area, how they affected organ donation, what steps the OPO took to overcome them, and the results.

* * * * *

Dated: October 24, 2019.

Seema Verma,

Administrator, Centers for Medicare and Medicaid Services.

Dated: October 28, 2019

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2019–24138 Filed 11–1–19; 4:15 pm]

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Part III

Department of Transportation

Federal Highway Administration

23 CFR Part 650

National Bridge Inspection Standards; Proposed Rule

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 650

[FHWA Docket No. FHWA–2017–0047]

RIN 2125–AF55

National Bridge Inspection Standards

AGENCY: Federal Highway Administration (FHWA), U.S. Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The Moving Ahead for Progress in the 21st Century Act (MAP–21) required the Secretary to update the National Bridge Inspection Standards (NBIS). Through this NPRM, FHWA proposes to update the NBIS to address MAP–21 requirements, incorporate technological advancements including the use of unmanned aerial systems, and address ambiguities identified since the last update to the regulation in 2009. The FHWA also proposes to repeal two outdated regulations: The Highway Bridge Replacement and Rehabilitation Program and the Discretionary Bridge Candidate Rating Factor.

DATES: Comments must be received on or before January 13, 2020. Late-filed comments will be considered to the extent practicable.

ADDRESSES: To ensure that you do not duplicate your docket submissions, please submit them by only one of the following means:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Ave. SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001;
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Ave. SE, between 9 a.m.–5 p.m., e.t., Monday through Friday, except Federal holidays. The telephone number is (202) 366–9329;
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FOR FURTHER INFORMATION CONTACT: Mr. John Thiel, P.E., Office of Bridges and Structures, HIBS–30, (202) 366–8795, or Mr. William Winne, Office of the Chief Counsel, HCC–30, (202) 366–1397, Federal Highway Administration, 1200 New Jersey Avenue SE, Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

Electronic Access and Filing

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Executive Summary

I. Purpose of the Regulatory Action

This regulatory action seeks to update the national standards for bridge inspections consistent with the provisions of the MAP–21 (Pub. L. 112–141, 126 Stat. 405) legislation, which includes new requirements for a highway bridge inspection program, maintaining a bridge inventory, and reporting to FHWA the inspection results and, in particular, critical findings, meaning any structural or safety-related deficiencies that require immediate follow-up inspection or action. The updated NBIS proposed in this NPRM apply to all structures defined as highway bridges on all public roads, on and off Federal-aid highways, including tribally and federally owned bridges. In addition, FHWA proposes to apply these standards to privately owned bridges that are connected to a public road on each end.

Periodic and thorough inspections of our Nation's bridges are necessary to maintain safe bridge operation and prevent structural and functional failures. In addition, data on the condition and operation of our Nation's bridges is necessary for bridge owners to make informed investment decisions as part of an asset management program for their bridges. Congress declared in MAP–21 that it is in the vital interest of the United States to inventory, inspect, and improve the condition of the Nation's highway bridges. As a result of this declaration and the authority established by MAP–21 in 23 U.S.C. 144, FHWA is proposing to update the NBIS.

This regulatory action also proposes to eliminate two outdated regulations: The Highway Bridge Replacement and Rehabilitation Program (23 CFR part 650, subpart D) and the Discretionary Bridge Candidate Rating Factor (23 CFR part 650, subpart G).

II. Summary of the Major Provisions of the Regulatory Action in Question

The FHWA proposes revisions to the existing NBIS relative to the National Bridge Inventory, including the requirement to collect element level data for National Highway System (NHS) bridges. The proposed regulations require inspections of bridges on all public roads, on and off Federal-aid highways, including tribally and federally owned bridges, and private bridges connected on each end by a public road. The regulations propose several new terms to provide consistency and clarity in the implementation of the regulations. This includes renaming some terms in a more descriptive way, such as fracture critical member being renamed nonredundant steel tension member.

The proposed regulations would require the bridge inspection organizations to maintain a registry of nationally certified bridge inspectors to align with a similar provision in the National Tunnel Inspection Standards (NTIS) in 23 CFR part 650, subpart E. The proposed regulations modify the training requirements for program managers and team leaders by defining a required amount of refresher training for both roles and defining training needed to be a team leader on a nonredundant steel tension member inspection.

The regulations propose the permissible inspection intervals for bridges, including options for more rigorous, risk-based intervals based on the consideration of certain factors. They propose options for establishing inspection intervals for each inspection type. An inspection interval tolerance of 3 months beyond the inspection date is proposed. Specific criteria would be established to allow for extended routine inspection intervals up to 48 months, and 72 months for underwater inspections. Similarly, proposed requirements are described to enable the establishment of more rigorous, risk-based intervals in consideration of certain factors associated with bridges for routine, underwater, and nonredundent steel tension member inspections that would allow some inspection intervals to be up to 72 months.

The proposed regulations require written reports to FHWA of critical findings identified during inspections and they provide minimum criteria for what a critical finding is, for national consistency. The regulations also propose that a bridge inspection organization is to provide information to FHWA for annual compliance reviews.

The regulations propose new time frames for updating inventory data, and a process for tracking the updates of inventory data. In addition, they propose a new document to identify data items for the National Bridge Inventory. This document, ''Specifications for the National Bridge Inventory,'' is proposed to replace the ''Recording and Coding Guide for the Structure Inventory and Appraisal of the Nation's Bridges.''

III. Costs and Benefits

The FHWA estimated the incremental costs associated with the requirements proposed in this regulatory action that represent a change to current practices for State departments of transportation (State DOT), Federal agencies, and Tribal governments. The FHWA derived the costs of components by assessing the expected increase in level of effort from labor and additional capital needed to standardize and update NBIS practices.

The FHWA multiplied the level of effort, expressed in labor hours, with a corresponding loaded wage rate that varied by the type of laborer needed to perform the activity to estimate costs.[1] Where necessary, capital costs were included, as well. Following this approach, the annualized cost of this rule, discounted to 2018 using a 7 percent discount rate, is $1.65 million expressed in 2016 dollars over the 10-year analysis period. The vast majority of the costs associated with this rulemaking are necessary to implement 23 U.S.C. 144, as amended by MAP–21.

The FHWA expects that, upon implementation, the proposed rule would result in significant benefits, although they are not easily quantifiable. Specifically, FHWA expects this proposed rule to result in improved bridge condition-related project, program, and policy choices due to improved data. In addition, the proposed rule would help focus the Federal-aid highway program on achieving improved bridge performance outcomes.

Background

The FHWA bridge inspection program regulations were developed as a result of the Federal-Aid Highway Act of 1968 (Pub. L. 90–495, 82 Stat. 815), which required the Secretary of Transportation to establish the NBIS to ensure the safety of the traveling public on highway bridges, and directed the States to maintain an inventory of Federal-aid highway system bridges. The Federal-Aid Highway Act of 1970 (Pub. L. 91–605, 84 Stat. 1713) limited the NBIS to bridges on the Federal-aid highway system. The Surface Transportation Assistance Act of 1978 (Pub. L. 95–599, 92 Stat. 2689) extended the NBIS requirements to bridges on all public roads. The Surface Transportation and Uniform Relocation Assistance Act of 1987 (Pub. L. 100–17, 101 Stat. 132) expanded the scope of highway bridge inspection programs to include special inspection procedures for fracture critical members and underwater inspection. Section 1111 of MAP–21 modified 23 U.S.C. 144 by revising the NBIS and adding requirements for a parallel NTIS framework. The FHWA adopted procedures for the NTIS via rulemaking on July 14, 2015, at 80 FR 41350. In order to update the NBIS regulations for MAP–21, and to align them with the successful procedures in place for NTIS, FHWA proposes a number of changes to 23 CFR part 650.

The framework of this proposed regulation is aligned with the current NBIS framework. Both start with sections discussing the purpose, applicability, and definitions. These are followed by sections on organization responsibilities, qualifications of select personnel, inspection interval, and inspection procedures. The current and proposed regulation end with sections on inventorying bridges, submitting data, and incorporated references. Specific discussions on each section are detailed later.

The FHWA is required by 23 U.S.C. 144(h), as amended by MAP–21, to update the NBIS to address the methodology, training, and qualifications for inspectors, as well as the frequency of bridge inspections. In carrying out the MAP–21 provisions, the Secretary is required to consider a risk-based approach to determining the frequency of bridge inspections.

The NBIS is required by 23 U.S.C. 144(h)(2), as amended by MAP–21, to specify the method by which the inspections shall be carried out by the States, Federal agencies, and Tribal governments, or their agents. The NBIS is also required to establish the maximum time period between inspections and the qualifications for those charged with carrying out the inspections. The NBIS requires each State, Federal agency, and Tribal government to maintain and make available to the Secretary, on request, written reports on the results of highway bridge inspections and notations of any action taken pursuant to the findings of the inspections and current inventory data for all highway bridges reflecting the findings of the most recent inspections conducted. The NBIS is to establish a procedure for national certification of highway bridge inspectors.

A requirement was introduced in 23 U.S.C. 144(d)(2), as amended by MAP–21, for each State and Federal Agency to report element level bridge inspection data to the Secretary, as each bridge is inspected, for all highway bridges on the NHS.

The Secretary is required by 23 U.S.C. 144(h)(3)(B), as amended by MAP–21, to establish procedures for States in reporting critical findings relating to structural or safety-related deficiencies of highway bridges and reports on subsequent monitoring activities and corrective actions taken in response to a critical finding.

Section-by-Section Discussion of the Proposal

Section 650.301 Purpose

The FHWA proposes to amend § 650.301 and be consistent with the amendments made by Section 1111(a) of MAP–21. The purpose of the NBIS is to set the national minimum standards for the proper inspection and evaluation of all highway bridges for safety and serviceability and to prepare and maintain an inventory of all bridges. The phrase ''preparing and maintaining an inventory'' of all bridges is proposed to be added to this section to align with 23 U.S.C. 144(h)(2)(D).

Section 650.303 Applicability

The FHWA proposes to amend § 650.303 to clarify the application of the NBIS to privately owned bridges. This will also align the NBIS with the NTIS. The NBIS applies to all highway bridges located on all public roads, on and off Federal-aid highways, including tribally owned, federally owned, and privately owned bridges connected to a public road on each end. The term ''public road'' is defined in 23 U.S.C. 101 as ''any road or street under the jurisdiction of and maintained by a public authority and open to public travel.'' A ''public authority'' is defined in 23 U.S.C. 101 as a Federal, State, county, town, or township, Indian Tribe, municipal or other local government with authority to finance, build, operate, or maintain toll or toll-free facilities.

Because of the seamless nature of the transportation infrastructure across the Nation, the motoring public generally is unaware of the difference between a privately owned and publicly owned highway bridge while traveling within a State, Federal land, or Tribal land. Therefore, State DOTs, Federal Agencies, and Tribal governments are

[1] Bureau of Labor Statistics Employee Cost Index, 2016.

responsible for ensuring the safety of the traveling public at all times by requiring all bridges on public roads within their boundaries to be inspected in accordance with the NBIS. State DOTs, Federal agencies, and Tribal governments are also responsible for ensuring all privately owned bridges that are connected to a public road on each end of such bridges, receive a proper inspection and evaluation.

The inspection of privately owned bridges connected to privately owned roads that are open to the public are not typically the responsibility of the public authority. State DOTs, Federal agencies, and Tribal governments are strongly encouraged to inspect or cause the inspection of these bridges in accordance with the NBIS.

Section 650.305 Definitions

The FHWA proposes to modify § 650.305 to clarify existing definitions, introduce definitions for new terms, and delete definitions that are no longer needed. In several cases, the changes in definitions are aligned with the NTIS.

The FHWA is proposing seven new definitions associated with the concept of the more rigorous assessment of risk in establishing inspection intervals. *Attribute* is used to describe characteristics that affect the reliability of a bridge. *Consequence* is used to describe the impacts if the bridge is allowed to deteriorate to a point a critical finding needs to be addressed. *Damage mode* is used to identify ways a bridge can deteriorate or be damaged by external events. *Probability* is used to identify the likelihood a damage mode may occur before the bridge's next inspection. *Risk* is proposed as a combination of the probability of an event occurring and its consequence. *Risk assessment panel* is proposed to describe the type of expertise needed for the more rigorous assessment of risk to establish inspection intervals. And, *Service inspection* is proposed as a new inspection type when there is a considerable amount of time between routine inspections. See the discussion of the Method 2 risk assessment process under § 650.311 for further explanation of these terms.

The definition of the term *Bridge* is proposed to be modified to clarify that a multiple pipe structure meeting the geometric requirements in the definition is a bridge.

The proposed modifications to the *Bridge inspection experience* definition clarify that some of the required experience may come from relevant bridge design, bridge construction, and bridge maintenance experience provided it develops the skills necessary to properly perform a NBIS bridge inspection.

The definition for *Complex bridge* is proposed to be deleted and replaced by a new definition for *Complex feature.* The proposed *Complex feature* definition strategically focuses an inspection on those parts of bridges that warrant additional attention due to their inherent complexity rather than an entire bridge that may have many other noncomplex elements.

Element level data for bridges on the NHS is required to be reported to FHWA by 23 U.S.C. 144(d)(2). A definition for *Element level bridge inspection data* is proposed to establish a uniform understanding of the data to be reported in order to satisfy the legislative requirement. *Element level bridge inspection data* would be defined as quantitative condition assessment data, collected during bridge inspections, that indicates the severity and extent of defects in bridge elements. The proposed definition is consistent with the common understanding of element level bridge inspection data that has existed in the highway bridge community for many years.

The term *End-of-course assessment* is proposed in the revisions to § 650.309. A definition is proposed to establish a uniform understanding that students who complete the various types of inspection training will be evaluated through the use of comprehensive examinations.

The definitions for *Fracture critical member* and *Fracture critical member inspection* are proposed to be deleted and replaced with new definitions for the new terms *Nonredundant member* and *Nonredundant steel tension member (NSTM) inspection.* See the proposed definitions below.

The definition of *Initial inspection* is proposed to be revised to clarify the data that is to be provided as part of the first inspection of a highway bridge and is to include a full inspection of all members of the bridge, including the nonredundant steel tension and underwater members. The definitions for *In-depth inspection* and *Routine inspection* are proposed to be revised to provide more clarity and to align with the definitions in the NTIS.

A new definition is proposed to clarify that the *Inspection date* is the date on which an inspection begins. In addition, a new definition is proposed for *Inspection due date* to identify when the next inspection must begin.

A new definition is proposed to clarify that an *Inspection report* is the document which summarizes inspection findings, results, and recommendations of the inspection for a bridge. The proposed definition also makes it clear that the report must be signed by a team leader.

A new definition is proposed for *Inventory data* to clarify that these terms include all data reported to the National Bridge Inventory in accordance with the ''Specifications for the National Bridge Inventory.'' A new *Load posting* definition is proposed to expand upon the definition of posting that exists in the American Association of State Highway and Transportation Officials ''Manual for Bridge Evaluation'' (AASHTO MBE). The proposed definition clearly states that the signing must be in accordance with the FHWA ''Manual for Uniform Traffic Control Devices.'' [2] All of these standards are proposed to be incorporated by reference.

Pursuant to 23 U.S.C. 144(h)(2)(E), procedures are required to be established within the NBIS for the national certification of bridge inspectors. Accordingly, the proposed definition for the new term *Nationally certified bridge inspector* is a team leader meeting the requirements of § 650.309(b). The team leader position has existed for many years and is ingrained in the National Bridge Inspection Program. The team leader is the on-site individual in charge of an inspection team and responsible for planning, preparing, performing, and reporting on bridge field inspection. It is logical and efficient to align the national certification expectations with the national qualification requirements that are proposed for team leaders. Each State DOT, Federal agency, and Tribal government may require higher requirements for their team leaders than in the NBIS which could require additional training, education or experience of a *Nationally certified bridge inspector* to practice as team leader within the respective State DOT, Federal agency, and Tribal government.

The FHWA proposes to delete the definition of *National Institute for Certification in Engineering Technologies (NICET)* to be consistent with the proposed changes to § 650.309. The material used in the current NICET certification for bridge inspectors is out of date. The FHWA does not control the NICET certification process and is not authorized to require that it be updated and maintained.

The FHWA proposes a definition of *Nonredundant member* for this regulation that more accurately reflects the engineering basis for identifying bridge members in this category.

[2] 23 CFR 655.601, *https://mutcd.fhwa.dot.gov/.*

A definition for the proposed term *Nonredundant steel tension member inspection training* is included in order to align with the proposed requirements in § 650.309(c) for training of team leaders who inspect NSTMs on bridges.

A new definition of *Plan of action (POA)* is proposed in order to establish uniformity and a level of consistency in the procedures bridge inspectors and engineers adhere to in managing bridges in their inventory that are determined to be scour critical or have unknown foundations.

A new definition of *Procedures* is proposed to be added to the rule in order to clarify what FHWA means by this term which is used extensively throughout this rule.

The FHWA proposes to modify the definition of *Professional engineer* to better align with the definition of the same term used in the NTIS.

The FHWA proposes to revise the definition of *Program manager* to reflect the possibility that there may be multiple individuals who serve in this role within an organization. The proposed § 650.307(g) requires that when there is more than one program manager, there must be one lead program manager who is responsible for coordinating the NBIS policies and procedures throughout the State, Federal agency, or Tribal government land. In addition, the proposed definition clarifies that program managers have an overall responsibility for ensuring that load ratings and load postings are completed since they are ultimately responsible for everything associated with the bridge inspection program.

A new definition of *Safe load capacity* is proposed in order to convey the term as used in § 650.311(a)(3). The wording of the definition comes directly from section 1.5 of the AASHTO MBE.

A new definition of *Scour appraisal* is proposed to define that either observed or evaluated scour will control the scour critical determination.

The current *Special inspection* definition is proposed to be revised to clarify that a bridge that does not have defects may need a special inspection when the bridge has details or characteristics that have been known to result in defects.

A new definition of *Special permit load* is proposed in order to define the term used in § 650.313(c)(3). The definition is intended to capture live loads crossing a bridge that do not conform with legal vehicles nor routine permit vehicles.

The current *Team leader* definition is proposed to be revised to clarify that the team leader is the individual on site during inspections. Team leaders would have some field inspection experience and meet the requirements of a team leader in § 650.309(b).

Inspection requirements for temporary bridges are proposed in § 650.313(a)(3). Accordingly, a definition of the new term *Temporary bridge* is proposed to identify the population of bridges to which the § 650.313(a)(3) requirements would apply.

The term *Underwater diver bridge inspection training* is proposed to be renamed *Underwater bridge inspection training* to align with the proposed language changes in the § 650.309.

Section 650.307 Bridge Inspection Organization Responsibilities

The FHWA proposes to amend § 650.307 to clarify the responsibilities of the State DOT's, Federal agency's, and Tribal government's bridge inspection organization. The documented policies and procedures referenced in § 650.307 would further support compliance with the inspection procedure provisions of § 650.313. Documented processes serve as the foundation for any successful business practice and have many benefits. They are key characteristics to ensuring continuity and uniformity in the bridge inspection operation. Other benefits of documented processes include ensuring that staff have a clear understanding of their responsibilities and authority in performing their day to day functions, describing the accountability of staff within the organization, ensuring program compliance with regulations and policies, serving as a resource for new staff, and providing a method for managing risk.

The FHWA proposes to amend the title of § 650.307 Bridge inspection organization by adding the term *responsibilities.* The reason for this modification is to make the title consistent with the requirements of this section, which are focused on the responsibilities of a bridge inspection organization. This is consistent with the NTIS.

The FHWA proposes to amend § 650.307(a) and (b) to clarify the responsibilities of the State DOTs and Federal agencies. The phrase ''must inspect, or cause to be inspected, all highway bridges'' is proposed to be replaced with ''perform, or cause to be performed, the proper inspection and evaluation of all highway bridges'' to be consistent with the language of 23 U.S.C. 144(h)(1)(A). Also, FHWA proposes to remove the term ''public roads'' from § 650.307(a) and (b) for consistency with the proposed changes to § 650.303.

The FHWA proposes to amend § 650.307(c) through (e) to accommodate new additions and to clarify current requirements. In accordance with 23 U.S.C. 144(h)(2), FHWA proposes a new § 650.307(c) that establishes the bridge inspection responsibilities of Tribal governments.

The FHWA proposes a new § 650.307(d) to address the bridge inspection responsibilities of jointly owned bridges that involve bordering States or combinations of State DOTs, Federal agencies, or Tribal governments ownership, or different entities within a State, or Federal, or Tribal jurisdiction. The FHWA's experience is that in some instances there has not been a clear delineation of the inspection responsibilities of border bridges between the affected agencies. The lack of a clear delineation of inspection responsibilities can lead to undue delays in conducting and completing the required inspections, and in the overall management of the bridge. To align the NBIS process with that of the existing requirements in the NTIS, this proposed language would require the affected agencies to have a written agreement in place to clarify the NBIS-related responsibilities for each agency for that particular bridge and help ensure that timely bridge inspections and follow-up actions are accomplished in accordance with these standards.

The FHWA proposes to replace current § 650.307(c)(1) and (2) with § 650.307(e)(1) through (11) to clarify the responsibilities of the bridge inspection organization for each State DOT, Federal agency, and Tribal government. In accordance with 23 U.S.C. 144(h)(2), FHWA proposes adding ''Tribal government'' to the proposed § 650.307(e), which would require each Tribal government with highway bridges open to the public on its land to provide for a bridge inspection organization responsible for addressing the various requirements in these standards. A Tribal government may delegate its responsibilities under this subpart to the Bureau of Indian Affairs (BIA) if the BIA agrees. A Tribal government that does not delegate its responsibilities to BIA would need to provide a bridge inspection organization.

The FHWA proposes to replace § 650.307(c)(1) with the new § 650.307(e)(1). The phrase ''Developing and implementing written'' is proposed to be added to the existing section to clarify the intent that bridge inspection organizations are to have documented policies and procedures.

The FHWA proposes a new § 650.307(e)(2), which would require each bridge inspection organization to have documented policies and procedures for setting inspection intervals as required under § 650.311.

The FHWA proposes a new § 650.307(e)(3), which would require each bridge inspection organization to document the roles and responsibilities of personnel involved in carrying out the requirements of the respective bridge inspection programs of the State DOTs, Federal agencies, and Tribal governments.

The FHWA proposes a new § 650.307(e)(4), which would require each bridge inspection organization to maintain a central registry of nationally certified bridge inspectors that are performing bridge inspections in their respective State, Federal, or Tribal government jurisdiction. This proposal is aligned with the requirements in the NTIS. This proposed requirement further clarifies the roles and responsibilities within the bridge inspection organization.

The FHWA proposes a new § 650.307(e)(5), which clarifies the intent of the current § 650.307(c)(2) that each bridge inspection organization is to have documented policies and procedures for managing bridge inspection reports and files.

The FHWA proposes a new § 650.307(e)(6), which clarifies the intent of the current § 650.307(c)(1) that each bridge inspection organization is to perform quality control and quality assurance.

The FHWA proposes a new § 650.307(e)(7), which clarifies the intent of the current § 650.307(c)(1) that each bridge inspection organization is to prepare and maintain bridge inventory data.

The FHWA proposes a new § 650.307(e)(8), which clarifies the intent of the current § 650.307(c)(2) that each bridge inspection organization is to have documented policies and procedures for load rating, load posting, and determining other restrictions. The current § 650.307(c)(2) does not include the phrase ''. . . load posting, and determining other restrictions;'' however, these are typically associated with load ratings, and thus would be added for clarity.

In accordance with 23 U.S.C. 144(h)(3)(B), FHWA proposes a new § 650.307(e)(9), which would require each bridge inspection organization to have documented policies and procedures for managing critical finding activities.

The FHWA proposes a new § 650.307(e)(10), which would require each bridge inspection organization to have documented policies and procedures for managing scour appraisals and associated plans of action that may result from such appraisals.

The FHWA proposes a new § 650.307(e)(11), which would require each bridge inspection organization to perform all other requirements of the NBIS that otherwise were not listed in this section.

The FHWA proposes to redesignate § 650.307(d) to § 650.307(f) and amend the content to clarify the functions that may be delegated as well as the documentation required for such delegation to occur. The FHWA's observation and experience is that the lack of clear and documented delegation of functions leads to situations of misunderstanding and disagreement among organizations. For example, there have been instances in which the lack of clearly documented delegations has led to delinquent inspections, neglected load postings, and delayed repairs. The States in these instances did not have a clear understanding as to what authority it had over the owners of these bridges, which led to inaction to correct these issues. A documented and agreed upon delegation of responsibilities could have prevented these situations. This proposal is aligned with the NTIS.

The FHWA proposes to redesignate § 650.307(e) to § 650.307(g) and amend the content to clarify that the intent is not to limit an agency to a single program manager. Rather an agency may organize itself so that it may have more than one program manager. In the event of an agency having more than one program manager fulfilling the responsibilities described in these standards, the agency would be required to identify a lead program manager to serve as the main point of contact. If any Tribal governments delegate their responsibilities under this subpart to BIA, a qualified employee of BIA may serve as the program manager for all such Tribal governments.

Section 650.309 Qualifications of Personnel

In § 650.309(a), FHWA proposes to clarify what is intended by successful completion of the comprehensive bridge inspection training by adding language defining a minimum passing score on an end-of-course assessment that is part of the comprehensive bridge inspection training, which is consistent with the NTIS. The 70 percent minimum passing score is proposed to align with the National Highway Institute's (NHI) threshold for issuance of continuing education units for students of its training courses. This is not intended to require current program managers who have successfully completed prior versions of the comprehensive bridge inspection training course to retake the course and achieve a minimum score on an end-of-course assessment. Completion of this training under prior regulations will satisfy the intent of this requirement. The FHWA proposes a new § 650.309(a)(3) that moves bridge inspection refresher training from current § 650.313(g). The FHWA proposes that program managers must complete 18 hours of FHWA-approved bridge inspection refresher training every 60 months, which is consistent with the NTIS. This is proposed to address concerns from stakeholders that the current regulation is not specific enough and results in a lack of national uniformity in the duration and content of the training. The NHI has a Bridge Inspection Refresher training course that offers 18 hours of training, and FHWA believes taking this course once every 60 months is reasonable. The FHWA also recognizes that some stakeholders have their own bridge inspection refresher programs that may comply with the NBIS training requirements.

The 18 hours of training would not have to be continuous and may be accumulated through multiple training events over a 60-month period. However, the program manager would be required to have the 18 hours of training during any 60-month time period that is reviewed by FHWA. For example, a program manager could not take the training at the beginning of one 60-month period and then again at the end of the next 60-month period as in between those trainings there would be a period of 60 months that no training was taken.

The FHWA proposes a new § 650.309(a)(4), which would require program managers to maintain the documentation needed to ensure that the qualifications of this section are met. The FHWA proposes to amend § 650.309(a) to allow current program managers who do not meet the proposed program manager qualifications to fulfill all requirements of this section within 24 months of the effective date of the final rule. During this time period, program managers may maintain their current role.

In § 350.309(b), FHWA proposes to reorganize the section by clearly defining two requirements that apply to all team leaders and then listing four ways to meet the remaining requirements for team leaders. The FHWA proposes to clarify what constitutes successful completion of the comprehensive bridge inspection

training by adding language defining a minimum passing score on an end-of-course assessment. The 70 percent minimum passing score is proposed to align with NHI's threshold for issuance of continuing education units for students of its training courses, which is consistent with the NTIS. This is not intended to require current team leaders who have successfully completed prior versions of the comprehensive bridge inspection training course to retake the course and achieve a minimum score on an end-of-course assessment. Completion of this training under prior regulations would satisfy the intent of this requirement.

The FHWA proposes a new § 650.309(b)(2) for team leaders that moves required bridge inspection refresher training to this section from current § 650.313(g).

The FHWA proposes that team leaders must complete 18 hours of FHWA-approved bridge inspection refresher training every 60 months, which is consistent with the NTIS. This proposed requirement addresses concerns from stakeholders that the current regulation is not specific enough and results in a lack of national uniformity in the duration and content of the training. The NHI has a Bridge Inspection Refresher training course that offers 18 hours of training and FHWA believes that taking this course once every 60 months is reasonable. The FHWA also recognizes that some stakeholders have their own bridge inspection refresher programs which meet NBIS training requirements and may be a viable option to team leaders.

The 18 hours of training would not have to be continuous and may be accumulated through multiple training events over a 60-month period. However, the team leader must have the 18 hours of training during any 60-month time period that is reviewed. For example, a team leader could not take the training at the beginning of one 60-month period and then again at the end of the next 60-month period as in between those trainings there would be a period of 60 months that no training was taken.

The FHWA proposes a new option in § 650.309(b)(3)(i) that allows a Professional Engineer with 6 months of bridge inspection experience to be a qualified team leader, assuming other requirements of § 650.309(b) are met. The bridge inspection experience requirement is proposed to ensure that all team leaders have some experience and are familiar with the collection and recording of bridge inspection information as well as the process and procedures associated with bridge inspection activities. The FHWA proposes to delete the team leader qualification option of using the NICET certification. The FHWA does not control the NICET certification process and is not authorized to require that it be updated and maintained. The FHWA proposes to add engineering technology as an eligible degree to § 650.309(b)(3)(iii)(A), which is consistent with the language used in § 650.309(b)(3)(iv)(A).

The FHWA proposes a new § 650.309(b)(4) to ensure that the program manager receives the documentation from team leaders to verify that they meet the qualifications of this section. Part of this verification involves the program manager's review and approval of the team leader's bridge inspection experience as defined in § 650.305. The FHWA proposes to amend § 650.309(b) to allow current team leaders who do not meet the proposed team leader qualifications 24 months from the effective date of the final rule to fulfill all requirements of this section. During this time period, team leaders may maintain their current role.

The FHWA proposes a new § 650.309(c) that establishes additional requirements for team leaders of NSTM inspections. The FHWA proposes that team leaders on these inspection types must complete additional training on NSTM inspections and achieve a minimum passing score on an end-of-course assessment. The proposed § 650.309(c)(2) is to ensure that team leaders of NSTM inspections possess the higher level of training commensurate with the importance of these members within a bridge system. The 70 percent minimum passing score for this training is proposed to align with NHI's threshold for issuance of continuing education units for students of its training courses. The FHWA proposes to allow current team leaders who no longer meet these proposed team leader qualifications to fulfill all requirements of this section within 24 months of the effective date of the final rule. During this time period, team leaders may maintain their current role.

The FHWA proposes to eliminate current § 650.309(c), which required each State DOT and Federal agency to have one person with the overall responsibility for load rating because the requirement does not align with the structure and function of some organizations. Due to this proposed deletion, FHWA proposes to modify the definition for program manager in § 650.305 to include responsibilities for load rating and load posting because this individual(s) is ultimately responsible for everything associated with the bridge inspection program.

The FHWA proposes a new § 650.309(d), requiring that load ratings be performed by, or under the direct supervision of, a registered professional engineer (PE). The FHWA acknowledges that bridge inspection organizations can be structured differently, which may result in one or more individuals performing these functions. The intent of this proposal is not to require everyone involved in the load rating and load posting processes to be a PE, but rather to ensure that the individuals performing the load rating, or those supervising the individuals performing the load rating, are PEs. The FHWA believes the PE requirement is necessary because load ratings require engineering calculations, evaluations, and judgments and are vitally important to the safety of the travelling public. This proposal is aligned with the NTIS.

The FHWA proposes in § 650.309(e) (current § 650.309(d)), to remove the comprehensive bridge inspection training as an option for an underwater bridge inspection diver to satisfy the training requirement. Robust underwater bridge inspection training was not readily available when this regulation was updated in 2004 and the comprehensive bridge inspection training was an acceptable alternate. Today, underwater bridge inspection training is readily available and the level of detail in this training to prepare underwater bridge inspection divers is much greater than the comprehensive bridge inspection training. In addition, FHWA proposes to add language defining a minimum passing score on an end-of-course assessment that is part of the underwater bridge inspection training. The proposed 70 percent minimum passing score aligns with NHI's threshold for issuance of continuing education units for students of its training courses. The proposed requirement of § 650.309(e) for underwater inspection diver applies to personnel performing the physical inspection of the underwater portion of the bridge. Non-inspection personnel supporting the underwater bridge inspection diver, such as the tender or safety diver, are not required to meet the proposed requirement of § 650.309(e).

The FHWA proposes a new § 650.309(f), requiring State DOTs, Federal agencies, and Tribal governments to determine the qualifications for the inspection personnel used on damage, service, and special inspections. This proposal provides flexibility to bridge inspection organizations for determining the personnel to be used on damage,

service, and special inspections as these inspection protocols can vary widely. The FHWA proposes this section to clarify that State DOTs, Federal agencies, and Tribal governments are to define the qualifications for personnel involved in these inspections.

The FHWA proposes two options for acceptable bridge inspection training that fulfills the requirements for comprehensive bridge inspection training, bridge inspection refresher training, underwater bridge inspection training, and NSTM inspection training. These options are to provide flexibility to bridge inspection organizations. One proposed option is the NHI's training courses, and the second proposed option allows for State, federally, and tribally developed training courses. The FHWA proposes to describe what training elements are needed in each of the NHI courses. For the second option, FHWA proposed the alternate training materials and end-of-courses assessments must include all the topics from the NHI courses and be submitted to FHWA for approval to ensure national consistency in course content and certification. It is the intent of FHWA that any program manager, team leader, or underwater bridge inspection diver who successfully completes an alternate course developed by a State, Federal agency, or Tribal government will meet the basic training necessary in this regulation to perform these roles for any State, Federal agency, or Tribal government.

The FHWA proposes that the program manager must review the approved alternate training courses at least once every 5 years to ensure that the material being delivered to bridge inspection personnel is still current and relevant. The FHWA proposes that any modifications and updates to the training material approved under the current regulation are to be resubmitted to FHWA for review and approval to ensure national consistency. Finally, FHWA proposes to amend this section by allowing State DOTs and Federal agencies with currently approved alternate training courses 24 months from the effective date of the final rule to review and modify, as necessary, course material (and end-of-courses assessments) to meet the proposed requirements. When a stakeholder determines a previously approved training course needs to be modified to maintain compliance, the course material and end-of-courses assessments must be resubmitted to FHWA for approval within 24 months of the effective date of the final rule before it can be offered.

The FHWA would make NHI bridge inspection course materials available to State DOTs, Federal agencies, and Tribal governments through a formal written agreement. The written agreement would establish controls on use of the material and the qualifications of those who deliver the training. The listing of the bridge inspection courses available would be: FHWA–NHI–130053 Bridge Inspection Refresher Training, FHWA–NHI–130054 Engineering Concepts for Bridge Inspectors, FHWA–NHI–130055 Safety Inspection of In-Service Bridges, FHWA–NHI–130056 Safety Inspection of In-Service Bridges for Professional Engineers, FHWA–NHI–130078 Fracture Critical Inspection Techniques for Steel Bridges, and FHWA–NHI–130091 Underwater Bridge Inspection.

Section 650.311 Inspection Interval

The FHWA proposes that the current section title ''Inspection frequency'' be changed to ''Inspection interval.'' The term interval is more accurate than frequency when referring to the time period for occurrence of inspections and is aligned with the language in the NTIS.

Existing regulations require highway bridges to be inspected at regular intervals not to exceed 24 months. The regulations also state that certain bridges require inspection at less than 24-month intervals, and require the establishment of criteria to determine the level and frequency to which these bridges are inspected. The regulations also allow bridges to be inspected at intervals greater than 24 months but not to exceed 48 months with written FHWA approval. The 2018 National Bridge Inventory shows that more than 39,000 bridges are currently inspected at intervals greater than 24 months based on FHWA approval of State developed extended interval policies.

In accordance with 23 U.S.C. 144(h)(7), FHWA proposes to amend the section to establish risk-based processes to establish intervals for routine, underwater, and NSTM inspections. The proposal includes two different options for State DOTs, Federal agencies, and Tribal governments to determine the proper inspection interval. The Method 1 option presents a simplified assessment approach while the Method 2 option presents a more rigorous assessment methodology.

The FHWA proposes to redesignate the current § 650.311(a)(1) to proposed § 650.311(a)(1)(i)).

The FHWA proposes to redesignate and amend the current § 650.311(a)(2), to proposed § 650.311(a)(1)(ii), to require that the criteria by which bridges are to be inspected at less than a 24-month interval must be documented. The amendment also adds more items to the list of criteria to be considered for a routine inspection interval less than 24 months. Lastly, the paragraph proposes minimum criteria at which routine inspections must be performed at intervals not to exceed 12 months.

The FHWA proposes to redesignate and amend § 650.311(a)(3), to proposed § 650.311(a)(1)(iii), by removing the FHWA approval process, which used FHWA Technical Advisory 5140.21 for guidance, and replacing it with a set of required criteria for when a bridge can be inspected at an extended interval of up to 48 months. The proposal is intended to provide a straightforward process for the State DOTs, Federal agencies, and Tribal governments to establish a policy for extended inspection intervals. State DOTs, Federal agencies, and Tribal governments may use their intimate knowledge of their bridge inventory and any other relevant factors to supplement these minimum criteria. The FHWA also proposes to provide State DOTs, Federal agencies, and Tribal governments that currently have approved extended interval policies 24 months from the effective date of the final rule to revise their current policies to meet these proposed criteria.

The FHWA proposes new § 650.311(a)(1)(iii)(A) through (I) to provide the minimum criteria for extended intervals for required bridge inspections. The proposed § 650.311(a)(1)(iii)(A) would require that a bridge must have a National Bridge Inspection (NBI) condition rating for the deck, superstructure, substructure, and culvert of a seven or higher to be eligible for extended intervals for inspection. This criterion is slightly more restrictive than the current FHWA Technical Advisory 5140.21 (see *http://www.fhwa.dot.gov/bridge/nbis/t514021.cfm*).

The proposed § 650.311(a)(1)(iii)(B) would require that the channel and channel protection NBI condition rating value for a bridge to be six or higher for the bridge to be eligible for an extended interval for inspection. The FHWA subject matter experts (SMEs) believe a condition rating value of six is the lowest acceptable value for a bridge to be on an extended interval without additional risk assessment. The description of a condition rating value of four (poor) states the channel has widespread moderate or isolated major defects and the bridge is at risk. The SMEs believe that without additional risk assessment, allowing a bridge with a channel or channel protection

condition rating value of a five to be on extended intervals for up to four years would be too long to potentially capture when the condition of this item would become poor. This criterion is consistent with the current FHWA Technical Advisory 5140.21.

The proposed § 650.311(a)(1)(iii)(C) would require that a bridge must have an operating rating factor or legal load rating factor of at least 1.1 for all vehicles legally permitted to cross the bridge to be eligible for an extended interval for inspection. The FHWA SMEs believe a factor of 1.1 is the lowest acceptable value for a bridge to be on an extended interval without additional risk assessment. A factor or 1.0 means the bridge has the same load carrying capacity as the legal vehicles that are allowed to use the bridge. The SMEs believe that without additional risk assessment, allowing a bridge with a factor less than 1.1 to be on extended intervals for up to four years would be too long to potentially capture deterioration of critical elements that are necessary for the safe load carrying capacity of the bridge. This criterion replaces the inventory level load rating criteria included in FHWA Technical Advisory 5140.21.

The proposed § 650.311(a)(1)(iii)(D) would make steel bridges with existing fatigue cracks, details with AASHTO ''LRFD Bridge Design Specifications'' fatigue categories E and E', details with a history of fatigue cracking, and fracture-prone details ineligible for extended intervals for inspection. This is a criterion that does not exist in FHWA Technical Advisory 5140.21. It is FHWA's position that bridges with these types of details are prone to rapid deterioration, similar to what the Daniel Webster Hoan Memorial Bridge in Milwaukee, Wisconsin experienced in December 2000, when two of the bridge's three support girders fractured and the bridge roadway sagged approximately four feet. The fractures in the steel girders occurred suddenly and propagated through the girders at an explosive rate. Due to the concern that sudden fractures could occur, FHWA SMEs believe bridges with these types of details are not suitable for an extended interval without the more extensive review process required in § 650.311(a)(2).

The proposed § 650.311(a)(1)(iii)(E) would require a bridge to have a vertical over or underclearance greater than or equal to 16′–0″ for Interstates, freeways, and other arterials or 14′–0″ for local roads and collectors and with no history of vehicular damage to be eligible for an extended interval for inspection. This criterion has been modified from the current FHWA Technical Advisory 5140.21 to account for different clearances based on the functional classification of the highway and is aligned with the vertical clearance standards in the AASHTO's ''A Policy of Geometric Designs of Highways and Streets, 7th Edition.''

The proposed § 650.311(a)(1)(iii)(F) and (G) would require that a bridge be of specific design, material, and environments to be eligible for an extended inspection interval. The FHWA SMEs believe more complex designs and aggressive environments should not be on an extended interval without additional risk assessment that is allowed in § 650.311(a)(2). This criterion is similar to the current FHWA Technical Advisory 5140.21 used to approve extended inspection policies but provides specificity to ensure consistent application.

The proposed § 650.311(a)(1)(iii)(H) makes certain bridges ineligible for extended inspection intervals. These ineligible bridges would consist of scour critical bridges, bridges that have not been evaluated for scour (including tidal bridges and bridges with unknown foundations), or bridges where scour condition rating is below six. The FHWA SMEs believe a condition rating value of six is the lowest acceptable value for a bridge to be on an extended interval without additional risk assessment. The description of a scour condition rating of four (poor) states there is widespread moderate or isolated major scour and the bridge is at risk. The SMEs believe that without additional risk assessment, allowing a bridge with a scour condition rating value of a five to be on extended intervals for up to four years would be too long to potentially capture when the condition of this item would become poor.

The original FHWA Technical Advisory 5140.21 did not include these criteria. The intent of FHWA is to remove structures that are vulnerable to scour from consideration for extended inspection intervals without the more extensive review process required in § 650.311(a)(2).

Finally, the proposed § 650.311(a)(1)(iii)(I) provides a list of additional criteria that would be considered to know the performance of the bridge is not a concern within the next 48 months.

The FHWA proposes a new § 650.311(a)(2), which would provide bridge inspection organizations with an optional, more rigorous, risk-based process for the determination of routine inspection intervals. This proposed paragraph is based largely on the recommendations of NCHRP Report 782 ''Proposed Guideline for Reliability Based Bridge Inspection Practices.'' Although the report makes mention of routine inspection intervals up to 96 months, the research recommends that routine inspection intervals up to 72 months should be pursued. Seventy-two months is the maximum inspection interval being proposed in this regulation in alignment with the research recommendation. Bridges typically exhibit structural deterioration in a controlled and stable manner over time; therefore, risk is considered to be an effective measure upon which to base the interval of inspections. When risk grows, bridges should be inspected more often, and when risk is reduced, bridges may be inspected less often.

In the development of § 650.311(a)(2), a SME, Dr. Glenn Washer, was contracted to review this one section and present comments to FHWA.

The risk considered herein refers to the development and significance of a scenario where structural safety or serviceability is lost to the point of requiring immediate action. If a bridge owner is aware of special features that may be problematic, the risk for the feature would need to be included in the assessment. This includes both loss of safe load carrying capacity, which is determined by load rating analysis and other damages involving serviceability, such as under-deck spalling or bearing support loss. Risk by basic mathematical definition is the product of the probability and consequence of an event.[3] Consequence herein focuses on the implications to the structure's safety and serviceability, and not necessarily the importance of the bridge or impacts to the users. Risk may be based on the frequency of events, such as in the quantitative probability of an event occurring, or on degree of belief or expectation from a panel of experienced professionals. Degrees of belief about probability can be chosen using qualitative scales, ranks or categories, such as remote/low/moderate/high or remote/unlikely/moderate/likely/almost certain.

Bridges all have features and attributes that will define the risk. Bridges all have a set of damage modes that may occur, which also define the risk. The risk of each potential damage mode must be evaluated and the one that is most critical is used to select the appropriate inspection interval. Additional information can be found in the following two documents which are

[3] National Cooperative Highway Research Program Report 782, ''Proposed Guideline for Reliability-Based Bridge Inspection Practices.''

available on the docket: NCHRP Report 782 ''Proposed Guideline for Reliability-Based Bridge Inspection Practices'' and a report for FHWA ''A Method for Determining the Interval for Hands-On Inspection of Steel Bridges with Fracture Critical Members'' by: Robert J. Connor and Michael J. Parr, November, 2008.

The proposed process in § 650.311(a)(2) for identifying risk-based intervals involves the identification and use of an interval that is commensurate with the risk of safety or service loss in a given bridge. It provides additional flexibility to bridge inspection organizations by applying their experience and engineering judgment to determining the use of limited resources in a more optimal way across their inventory.

The proposed § 650.311(a)(2)(i) through (vi) would establish a general framework and process for assessment of risk, and provides bridge inspection organizations the latitude for exercising their interpretations in determination of probability, consequence, and risk for bridges in their inventory.

The proposed process in § 650.311(a)(2) would require that bridges be classified into one of four general risk levels for consistency and uniformity with routine inspection intervals not to exceed 12, 24, 48, and 72 months. This process allows for risk assessment by quantified statistical analysis, when possible, or by qualitative expert judgment. The expectation is that this classification would result in an appropriate distribution of bridges in the four risk categories. These risk assessment criteria would be submitted to FHWA for approval.

As part of the proposed process in § 650.311(a)(2)(i), the criteria to be used by the bridge inspection organization to determine risk would be developed and documented by consensus of at least three experts and a program manager with collective experience in bridge design, materials, including ultra-high performance concrete or similar highly durable materials, construction, inspection, and evaluation. It is recognized that there may be too few quantified measures to make mathematical risk calculations; therefore, the experience of engineers to make judgments about expected performance and outcomes would be acceptable.

Another part of the proposed process allows for applying the risk-based interval in § 650.311(a)(2) to individual bridges and a group of bridges. A bridge may have unique features or attributes that require customized risk assessment. The intent of the proposal is not to mandate the application of the rigorous risk-based approach to an entire inventory, although it is an option.

The FHWA proposes a new § 650.311(a)(3), which would require that any new, rehabilitated, or structurally modified bridge must have an initial inspection completed, be in service for 24 months, receive its next routine inspection, and have any other required NBIS inspection completed before it can be considered for a routine inspection interval greater than 24 months. It is FHWA's position that the initial inspection is needed to capture unforeseen problems in a new, rehabilitated, or modified bridge before it is allowed to be inspected at an interval longer than 24 months. This is similar to the current FHWA Technical Advisory 5140.21 used to approve extended inspection policies. The regulation differs in that the 12- to 24-month in-service period specified in Technical Advisory 5140.21 is proposed to change in the regulation to 24 months and the in-depth inspection criterion is omitted in the regulation.

The FHWA proposes to redesignate and amend § 650.311(b)(2) to proposed § 650.311(b)(1)(ii), and to require that the criteria used to determine the interval by which underwater members are inspected at less than 60 months be documented. The proposal also adds more items to the list of criteria to be considered for an underwater inspection interval less than 60 months. Lastly, the paragraph proposes minimum criteria at which underwater inspections must be performed at intervals not to exceed 36 months.

The FHWA proposes to redesignate and amend current § 650.311(b)(3) to proposed § 650.311(b)(1)(iii) by removing the FHWA approval process and replacing it with a set of requirements for the underwater portions of a bridge to be inspected at an extended interval of up to 72 months. These criteria were developed using the current guidance from FHWA Technical Advisory 5140.21, American Society of Civil Engineers Manuals and Reports on Engineering Practice No. 101, Underwater Investigations, Standard Practice Manual and the Waterfront Facilities Inspection & Assessment Standard Practice Manual, American Society of Civil Engineers Coasts, Oceans Ports & Rivers Institute Ports and Harbors Committee Waterfront Inspection Task Committee, October 28, 2013.

The FHWA proposes a new § 650.311(b)(2), which allows the use of the more rigorous, risk-based process as described in the new § 650.311(a)(2) in determining appropriate underwater inspection intervals. For underwater inspections in this process, bridges are to be classified into one of three general risk levels with inspection intervals not to exceed 36, 60, and 72 months.

The FHWA proposes to amend § 650.311(c) by changing the name of the section to ''Nonredundant steel tension member inspections.''

The FHWA proposes to redesignate and amend § 650.311(c)(2) to proposed § 650.311(c)(1)(ii) to require that the State, Federal agency, or Tribal government must document the criteria used to determine the interval by which NSTMs are inspected at less than 24 months. The proposal also adds more items to the list of criteria to be considered for a NSTM inspection interval less than 24 months. Lastly, the paragraph proposes minimum criteria at which NSTM inspections must be performed at intervals not to exceed 12 months.

The FHWA proposes a new § 650.311(c)(1)(iii), which allows the use of the more rigorous, risk-based process as described in the new § 650.311(a)(2) in determining appropriate NSTM inspection intervals. For NSTM inspections in this process, bridges are to be classified into one of three general risk levels with inspection intervals not to exceed 12, 24, and 48 months.

The FHWA proposes to amend § 650.311(d) to require the State DOT, Federal agency, or Tribal government to document the criteria used to determine the level and interval to which damage, in-depth, and special inspections are to completed.

The FHWA proposes a new § 650.311(e)(1), which describes bridge inspection interval tolerance. Through discussions with stakeholders and FHWA's experience with the National Bridge Inspection Program, it was determined that a formalized inspection tolerance period would greatly improve the management of inspection scheduling. This proposed paragraph provides a tolerance that is the inspection due date plus 3 months. Although the expectation is that the inspection due date be met, this proposed tolerance provides a 3-month time period beyond the due date for a bridge inspection organization to begin an inspection and still be in compliance with the NBIS. The next inspection due date would be established by adding the interval to the actual inspection date. Inspections done before the inspection due date would have the effect of making the following inspection due date earlier; however, with the establishment of an inspection tolerance, this should not represent a

problem. Inspections beyond the inspection due date plus the tolerance would not comply with the proposed regulation provisions.

As an example, if the inspection of a bridge was performed in June 2017 and the interval for the inspection is 24 months, the next inspection due date would be June 2019. With a 3-month tolerance, the next inspection could be performed any time before the June 2019 inspection due date or in July, August, or September of 2019 and still meet the inspection tolerance. Below are three examples demonstrating how the next inspection due date would be determined for this bridge with a 24-month inspection interval depending on when the actual inspection occurred.

- If the 2019 inspection occurred in April 2019, ahead of schedule, the next inspection due date would be April 2021.
- If the 2019 inspection occurred in September 2019, within the tolerance, the next inspection due date would be September 2021.
- If the 2019 inspection occurred in October 2019, then the tolerance has been exceeded and the inspection would be out of compliance with this regulation unless prior FHWA approval was granted.

It should be noted that FHWA does not intend the normal inspection interval to be the interval plus the 3-month tolerance. The tolerance is to cover weather and other inspection program administration considerations.

The FHWA proposes a new § 650.311(e)(2). This section provides for an exception to the inspection tolerance with prior FHWA approval before the current inspection tolerance is exceeded. It is understood that unpredictable events, such as extreme weather, may make it impossible to seek prior approval, but these cases should be rare.

The FHWA proposes a new § 650.311(f). This proposed section would require that, at the completion of every inspection, the bridge information that is gathered is to be reviewed to determine if the current interval is still applicable for all inspection types or if a different interval is appropriate. This is a common practice under the current regulation; however, with the introduction of risk-based processes to establish appropriate inspection intervals into the proposed regulation, FHWA believes it is important to emphasize this step in the inspection process within the regulation.

Section 650.313 Inspection Procedures

The FHWA proposes to amend § 650.313(a) to clarify the expected outcomes of an inspection by adding the phrase ''to determine condition, identify deficiencies, and document results in an inspection report.'' The FHWA proposes to amend the reference to the AASHTO MBE to specifically cite Section 1.4, Section 2.1, Section 4, and Section 6. The more exact reference would point the reader to the specific material within the AASHTO MBE that is applicable to this proposed provision. In addition, FHWA proposes to clarify that an inspection plan would be required and proposes that the plan should document the inspection equipment, including advanced technologies, that are needed to complete the inspection.

Bridge inspections are multisensory operations requiring inspectors to see, feel, and listen as they perform inspections. Equipment to perform bridge inspections take on many forms, including personal safety equipment, access equipment, and tools to complete the inspection. Personal safety equipment includes items such as hard hats, vests, gloves, safety goggles, and more. Access equipment includes items such as ladders, under bridge inspection trucks, boats, and diving equipment. Tools for performing the inspection include cleaning tools (brushes, scrapers, etc.), sounding tools (hammers, chain drag, etc.), visual aid tools (binoculars, flashlights, mirrors, etc.), tools for measuring (tape measures, crack gauges, tiltmeter, etc.), and tools for documentation (cameras, kiel, clipboards, etc.).

Advancements in technology have played a critical role in the inspection program. Today, inspectors use a variety of advancements that were not commonplace decades ago. Laser measuring devices are replacing range poles and tape measures to determine bridge clearances and component lengths. Non-destructive evaluation equipment are used to assist in determining structural integrity without damaging the bridge members or to find deficiencies inside bridge members that are not visible with the naked eye. Depth measuring and monitoring devices are helping inspectors identify scour in waterways. Computers, tablets, and other electronic devices readily replace clipboards and paper forms.

In this day of significant technological advancements, other disruptive technologies will be developed that will change the way inspectors perform bridge inspection. As they are developed, FHWA will continue to evaluate these new tools in partnership with our stakeholders and update its bridge inspection guidance document, the Bridge Inspector's Reference Manual, to allow these technological advancements to make their way into the National Bridge Inspection Program (NBIP). Two recent examples of new technologies that FHWA is evaluating are sonar technologies for underwater bridge inspection and unmanned aerial systems (UAS).

The FHWA issued a report in 2018 to evaluate the use of sonar devices for underwater inspection. The study led to two broad conclusions. First, sonar technologies offer significant opportunities for improving underwater bridge inspections, especially in adverse environments or to inspect extensive areas. Second, sonar inspections have not demonstrated the ability to identify some smaller scale elements of substructure condition that may be important in assessing the bridge and recommending maintenance. The FHWA can now use this information to identify the proper uses of this technology to replicate typical diver experience to improve diver safety without jeopardizing the safety to the public.

The FHWA is currently performing research on UAS technologies since this industry is experiencing significant growth. The ability to fly UAS into positions that are difficult to reach by an inspector has the potential to save time, reduce costs, and improve safety margins. An increasing number of bridge owners are exploring the use of UAS for bridge inspections through pilot studies and exploring the potential of these versatile systems. The FHWA is aware of the introduction of UAS into the bridge inspection process and commissioned this research to enhance its understanding of the benefits and limitations of UAS. As this research continues, FHWA will be in a better position to provide guidance on the proper use of UAS in the NBIP.

These are just two examples of recent technological advancements the FHWA is evaluating to improve the NBIP. The FHWA will continue to monitor the advancement of UAS and other technologies and update the bridge inspection policies accordingly. The FHWA would like to hear from users of these technologies as FHWA continues its evaluation and research of these technologies to develop guidance for their use in the National Bridge Inspection Program. What bridge inspection environments are better suited for these technologies? What are minimum standards (device offset, camera resolution, optical and digital zoom capabilities, payload capacity, member cleanliness, etc.) FHWA should consider for the use of these technologies? How often should an in-depth inspection (diver be placed in the

water to check the results of the sonar devices or a hands-on inspection be performed for members inspected with a UAS) to verify no defects are missed?

The FHWA proposes to establish the inspection requirements for initial, routine, and in-depth inspections in § 650.313(b) through (d), respectively, and proposes procedures be developed to inspect bridges in phased construction and temporary bridges. For the purposes of these sections, the phrase ''entire bridge being open to traffic'' means construction is substantially complete and all lanes of the final cross section are completed and open to traffic. The term ''phased construction'' means building a bridge's cross section in stages and opening to traffic as such until the final cross section is completed. The FHWA proposes that State DOTs, Federal agencies, and Tribal governments establish the requirements for the inspection type, inspection frequency, and inspector qualifications for bridges during phased construction and temporary bridges based upon their knowledge and practice. It is FHWA's position that ensuring the safety of the travelling public is important during these situations.

The FHWA proposes a new § 650.313(e), to discuss underwater inspection procedures by using language from current § 650.313(e) introductory text and (e)(2). In addition, FHWA is proposing to require that the first underwater inspection for new, replaced, and rehabilitated bridges occurs within 6 months of the bridge opening to traffic. Unlike the initial inspection which is proposed to be performed before the bridge is open to traffic, FHWA realizes owners may need some discretion in scheduling this type of inspection. However, FHWA believes it is important for the safety of the travelling public that an underwater inspection occur relatively soon to understand the overall condition of the bridge and to develop a baseline for the future inspections.

The FHWA proposes a new § 650.313(f) to discuss nonredundant steel tension member inspection procedures by using language from the current § 650.313(e) introductory text and (e)(1). The paragraph also proposes to change the term fracture critical member to nonredundant steel tension member to be consistent with the other proposed changes in §§ 650.305, 650.309, and 650.311. This paragraph also proposes to clarify that NSTM inspections must be hands-on inspections. The current regulation addresses hands-on inspection of fracture critical members in § 650.305, which FHWA believes is not an appropriate location for a procedural process. In addition, FHWA is proposing the first nonredundant steel tension member inspection for new, replaced, and rehabilitated bridges would occur within 6 months of the bridge being open to traffic. Unlike the initial inspection, which is proposed to be performed before the bridge is open to traffic, FHWA realizes owners may need some discretion in scheduling this type of inspection. However, FHWA believes it is important for the safety of the travelling public that a nonredundant steel tension member inspection occur relatively soon to understand the overall condition of the bridge and to develop a baseline for the future inspections.

The FHWA proposes to establish the requirements for NSTM, underwater, in-depth, and complex feature inspection procedures in a new § 650.313(g). These requirements were previously covered in § 650.313(e)(1) and (2) and (f). The FHWA proposes that inspection procedures for NSTM, underwater, in-depth, and complex feature inspections be in accordance with Section 4.2 of the AASHTO MBE. It is FHWA's position that the intent of § 650.313(f) still be included in the NBIS but be more strategically focused on those parts of bridges that warrant additional attention due to their inherent complexity rather than an entire bridge that may have many noncomplex and complex elements. The FHWA proposes to incorporate by reference this section of the AASHTO MBE. In addition, this section proposes to clarify that some inspection procedures can be contained in an agency-wide procedures manual while procedures for unique situations and complex features should be bridge specific and contained in the bridge file.

The FHWA proposes to redesignate and amend the current § 650.313(b), proposed § 650.313(h). The proposal modifies the language to highlight the importance of the team leader to participate actively in the initial, routine, in-depth, NSTM, and underwater inspections.

The FHWA proposes to redesignate and amend the current § 650.313(c) to be proposed § 650.313(i). The FHWA proposes to require State DOTs, Federal agencies, and Tribal governments to establish documented procedures for timely completion of load ratings. Timely completion of load ratings is important for maintaining the safety of the traveling public; therefore, it is proposed that the time for completion of load ratings shall not exceed 3 months from the time the need for a load rating is identified by such things as a change in condition of a structural element, change in dead load, change in live load, or completion of construction. The requirement to load rate a bridge in 3 months for State and Federal agency bridges is required by the current § 650.315. The proposed provision would reduce the time for all other bridges to be load rated from 180 days to 3 months, which is aligned with the NTIS. In addition, FHWA proposes language to clarify the intent that all permit vehicles must be analyzed to ensure the bridge can safely carry the load.

The FHWA proposes to add § 650.313(j), which establishes requirements for timely installation of load posting signs aligned with the NTIS. The requirement of the proposed § 650.313(j)(1) for load posting, which is currently addressed in the existing § 650.313(c), is also proposed to be amended by replacing the phrase ''or equivalent rating factor'' with ''legal load rating or permit load analysis.'' The reason for this proposed change is to clearly account for the Load and Resistance Factor Rating method. For the Load and Resistance Factor Rating method, a legal load rating or permit load analysis that result in a rating factor of less than one is an indication that a bridge needs to be posted. The existing regulation also does not identify a maximum timeframe for the installation of load posting signs. Timely installation of load posting signs is important for maintaining the safety of the traveling public; therefore, it is proposed that the State DOTs, Federal agencies, and Tribal governments establish procedures for timely installation of load posting signs based upon the associated risks and need. The FHWA also proposes that the maximum timeframe for proper load posting of a bridge be no more than 30 days from the time the need is identified, which is consistent with the NTIS.

The FHWA proposes to add § 650.313(k) for closing of bridges. Section 6A.8.1 of the AASHTO MBE describes that a bridge owner must close a bridge when it cannot carry three tons and lists some factors to consider when closing bridges that can carry more than three tons. It is unclear as to the type of vehicle(s) that is to be considered when a determination to close a bridge needs to be made. The proposal would require State DOTs, Federal agencies, and Tribal governments to establish condition thresholds at which a bridge must be closed. This includes identifying vehicle types for the rating analysis for the minimum load carrying capacity.

The FHWA proposes to redesignate and amend the current § 650.313(d), to

proposed § 650.313(l). The FHWA proposes that the preparation and maintenance of bridge files are to be in accordance with Section 2.1 of the AASHTO MBE. The more exact reference will point the reader to the specific material within the AASHTO MBE that is applicable to this proposed provision.

The FHWA proposes to delete current § 650.313(e)(2). The requirements for underwater inspection procedures would be addressed in proposed § 650.313(g).

The use of underwater imaging technology for performing an underwater inspection is not excluded in the current or proposed NBIS; however, FHWA Technical Advisory 5140.21 clarifies minimum level I and level II inspection protocols for an underwater inspection. FHWA recently completed a research project, ''Underwater Inspection of Bridge Substructures Using Underwater Imaging Technology'' (*http://trid.trb.org/view.aspx?id=1328379*) to determine the effectiveness of underwater imaging technology as a possible alternative to the accepted level I underwater inspection protocols. In the meantime, there may be instances in which an underwater inspection cannot be safely performed using traditional methods. In these instances, underwater imaging technologies may be used for a level I underwater inspection. The program manager must identify and document all requirements for performing underwater acoustic imaging for underwater inspection.

The FHWA proposes a new § 650.313(m), which requires a ''scour appraisal'' for all bridges over water. The FHWA has interpreted existing § 650.313(e)(3) to mean that in order to determine whether a bridge requires a plan of action, the bridge owner must first perform a scour appraisal. The scour appraisal considers both the scour evaluation and observed scour. Also, if a bridge has unknown foundations, no appraisal can determine scour susceptibility, therefore, such a bridge requires a plan of action. The intent of the proposed section is to make clear that all bridges over water must have a scour appraisal and bridges that are scour critical or have unknown foundations must have a plan of action to address the associated risks. The proposal also specifies that a plan of action document must establish a schedule for repairing or installing physical and/or hydraulic scour countermeasures, and/or the use of monitoring countermeasures that includes inspecting, closing, and opening of each applicable bridge to traffic during and after flood events to protect the traveling public. The FHWA recognizes that Hydraulics Engineering Circular (HEC) 18, 20, and 23 are the state of knowledge and practice for the appraisal, design, evaluation, observation, and inspection of stream stability, bridge scour, and scour countermeasures.

The FHWA proposes to redesignate and amend § 650.313(g) to proposed § 650.313(n). A proposed reference to Section 1.4 of the AASHTO MBE would be incorporated to improve alignment and consistency between the regulations and the AASHTO MBE. In addition, the proposed language clarifies that quality assurance is to be performed by individuals other than those who completed the initial work. The importance of documenting quality assurance activities is also emphasized through the proposed language. Documentation is important in order to track and implement improvement opportunities.

The FHWA proposes to move the requirements for periodic bridge inspection refresher training for program managers and team leaders in the current § 650.313(g) to the proposed § 650.309(a)(3) and (b)(2). This requirement is directly related to the qualifications of the program manager and team leaders rather than a bridge inspection organization's quality control (QC) and quality assurance (QA) program.

In accordance with 23 U.S.C. 144(h)(3)(b), FHWA proposes to establish procedures for States to follow in reporting information on critical findings by redesignating and amending § 650.313(h) to proposed § 650.313(o). The need for clarity in the current § 650.313(h) was identified in FHWA's Summary Report of Critical Findings Reviews for the National Bridge Inspection Standards dated December 2011 (*http://www.fhwa.dot.gov/bridge/nbip/critical.pdf*) and the initial FHWA outreach to stakeholders regarding the current NBIS. Under the proposed rule, the definition for critical finding does not substantially change from the existing regulations; however, State DOTs, Federal agencies, and Tribal governments would be required to identify what it considers a critical finding based upon the minimum requirements proposed in § 650.313(o). The FHWA proposes an improved reporting process for monitoring activities and corrective actions taken in response to critical findings.

For the proposed reporting procedures, State DOTs are to report critical findings information to their respective FHWA Division office. Similarly, Federal agencies and Tribal governments should report required information to the Federal Lands Highway Division office. Although 23 U.S.C. 144(h)(3)(B) only specifies that States are to report on critical findings, Federal agencies and Tribal governments should also report on critical findings. The FHWA's goal is safety and national consistency. Therefore, it is appropriate that Federal agencies and Tribal governments should follow the same procedures as those proposed for State DOTs.

Specific requirements of the proposed § 650.313(o) would direct State DOTs, Federal agencies, and Tribal governments to include in their procedures that a nonredundant bridge member on a bridge on the National Highway System with a quantity in condition state 4 [4] is a critical finding. Bridges are composed of many members and some members may be nonredundant. The intent of the proposed requirement is to report on critical findings that affect structural, nonredundant members such as beams and piers, not members that do not affect the structural integrity of a bridge such as bridge rails and ancillary structures.

In accordance with 23 U.S.C. 144(h)(4), FHWA proposes a new § 650.313(p) to assist in FHWA's assessment of State DOTs, Federal agencies, and Tribal governments for compliance with these standards. Although the statute only refers to States' compliance with these regulations, Federal agencies' and Tribal governments' compliance with these regulations is vital to ensuring safety and consistency.

Section 650.315 Inventory

The FHWA proposes to amend § 650.315(a) to replace the term ''Structure Inventory and Appraisal data'' with ''inventory data.'' The proposed term ''inventory data'' as defined in § 650.305 provides clarity as to the type of information that bridge owners would provide to FHWA for bridges subject to the NBIS. The FHWA also proposes to amend this section to add Tribal governments to be consistent with 23 U.S.C. 144(h)(2). The FHWA proposes to revise the language to align with current FHWA language requiring annual inventory data submittal.

The FHWA proposes to replace the reference to the ''Recording and Coding Guide for the Structure Inventory and

[4] See the AASHTO document ''Manual for Element Level Inspection.'' Condition State 4 is described for each of the individual elements included in the manual.

Appraisal of the Nation's Bridges'' with a reference to the ''Specifications for the National Bridge Inventory'' in order to align with the reference in § 650.317. The FHWA proposes the addition of the requirement to include element level bridge inspection data for bridges on the NHS as required by 23 U.S.C. 144(d)(2).

The FHWA proposes to have State DOTs, Federal agencies, and Tribal governments enter changes to inventory data in § 650.315(b) for all inspection types.

The FHWA proposes to amend § 650.315(b) through (d) by replacing ''SI&A data'' with ''inventory data.'' The proposed term ''inventory data'' as defined in § 650.305 provides clarity as to the type of information that is to be provided for bridges subject to the NBIS. The FHWA proposes to further amend this section to add ''Tribal governments'' to be consistent with 23 U.S.C. 144(h)(2). The FHWA proposes to revise the requirement of submitting inventory data within 90 days to 3 months to be consistent with other proposed units of time in the NBIS. The FHWA proposes to change the requirement for submittal of inventory data for all bridges to 3 months. It is FHWA's position that due to current technological capabilities, the current requirement of 180 days for non-State DOT- and Federal-owned bridges is an excessive amount of time for inventory data to be submitted to a centralized database. This is also consistent with the NTIS. A 3-month limit would help keep the NBI more current. The FHWA proposes to revise the beginning of the referenced timeframe from ''date of inspection'' to ''field portion of the inspection is completed'' to clarify when the time limit starts.

The FHWA proposes to add § 650.315(e), requiring State DOTs, Federal agencies, and Tribal governments to document processes to track and measure their performance in submitting inventory data within the required time constraint.

Section 650.317 Reference Manuals

The FHWA proposes to amend this section by incorporating by reference the more current versions of the manuals listed and updating the section to be consistent with requirements of the Office of the Federal Register.

The AASHTO's 2008 ''Manual for Bridge Evaluations,'' is proposed to be replaced with a more current edition of the ''AASHTO Manual for Bridge Evaluation.'' This document was developed by AASHTO to assist bridge owners by establishing inspection procedures and evaluation practices that meet the FHWA's National Bridge Inspection Standards regulatory requirements. The manual is been divided into eight sections, with each section representing a distinct phase of an overall bridge inspection and evaluation program.

In addition, FHWA proposes to add the AASHTO's ''Manual for Bridge Element Inspection'' (AASHTO MBEI), First Edition, and its Interim Revision. This document is a reference for standardized element definitions, element quantity calculations, condition state definitions, element feasible actions, and inspection conventions. Its goal is to capture the condition of bridges in a simple, effective way that can be standardized nationwide, while providing enough flexibility to be adapted by both large and small agencies. AASHTO designed the document for use by State departments of transportation and other agencies that perform element-level bridge inspections. This reference is proposed to support the Section 1111(a) of MAP–21 for element level data to be reported to FHWA for bridges on the NHS. The AASHTO MBEI is referenced in FHWA's ''Specification for the National Bridge Inventory Bridge Elements,'' and would establish a uniform understanding of the inventory data to be reported in order to satisfy the statutory requirement.

The FHWA proposes to incorporate by reference FHWA's ''Specifications for the National Bridge Inventory'' (SNBI). The SNBI details how to code and submit data gathered on highway bridges for the national bridge inventory, including items on location, structure type, condition ratings, and inspection dates. This document replaces the current Recording and Coding Guide for the Structure Inventory and Appraisal of the Nation's Bridges (Coding Guide) and define the required inventory data that is submitted to FHWA to fulfill the requirements of § 650.315. The FHWA recognizes that bridge owners reporting data would incur a one-time cost associated with changing from the Coding Guide to the SNBI. However, as many of the data items are the same or similar and there is a wide variety of data management and reporting systems being used, FHWA was unable to estimate these costs. The FHWA requests information regarding any costs associated with this proposed change.

The documents that FHWA proposes to incorporate by reference are reasonably available to interested parties, primarily State DOTs and local agencies carrying out Federal-aid highway projects. The documents listed in this section are available on the docket with this notice of proposed rulemaking and at the sources identified in the regulatory text below. The specific standards are discussed in greater detail elsewhere in this preamble.

Subpart D—Highway Bridge Replacement and Rehabilitation Program

The Highway Bridge Program was not reauthorized by MAP–21. The MAP–21 restructured core highway formula programs. Activities that were carried out under the Highway Bridge Program were incorporated into the National Highway Performance Program and the Surface Transportation Program (now Surface Transportation Block Grant Program). The Highway Bridge Program was first authorized under Section 124 of the Surface Transportation Assistance Act of 1978 (initially called the Highway Bridge Replacement and Rehabilitation Program) and was last reauthorized under Section 1114 of the Safe, Accountable, Flexible, Efficient, Transportation Equity Act: A Legacy for Users. As such, FHWA no longer needs the Highway Bridge Replacement and Rehabilitation Program regulations found in 23 CFR part 650, subpart D, and proposes to rescind the regulations.

Subpart G—Discretionary Bridge Candidate Rating Factor

The Discretionary Bridge Program was a component of the Highway Bridge Replacement and Rehabilitation Program. The Discretionary Bridge Program was initially authorized under Section 124 of the Surface Transportation Assistance Act of 1978, and was last reauthorized under Section 1109 of the Transportation Equity Act for the 21st Century. Since no new funds have been authorized for this program, FHWA proposes to repeal the regulations found in 23 CFR part 650, subpart G, which were used to describe the rating factors FHWA would use when awarding Discretionary Bridge Program grants.

Executive Order 12866 (Regulatory Planning and Review), Executive Order 13563 (Improving Regulation and Regulatory Review), Executive Order 13771 (Reducing Regulations and Controlling Regulatory Costs), and DOT Regulatory Policies and Procedures

The proposed rule is a significant regulatory action within the meaning of Executive Order (E.O.) 12866 and DOT regulatory policies and procedures. This action complies with E.O.s 12866, 13563, and 13771 to improve regulation. This action is considered significant because of widespread public interest in

the safety of highway bridges, although not economically significant within the meaning of E.O. 12866. The FHWA has filed into the docket a Regulatory Impact Analysis (regulatory analysis or RIA) in support of the NPRM on NBIS. The regulatory analysis estimates the economic impact, in terms of costs and benefits, on Federal, State, and local governments, as well as private entities regulated under this action, as required by E.O. 12866 and E.O. 13563.

This section of the NPRM identifies the estimated costs and benefits resulting from the proposed rule in order to inform policy makers and the public of the relative value of the current proposal. The complete RIA may be accessed from the rulemaking's docket (FHWA–2017–0047) and contains a discussion of the benefits. The proposed regulation will result in both qualitative and quantitative benefits. On the qualitative side, the rule adds several features that are aimed at improving bridge safety including, more consistent inspection procedures, better qualified inspection personnel, and reporting of structural and safety-related deficiencies. The incorporation of the more rigorous, risk-based process for the determination of routine inspection intervals can result in quantitiave benefits. By assuming as additional one percent of bridges will be inspected at longer intervals, the cost analysis performed resulted in an estimated annualized savings of more than $250,000 discounted at 7 percent, or nearly $2.63 million dollars in the first 10 years. The proposed rule is expected to be an E.O. 13771 regulatory action. Details on the estimated costs of this proposed rule can be found in the rule's economic analysis, which may be accessed from the docket.

Estimated Cost of the Proposed Rule

Table 1 displays the total cost of the proposed rule for the 10-year study period (2020–29). Total annualized costs are estimated to be $1.65 million discounted at 7 percent, and $1.62 million discounted at 3 percent.

TABLE 1—TOTAL COST OF THE PROPOSED RULE

Cost components	10-year total cost		Annualized cost	
	0.07	0.03	0.07	0.03
Section 650.303, 650.307—Applicability	$3,948,096	$4,981,212	$562,120	$583,950
Inspection of Bridges on and off Federal-aid Highways	−2,150,904	−2,713,740	−306,240	−318,133
Establish Inspection Organizations	6,099,000	7,694,952	868,360	902,083
Section 605.305—Definitions	0	0	0	0
Section 650.307—Bridge Inspection Organization Responsibilities	1,749,810	1,930,116	249,134	226,268
Establish Agreements for Border Bridges	1,520,985	1,641,414	216,554	192,424
Maintain Registry of Certified Inspectors	228,824	288,702	32,579	33,845
Section 650.309—Qualifications of Personnel	2,683,459	3,029,054	382,064	355,098
Refresher Training for Program Managers and Team Leaders	1,226,175	1,438,843	174,580	168,676
Training on NSTM Inspections for Team Leaders	1,271,182	1,371,831	180,988	160,820
Proprietary Training Review	186,102	218,379	26,497	25,601
Section 650.313—Inspection Procedures	2,055,326	2,394,884	292,632	280,754
Initial and Routine Inspections for Bridges with Phased Const. or Temp. Bridges	438,203	552,870	62,390	64,813
Written Policies for Closing Bridges	1,086,418	1,172,438	154,681	137,446
Critical Findings Reporting and Tracking	530,704	669,576	75,560	78,495
Section 315—Inventory	1,186,836	1,497,400	168,979	175,541
Bridge Inventory for Tribal Governments	1,186,836	1,497,400	168,979	175,541
Total Cost of Proposed Rule	11,623,526	13,832,666	1,654,929	1,621,610

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (Pub. L. 96–354, 5 U.S.C. 601–612), FHWA has evaluated the effects of this NPRM on small entities. Because the regulations are primarily intended for States and Federal agencies, FHWA has determined that the action is not anticipated to have a significant economic impact on a substantial number of small entities. States and Federal agencies are not included in the definition of small entity set forth in 5 U.S.C. 601. Therefore, FHWA certifies that the action will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

The FHWA has determined that this NPRM will not impose unfunded mandates as defined by the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, March 22, 1995, 109 Stat. 48). The NBIS is needed to ensure safety for the users of the Nation's bridges and to help protect Federal infrastructure investment. As discussed above, FHWA finds that this regulatory action will not result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $155,000,000 or more in any one year (2 U.S.C. 1532). In addition, the definition of ''Federal mandate'' in the Unfunded Mandates Reform Act excludes financial assistance of the type in which State, local, or Tribal governments have authority to adjust their participation in the program in accordance with changes made in the program by the Federal Government. The Federal-aid highway program permits this type of flexibility.

Executive Order 13132 (Federalism Assessment)

The FHWA has analyzed this NPRM in accordance with the principles and criteria contained in E.O. 13132. The FHWA has determined that this action will not have sufficient federalism implications to warrant the preparation of a federalism assessment. The FHWA has also determined that this action will not preempt any State law or State regulation or affect the States' ability to discharge traditional State governmental functions.

Executive Order 12372 (Intergovernmental Review)

The regulations implementing E.O. 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program. Local entities should refer to the Catalog of Federal Domestic Assistance Program

Number 20.205, Highway Planning and Construction, for further information.

Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501, *et seq.*), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct, sponsor, or require through regulations. This action contains a collection of information requirement under the PRA that is covered under existing OMB Control number 2125–0501.

National Environmental Policy Act

The Department has analyzed this action for the purpose of the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321 *et seq.*), and has determined that this action would not have a significant effect on the quality of the environment and qualifies for the categorical exclusion at 23 CFR 771.117(c)(20).

Executive Order 12630 (Taking of Private Property)

This action will not affect a taking of private property or otherwise have taking implications under E.O. 12630, Governmental Actions and Interference With Constitutionally Protected Property Rights.

Executive Order 12988 (Civil Justice Reform)

This action meets applicable standards in section 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Executive Order 13045 (Protection of Children)

The FHWA has analyzed this action under E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks. This proposed rule does not concern an environmental risk to health or safety that may disproportionately affect children.

Executive Order 13175 (Tribal Consultation)

In accordance with E.O. 13175, FHWA identified potential effects on federally recognized Indian tribes that might result from this proposed rule. Accordingly, on August 7, 2014, a webinar was conducted by FHWA in furtherance of its duty to consult with Tribal governments under E.O. 13175 ''Consultation and Coordination With Indian Tribal governments.'' The webinar dealt with the NBIS and mentioned that FHWA was planning to publish an NPRM sometime in the future that would include requirements for bridges owned by Tribal governments. The date and time of the webinar had been announced to the Tribal governments through the seven Tribal Technical Assistance Program (TTAP) centers. A total of 35 connections were on the webinar with one or more persons on each connection. Two Tribal governments were identified on the connections and at least one consultant that works with the Tribes was on the webinar. A number of the personnel on the webinar were from the BIA and FHWA.

The webinar was conducted by three bridge engineers and one attorney all from FHWA. The PowerPoint presentation and narrative covered the history of the NBIS, the NBIS general requirements based on the current NBIS, and a final section considering the impacts on the Tribal governments caused by the 23 U.S.C. 144(h)(2) amendments to the NBIS. There was a question and answer period after the presentation where general questions about the NBIS were discussed as well as impacts to bridges owned by Tribal governments. Issues discussed included why a NPRM was needed, if trail bridges and pedestrian bridges were subject to the NBIS, and what funding was available for the bridge inspections. The webinar lasted for nearly an hour and was terminated when no more questions were asked. The webinar was recorded and uploaded onto the Tribal Transportation Program Bridge website [5] maintained by FHWA.

The FHWA will fully consider tribal views in the development of further rulemaking proceedings.

Executive Order 13211 (Energy Effects)

The FHWA has analyzed this proposed rule under E.O. 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that the rule will not constitute a significant energy action under that order because, although it is considered a significant regulatory action under E.O. 12866, it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

Regulation Identification Number

A regulation identification number (RIN) is assigned 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. The RIN contained in the heading of this document can be used to cross reference this action with the Unified Agenda.

List of Subjects in 23 CFR Part 650

Bridges, Grant programs—transportation, Highways and roads, Incorporation by reference, Reporting and recordkeeping requirements.

Issued in Washington, DC, under authority delegated in 49 CFR 1.85(a)(1).

Nicole R. Nason,

Administrator, Federal Highway Administration.

In consideration of the foregoing, FHWA proposes to amend title 23, Code of Federal Regulations, part 650, as set forth below:

PART 650—BRIDGES, STRUCTURES, AND HYDRAULICS

■ 1. The authority citation for part 650 continues to read as follows:

Authority: 23 U.S.C. 119, 144, and 315.

■ 2. Revise subpart C to read as follows:

Subpart C—National Bridge Inspection Standards

Sec.
650.301 Purpose.
650.303 Applicability.
650.305 Definitions.
650.307 Bridge inspection organization responsibilities.
650.309 Qualifications of personnel.
650.311 Inspection interval.
650.313 Inspection procedures.
650.315 Inventory.
650.317 Reference manuals.

Subpart C—National Bridge Inspection Standards

§ 650.301 Purpose.

This subpart sets the national minimum standards for the proper safety inspection and evaluation of all highway bridges in accordance with 23 U.S.C. 144(h) and the requirements for preparing and maintaining an inventory in accordance with 23 U.S.C. 144(b).

§ 650.303 Applicability.

The National Bridge Inspection Standards (NBIS) in this subpart apply to all structures defined as highway bridges located on all public roads, on and off Federal-aid highways, including tribally-owned, federally-owned, and privately-owned bridges that are connected to a public road on both ends of the bridge.

§ 650.305 Definitions.

The following terms used in this subpart are defined as follows:

AASHTO Manual. The term ''AASHTO Manual'' means the

[5] *https://flh.fhwa.dot.gov/programs/ttp/bridges/bip.htm.*

American Association of State Highway and Transportation Officials (AASHTO) ''Manual for Bridge Evaluation'' incorporated by reference in § 650.317.

Attribute. Characteristic of the design, loading, conditions, and environment that affect the reliability of a bridge or bridge element.

Bridge. A structure including supports erected over a depression or an obstruction, such as water, highway, or railway, and having a track or passageway for carrying traffic or other moving loads, and having an opening measured along the center of the roadway of more than 20 feet between under copings of abutments or spring lines of arches, or extreme ends of openings for multiple boxes; it includes multiple pipes, where the clear distance between openings is less than half of the smaller contiguous opening.

Bridge inspection experience. Active participation in bridge inspections in accordance with the NBIS, in either a field inspection, supervisory, or management role. Some of the experience may come from relevant bridge design, bridge construction, and bridge maintenance experience provided it develops the skills necessary to properly perform a NBIS bridge inspection.

Bridge inspection refresher training. The National Highway Institute [1] (NHI) ''Bridge Inspection Refresher Training Course'' or other State, federally, or tribally developed instruction aimed to improve quality of inspections, introduce new techniques, and maintain consistency in the inspection program.

Bridge Inspector's Reference Manual (BIRM). A comprehensive FHWA manual on procedures and techniques for inspecting and evaluating a variety of in-service highway bridges. This manual may be purchased from the U.S. Government Publishing Office, Washington, DC 20402 and from National Technical Information Service, Springfield, Virginia, 22161, and is available at the following URL: *http://www.fhwa.dot.gov/bridge/bripub.htm.*

Complex feature. Bridge component(s) or member(s) with advanced or unique structural elements or operational characteristics, construction methods, and/or requiring specific inspection procedures. This includes mechanical and electrical elements of moveable spans and cable-related elements of suspension and cable-stayed superstructures.

Comprehensive bridge inspection training. Training that covers all aspects of bridge inspection and enables inspectors to relate conditions observed on a bridge to established criteria (see the BIRM for the recommended material to be covered in a comprehensive training course).

Consequence. A measure of impacts to structural safety and serviceability in a hypothetical scenario where a damage mode progresses to the point of requiring immediate action. This may include costs to restore the bridge to safe operating condition or other costs.

Critical finding. A structural or safety related deficiency that requires immediate action to ensure public safety.

Damage inspection. An unscheduled inspection to assess structural damage resulting from environmental factors or human actions.

Damage mode. Typical damage affecting the condition of a bridge element that may affect the structural safety or serviceability of the bridge.

Element level bridge inspection data. Quantitative condition assessment data, collected during bridge inspections, that indicates the severity and extent of defects in bridge elements.

End-of-course assessment. A comprehensive examination given to students after the completion of the delivery of a training course.

Hands-on inspection. Inspection within arms length of the member. Inspection uses visual techniques that may be supplemented by nondestructive evaluation techniques.

Highway. The term ''highway'' is defined in 23 U.S.C. 101.

In-depth inspection. A close-up, detailed inspection of one or more bridge members located above or below water, using visual or nondestructive evaluation techniques as required to identify any deficiencies not readily detectable using routine inspection procedures. Hands-on inspection may be necessary at some locations. In-depth inspections may occur more or less frequently than routine inspections, as outlined in bridge specific inspection procedures.

Initial inspection. An initial inspection is the first routine inspection and first underwater and nonredundant steel tension member inspections, when necessary, of a new, replaced, or rehabilitated bridge. This inspection serves to record required bridge inventory data, establish baseline conditions, and establish the intervals for other inspection types.

Inspection date. The date on which an inspection begins for a bridge.

Inspection due date. The last inspection date plus the current inspection interval.

Inspection report. The document which summarizes the bridge inspection findings and recommendations, signed by a team leader.

Inventory data. All data reported to the National Bridge Inventory in accordance with the ''Specifications for the National Bridge Inventory'' incorporated by reference in § 650.317.

Legal load. The maximum legal load for each vehicle configuration permitted by law for the State in which the bridge is located.

Load posting. Regulatory signs installed in accordance with the ''Manual on Uniform Traffic Control Devices'' and State or local law which represent the maximum vehicular live load which the bridge may safely carry.

Load rating. The analysis to determine the safe vehicular live load carrying capacity of a bridge using bridge plans and supplemented by measurements and other information gathered from an inspection.

Nationally certified bridge inspector. An individual meeting the team leader requirements of § 650.309(b).

Nonredundant member. A member without load path redundancy or other redundancy demonstrated through an FHWA-approved process.

Nonredundant steel tension member (NSTM) inspection. A hands-on inspection of nonredundant steel members subject to tension.

Nonredundant steel tension member inspection training. Training that covers all aspects of NSTM inspections to relate conditions observed on a bridge to established criteria.

Operating rating. The maximum permissible live load to which the structure may be subjected for the load configuration used in the load rating.

Plan of action (POA). Procedures for bridge inspectors and engineers in managing each bridge determined to be scour critical or that has unknown foundations.

Procedures. Written documentation of policies, methods, considerations, criteria, and other conditions that direct the actions of personnel so that a desired end result is achieved consistently.

Probability. Extent to which an event is likely to occur during a given interval. This may be based on the frequency of events, such as in the quantitative probability of failure, or on degree of belief or expectation. Degrees of belief about probability can be chosen using qualitative scales, ranks, or categories such as, remote, low, moderate, or high.

Professional engineer (PE). An individual, who has fulfilled education and experience requirements and passed examinations that, under State

[1] The NHI training may be found at the following URL: *http://www.nhi.fhwa.dot.gov/.*

licensure laws, permits the individual to offer engineering services within areas of expertise directly to the public.

Program manager. The individual(s) responsible for bridge inspection, load rating, load posting, reporting, and inventory. The individual(s) provide(s) overall leadership and is available to inspection teams and load raters to provide guidance.

Public road. The term ''public road'' is defined in 23 U.S.C. 101.

Quality assurance (QA). The use of sampling and other measures to assure the adequacy of quality control procedures in order to verify or measure the quality level of the entire bridge inspection and load rating program.

Quality control (QC). Procedures that are intended to maintain the quality of a bridge inspection and load rating at or above a specified level.

Risk. The exposure to the possibility of structural safety or serviceability loss during the interval between inspections. It is the combination of the probability of an event and its consequence.

Risk assessment panel. A group, made up of the NBIS program manager and at least three experts with collective experience in bridge design, evaluation, inspection, maintenance, materials, and construction, that develops the policy for a more rigorous assessment of risk when establishing inspection intervals.

Routine inspection. Regularly scheduled comprehensive inspection consisting of observations and measurements needed to determine the physical and functional condition of the bridge, identifying changes from previously recorded conditions, and identifying critical findings.

Routine permit load. A live load, which has a gross weight, axle weight or distance between axles not conforming with State statutes for legally configured vehicles, authorized for unlimited trips over an extended period of time to move alongside other heavy vehicles on a regular basis.

Safe load capacity. A live load that can safely utilize a bridge repeatedly over the duration of a specified inspection interval.

Scour. Erosion of streambed or bank material due to flowing water; often considered as being localized around piers and abutments of bridges.

Scour appraisal. A determination of the stability of a bridge from scour made using either an evaluation process, an observed condition, or both.

Scour critical bridge. A bridge with a foundation element that has been determined to be unstable for the observed or evaluated scour condition.

Service inspection. An inspection to detect major visible safety deficiencies, performed by personnel with general knowledge of bridges with the results documented in the bridge file.

Special inspection. An inspection scheduled at the discretion of the bridge owner, used to monitor a particular known or suspected deficiency, or to monitor special details or unusual characteristics of a bridge that do not necessarily have defects.

Special permit load. A live load, which has a gross weight, axle weight or distance between axles not conforming with State statutes for legally configured vehicles and routine permit loads, typically authorized for single or limited trips.

State transportation department. The term ''State transportation department'' is defined in 23 U.S.C. 101.

Team leader. The on-site, nationally certified bridge inspector in charge of an inspection team and responsible for planning, preparing, performing, and reporting on bridge field inspections.

Temporary bridge. A bridge which is constructed to carry highway traffic until the permanent facility is built, repaired, rehabilitated, or replaced.

Underwater bridge inspection training. Training that covers all aspects of underwater bridge inspection to relate the conditions of underwater bridge elements to established criteria (see the Bridge Inspector's Reference Manual section on underwater inspection for the recommended material to be covered in an underwater bridge inspection training course).

Underwater inspection. Inspection of the underwater portion of a bridge substructure and the surrounding channel, which cannot be inspected visually at low water or by wading or probing, and generally requiring diving or other appropriate techniques.

§ 650.307 Bridge inspection organization responsibilities.

(a) Each State transportation department must perform, or cause to be performed, the proper inspection and evaluation of all highway bridges that are fully or partially located within the State's boundaries, except for bridges that are owned by Federal agencies or tribal governments.

(b) Each Federal agency must perform, or cause to be performed, the proper inspection and evaluation of all highway bridges that are fully or partially located within the respective Federal agency's responsibility or jurisdiction.

(c) Each tribal government, in consultation with the Bureau of Indian Affairs (BIA), must perform, or cause to be performed, the proper inspection and evaluation of all highway bridges that are fully or partially located within the respective tribal government's responsibility or jurisdiction.

(d) Where a border bridge crosses between a State transportation department, Federal agency, or tribal government jurisdictions, all bordering entities must determine through a joint written agreement the inspection responsibilities of each entity for that bridge.

(e) Each State transportation department, Federal agency, and tribal government must include a bridge inspection organization that is responsible for the following:

(1) Developing and implementing written Statewide, Federal agency wide, or tribal government wide bridge inspection policies and procedures;

(2) Documenting inspection intervals for the inspection types identified in the standards in this subpart;

(3) Documenting the roles and responsibilities of personnel involved in the bridge inspection program;

(4) Maintaining a central registry of nationally certified bridge inspectors that work in their State or for their Federal agency or tribal government that includes, at a minimum, a method to positively identify each inspector, inspector's qualification records, inspector's current contact information, and detailed information about any adverse action that may affect the good standing of the inspector;

(5) Managing bridge inspection reports and files;

(6) Performing quality control and quality assurance activities;

(7) Preparing, maintaining, and reporting bridge inventory data;

(8) Load rating, load posting, and determining other restrictions;

(9) Managing the critical finding activities;

(10) Managing scour appraisals and plans of action; and

(11) Managing other requirements of the standards in this subpart.

(f) Functions identified in paragraphs (e)(1) through (11) of this section may be delegated to other individuals, agencies, or entities. The delegated roles and functions of all individuals, agencies, and entities involved must be documented in a formal written agreement by the responsible State transportation department, Federal agency, or tribal government. Except as provided in paragraph (f) of this section, such delegation does not relieve the State transportation department, Federal agency, or tribal government of any of its responsibilities under this subpart. A tribal government may, with BIA's concurrence via a formal written agreement, delegate its functions and

responsibilities under this subpart to the BIA.

(g) Each State transportation department, Federal agency, or tribal government bridge inspection organization must have a program manager(s) with the qualifications defined in § 650.309(a). An employee of the BIA having the qualification of a program manager as defined in § 650.309(a) may serve as the program manager for a tribal government if the tribal government delegates this responsibility to the BIA in accordance with paragraph (f) of this section. When there is more than one program manager, a lead program manager who is responsible for coordinating the Statewide, Federal agency wide, or tribal government wide policies and procedures must be identified.

§ 650.309 Qualifications of personnel.

(a) A program manager must, at a minimum:

(1) Be a registered professional engineer, or have ten years of bridge inspection experience;

(2) Complete an FHWA-approved comprehensive bridge inspection training course as described in paragraph (g) of this section and score 70 percent or greater on an end-of-course assessment (completion of comprehensive bridge inspection training under prior regulations satisfy the intent of the requirement in this paragraph (a));

(3) Complete a cumulative total of 18 hours of FHWA-approved bridge inspection refresher training over each 60 month period;

(4) Maintain documentation supporting the satisfaction of paragraphs (a)(1) through (3) of this section; and

(5) Satisfy the requirements of this paragraph (a) within 24 months from [EFFECTIVE DATE OF FINAL RULE] if serving as a program manager who was qualified under prior regulations.

(b) A team leader must, at a minimum:

(1) Complete an FHWA-approved comprehensive bridge inspection training course as described in paragraph (g) of this section and score 70 percent or greater on an end-of-course assessment (completion of comprehensive bridge inspection training under prior regulations satisfies the intent of the requirement in this paragraph (b));

(2) Complete a cumulative total of 18 hours of FHWA-approved bridge inspection refresher training over each 60 month period; and

(3) Meet one of the four qualifications listed in paragraphs (b)(3)(i) through (iv) of this section:

(i) Be a registered professional engineer and have six months of bridge inspection experience;

(ii) Have five years of bridge inspection experience;

(iii) Have all of the following:

(A) A bachelor's degree in engineering or engineering technology from a college or university accredited by or determined as substantially equivalent by the Accreditation Board for Engineering and Technology; and

(B) Successfully passed the National Council of Examiners for Engineering and Surveying Fundamentals of Engineering examination; and

(C) Two years of bridge inspection experience; or

(iv) Have all of the following:

(A) An associate's degree in engineering or engineering technology from a college or university accredited by or determined as substantially equivalent by the Accreditation Board for Engineering and Technology; and

(B) Four years of bridge inspection experience.

(4) Provide documentation supporting the satisfaction of paragraphs (b)(1) through (3) of this section to the program manager of each State transportation department, Federal agency, or tribal government for which they are performing bridge inspections.

(5) Satisfy the requirements of this paragraph (b) within 24 months from [EFFECTIVE DATE OF FINAL RULE] if serving as a team leader who was qualified under prior regulations.

(c) Team leaders on nonredundant steel tension member inspections must, at a minimum:

(1) Meet the requirements in paragraph (b) of this section; and

(2) Complete an FHWA-approved training course on the inspection of nonredundant steel tension members as defined in paragraph (g) of this section and score 70 percent or greater on an end-of-course assessment.

(3) Satisfy the requirements of this paragraph (c) within 24 months from [EFFECTIVE DATE OF FINAL RULE] if serving as a team leader for inspections of NSTMs under prior regulations.

(d) Load ratings must be performed by, or under the direct supervision of, a registered professional engineer.

(e) An underwater bridge inspection diver must complete FHWA-approved underwater bridge inspection training as described in paragraph (g) of this section and score 70 percent or greater on an end-of-course assessment.

(f) State transportation departments, Federal agencies, and tribal governments must establish and document inspection personnel qualifications for damage, service, and special inspections.

(g) The following are considered acceptable bridge inspection training:

(1) *National Highway Institute (NHI) training.* Acceptable NHI courses include:

(i) Comprehensive bridge inspection training which must include topics on importance of bridge inspection; bridge mechanics and terminology; personal and public safety issues associated with bridge inspections; properties and deficiencies of concrete, steel, timber and masonry; inspection equipment needs for various types of bridges and site conditions; inspection procedures, evaluations, documentation, data collection and critical findings for bridge decks, superstructures, substructures, culverts, waterways (including underwater elements), joints, bearings, drainage systems, lighting, signs, and traffic safety features; inspection procedures, evaluations, documentation, data collection; nondestructive evaluation techniques; load path redundancy and fatigue concepts; and practical applications of the concepts listed in this paragraph (g)(1)(i);

(ii) Bridge inspection refresher training, which must include topics on documentation of inspections, commonly miscoded items, recognition of critical inspection findings, recent events impacting bridge inspections, and quality assurance activities;

(iii) Underwater bridge inspection training, which must include topics on the need for and benefits of underwater bridge inspections; typical defects and deterioration in underwater members; inspection equipment needs for various types of bridges and site conditions; inspection planning and hazard analysis; and underwater inspection procedures, evaluations, documentation, data collection and critical findings; and

(iv) Nonredundant steel tension member inspection training, which must include topics on the identification of NSTMs and related problematic structural details, the recognition of areas most susceptible to fatigue and fracture, the evaluation and recording of defects on NSTM, and the application of nondestructive evaluation techniques.

(2) *FHWA approval of alternate training.* Alternates to the NHI training courses listed in paragraph (g)(1) of this section must include all the topics described in paragraph (g)(1) and be submitted to the FHWA by a State transportation department, Federal

agency, or tribal government. The FHWA must approve alternate course materials and end-of-course assessments for national consistency and certification purposes. Alternate training courses must be reviewed by the program manager every five years to ensure the material is current. Updates to approved course materials and end-of-course assessments must be resubmitted to the FHWA for approval. Instructors of alternate training courses shall meet the qualification requirements for a program manager or team leader as defined in this section.

(3) *Existing FHWA-approved alternate training.* Agencies that have alternate training courses approved by the FHWA prior to [EFFECTIVE DATE OF FINAL RULE] have 24 months to review the prior training materials and certify to the FHWA that the training satisfies the requirements as defined in § 650.305.

§ 650.311 Inspection interval.

(a) *Routine inspections.* Inspect each bridge at regular intervals not to exceed the maximum intervals established using the risk-based processes outlined in paragraph (a)(1) or (2) of this section.

(1) *Method 1.* In the method in this paragraph (a)(1), inspection intervals are determined by a simplified assessment of risk to classify each bridge into one of three risk levels with an inspection interval not to exceed 12, 24, or 48 months.

(i) Inspect each bridge at regular intervals not to exceed 24 months.

(ii) Certain bridges must be inspected at intervals less than 24 months. State transportation departments, Federal agencies, or tribal governments must develop and document criteria used to determine the interval to which these inspections will occur considering such factors as structure type, design characteristics, materials, age, condition, scour characteristics, environment, traffic characteristics, history of vehicle impact damage, loads and safe load capacity, and other known deficiencies. Bridges meeting any of the following criteria must have a maximum inspection interval of 12 months:

(A) The lowest condition rating for the deck, superstructure, substructure, or culvert items as recorded in the National Bridge Inventory (see § 650.315) is coded three (3) or less;

(B) Scour condition rating as recorded in the National Bridge Inventory (see § 650.315) that is coded three (3) or less; or

(C) Details, loading, conditions, or inspection findings that are known to affect the performance of the bridge or its elements within the next 24 months.

(iii) Certain bridges may be inspected at intervals greater than 24 months, not to exceed 48 months. State transportation departments, Federal agencies, or tribal governments must have a documented extended interval policy and notify the FHWA in writing prior to implementation. All FHWA approved extended inspection interval policies prior to the [EFFECTIVE DATE OF FINAL RULE] must be reviewed and updated, if necessary, within 24 months to meet the criteria in this section. Bridges with a maximum inspection interval of more than 24 months must meet all of the following criteria:

(A) Condition ratings for the deck, superstructure, substructure, and culvert items as recorded in the National Bridge Inventory (see § 650.315) are coded seven (7) or greater;

(B) Condition ratings for the channel and channel protection items as recorded in the National Bridge Inventory (see § 650.315) are coded six (6) or greater;

(C) Operating rating factor or legal load rating factor greater than or equal to 1.1 for all vehicles legally allowed to cross the selected bridges, including any routine permit loads;

(D) Steel bridges with existing fatigue cracks which have been arrested, no details with AASHTO fatigue categories E and E', no details with a history of fatigue cracking, or no fracture-prone details in primary members;

(E) Have no history of overheight vehicular damage and have a minimum vertical over or underclearances of 16′-0″ for interstates, freeways, and other arterials or 14′-0″ for local roads and collectors;

(F) Designs limited to a concrete slabs, multi-girders, frames, or culverts or steel multi-girders or frames;

(G) Substructure materials limited to concrete in all environments; steel or timber in dry environments;

(H) Evaluated for scour, is not scour critical, and has a scour condition rating as recorded in the National Bridge Inventory (see § 650.315) that is coded six (6) or greater; and

(I) Details, loading, conditions, and inspection findings that are not expected to affect the performance of the bridge or its elements within the next 48 months.

(2) *Method 2.* In the method in this paragrpah (a)(2), inspection intervals are determined by a more rigorous assessment of risk to classify each bridge, or a group of bridges, into one of four risk levels with an inspection interval not to exceed 12, 24, 48, or 72 months. The risk assessment process, criteria, and resulting intervals must be documented and submitted by the State transportation department, Federal agency, or tribal government with a request for FHWA approval. Changes to the risk assessment process or criteria must be resubmitted for FHWA approval. The request must include paragraphs (a)(2)(i) through (vi) of this section:

(i) Endorsement from a Risk Assessment Panel (RAP), which must be used to develop a formal policy.

(ii) Definitions for risk levels, categories, and the probability and consequence levels that are used to define the risk for each bridge to be assessed.

(iii) Damage modes and attributes that are used in classifying probability and consequence levels, depending on their relevance to the bridge being considered. A system of screening, scoring, and thresholds are defined by the RAP to assess the risks. Scoring is based on prioritizing attributes and their relative influence on damage modes.

(A) A set of screening criteria must be used to determine if a bridge should be considered in the assessment and to establish maximum inspection intervals. The screening criteria must include:

(*1*) Requirements for flexure and shear cracking in concrete primary load members;

(*2*) Requirements for fatigue cracking and corrosion in steel primary load members;

(*3*) Requirements for other details, loadings, conditions, and inspection findings that are known to affect the performance of the bridge or its elements;

(*4*) Bridges classified as in poor condition cannot have an inspection interval greater than 24 months; and

(*5*) Bridges classified as in fair condition cannot have an inspection interval greater than 48 months.

(B) The attributes in each assessment must include material properties, loads and safe load capacity, and condition.

(C) The damage modes in each assessment must include:

(*1*) For steel elements: section loss, fatigue, and fracture;

(*2*) For concrete elements: flexural cracking, shear cracking, and reinforcing steel corrosion;

(*3*) For superstructure elements: seismic, overload, and vehicle/vessel impact; and

(*4*) For substructure elements: seismic, scour, and settlement.

(D) A set of criteria to assess risk for each bridge element in terms of probability and consequence of structural safety or serviceability loss in the time between inspections.

(iv) A set of risk assessment criteria, written in standard logical format amenable for computer programming.

(v) Supplemental inspection procedures and data collection that are aligned with the level of inspection required to obtain the data to apply the criteria.

(vi) A list classifying each bridge into one of four risk levels with a routine inspection interval not to exceed 12, 24, 48, or 72 months.

(3) *Service inspection.* A service inspection must be performed every 24 months when a risk-based, routine inspection interval exceeds 48 months. The results of the service inspection must be documented in the bridge file.

(4) *Additional routine inspection interval eligibility.* Any new, rehabilitated, or structurally modified bridge must receive an initial inspection, be in service for at least 24 months, and receive its next routine inspection before being eligible for inspection intervals greater than 24 months.

(b) *Underwater inspections.* Inspect each bridge at regular intervals not to exceed the maximum intervals established using the risk-based processes outlined in paragraph (b)(1) or (2) of this section.

(1) *Method 1.* In the method in this paragraph (b)(1), inspection intervals are determined by a simplified assessment of risk to classify each bridge into one of three risk levels with an interval not to exceed 36, 60, or 72 months.

(i) Inspect underwater structural elements and the surrounding channel of bridges at regular intervals not to exceed 60 months.

(ii) Certain underwater structural elements and the surrounding channel of bridges must be inspected at intervals less than 60 months. State transportation departments, Federal agencies, or tribal governments must develop and document criteria used to determine the interval to which these inspections will occur considering such factors as structure type, design characteristics, materials, age, condition, scour characteristics, environment, traffic characteristics, history of vehicle/vessel impact damage, loads and safe load capacity, and other known deficiencies. Bridges meeting either of the following criteria must have a maximum underwater inspection interval of 36 months:

(A) The lowest rating for the substructure, culvert, channel, and channel condition ratings items as recorded in the National Bridge Inventory (see § 650.315) is coded three (3) or less; or

(B) Scour condition rating as recorded in the National Bridge Inventory (see § 650.315) that is coded three (3) or less.

(iii) Certain underwater structural elements and the surrounding channel of bridges may be inspected at intervals greater than 60 months, not to exceed 72 months. States, Federal agencies, or tribal governments must have a documented underwater extended interval policy and must notify the FHWA in writing prior to implementation. Bridges with a maximum underwater inspection interval of more than 60 months must meet all of the following criteria:

(A) Benign freshwater environments;

(B) Condition rating values for the substructure, culvert, channel, and channel protection items as recorded in the National Bridge Inventory (see § 650.315) that are coded six (6) or greater;

(C) The bridge has been evaluated for scour, is not scour critical, and has a scour condition rating as recorded in the National Bridge Inventory (see § 650.315) that is coded six (6) or greater; and

(D) Details, loading, conditions, and inspection findings that are not expected to affect the performance of the bridge or its elements within the next 72 months.

(2) *Method 2.* In the method in this paragraph (b)(2), inspection intervals are determined by a more rigorous assessment of risk. The risk assessment process, criteria, and resulting intervals must be documented and submitted by the State transportation department, Federal agency, or tribal government with a request for FHWA approval. The process and criteria must be similar to that outlined in paragraph (a)(2) of this setion except that each bridge must be classified into one of three risk levels with an underwater inspection interval not to exceed 36, 60, and 72 months.

(c) *Nonredundant steel tension member inspections.* Inspect each member at regular intervals not to exceed the maximum intervals established using the risk-based processes outlined in paragraph (c)(1) or (2) of this section.

(1) *Method 1.* In the method in this paragraph (c)(1), inspection intervals are determined by a simplified assessment of risk to classify each bridge into one of three risk levels with an interval not to exceed 12, 24, or 48 months.

(i) Inspect nonredundant steel tension members at intervals not to exceed 24 months.

(ii) Certain nonredundant steel tension members must be inspected at intervals less than 24 months. State transportation departments, Federal agencies, or tribal governments must develop and document criteria used to determine the interval to which these inspections will occur considering such factors as structure type, design characteristics, materials, age, condition, scour characteristics, environment, traffic characteristics, history of vehicle impact damage, loads and safe load capacity, and other known deficiencies. Nonredundant steel tension members meeting any of the following criteria must have a maximum inspection interval of 12 months:

(A) Primary member with fatigue cracks which have not been arrested;

(B) Primary member with significant corrosion; or

(C) Primary member with details, loading, conditions, or inspection findings that are known to affect the expected fatigue performance.

(iii) Certain nonredundant steel tension members of bridges may be inspected at intervals greater than 24 months, not to exceed 48 months. State transportation departments, Federal agencies, or tribal governments must have a documented extended interval policy, and notify the FHWA in writing prior to implementation. Bridges with a maximum nonredundant steel tension member inspection interval of more than 24 months must meet all of the following criteria:

(A) Bridge was constructed after 1978 in accordance with a fracture control plan;

(B) Member has no fatigue details with finite life;

(C) Member has no history of fatigue cracks; and

(D) Member has details, loading, conditions, and inspection findings that are not expected to affect the fatigue performance within the next 48 months.

(2) *Method 2.* In the method in this paragraph (c)(2), inspection intervals are determined by a more rigorous assessment of risk. The risk assessment process, criteria, and resulting intervals must be documented and submitted by the State transportation department, Federal agency, or tribal government with a request for FHWA approval. The process and criteria must be similar to that outlined in paragraph (a)(2) of this section except that each bridge must be classified into one of three risk levels with a nonredundant steel tension member inspection interval not to exceed 12, 24, or 48 months.

(d) *Damage, in-depth, and special inspections.* State transportation department, Federal agency, or tribal government must document the criteria to determine the level and interval for these inspections in its bridge inspection policies and procedures.

(e) *Bridge inspection interval tolerance.* (1) The acceptable tolerance

for the next inspection is up to three months after the inspection due date.

(2) Exceptions to the inspection interval tolerance due to rare and unusual circumstances must be approved by FHWA in advance of the inspection due date.

(f) *Next inspection.* Review intervals for every inspection type after each inspection to ensure the proper interval is assigned. Establish the next inspection due date for each inspection type based on the established interval and the last inspection date.

§ 650.313 Inspection procedures.

(a) *General.* Inspect each bridge to determine condition, identify deficiencies, and document results in an inspection report in accordance with the inspection procedures in Section 4, AASHTO Manual (incorporated by reference, *see* § 650.317). Any portion of the bridge not visible using standard access methods must be assessed via another method. Appropriate equipment to complete the inspection must be documented in the inspection plan. The equipment may include advanced technologies listed in the Bridge Inspector's Reference Manual to access and determine the condition of the bridge.

(b) *Initial inspection.* (1) Perform an initial inspection for each new, replaced, and rehabilitated bridge after all construction is completed and prior to the entire bridge being open to traffic. Submit NBI data after the initial inspection of the entire bridge being open to traffic.

(2) Develop and implement inspection procedures for bridges in phased construction and temporary bridges open to traffic. The portion of the bridge under phased construction must be inspected prior to it being open to traffic.

(c) *Routine inspection.* (1) Each routine inspection must include observations of all areas and elements of the bridge including viewable access from the deck, ground surfaces, water surfaces by boat, and by wading or probing underwater elements. Any portion of the bridge not visible using the standard access methods in the preceding sentence must be accessed or viewed by other methods to determine the condition of the bridge for all areas and elements.

(2) Develop and implement routine inspection procedures for bridges in phased construction and temporary bridges open to traffic. The routine interval for inspections for the portions of a bridge open to traffic shall not be greater than the intervals established in § 650.311. Submit NBI data for temporary bridges which are to remain open for more than 24 months.

(d) *In-depth inspection.* Identify the location of bridge members that need an in-depth inspection in the bridge files. Perform in-depth inspections in accordance with the procedures developed in paragraph (g) of this section.

(e) *Underwater inspection.* Identify the locations of underwater elements in the bridge files that cannot be inspected using wading and probing during a routine inspection. Perform underwater inspections in accordance with the procedures developed in paragraph (g) of this section. Perform the first underwater inspection for each new, replaced, and rehabilitated bridge after all construction is completed and within 6 months of the entire bridge being open to traffic.

(f) *Nonredundant steel tension member inspection.* Identify the location of the NSTMs in the bridge files. Perform hands-on inspections of NSTMs in accordance with the procedures developed in paragraph (g) of this section. Perform the first NSTM inspection for each new, replaced, and rehabilitated bridge after all construction is completed and within 6 months of the entire bridge being open to traffic.

(g) *NSTM, underwater, in-depth, and complex feature inspection procedures.* Develop and document inspection procedures for bridges which require NSTM, underwater, in-depth, and complex feature inspections in accordance with Section 4.2, AASHTO Manual (incorporated by reference, see § 650.317). Exceptions to traditional inspection methods must be approved by FHWA. State transportation departments, Federal agencies, and tribal governments can include general procedures applicable to many bridges in their procedures manual. Specific procedures for unique and complex structural elements must be developed for each bridge and contained in the bridge file.

(h) *Team leader.* Provide at least one team leader, who meets the minimum qualifications stated in § 650.309, at the bridge and actively participating in the inspection at all times during each initial, routine, in-depth, NSTM, and underwater inspection.

(i) *Load rating.* (1) Rate each bridge as to its safe load capacity in accordance with Section 6, AASHTO Manual (incorporated by reference, *see* § 650.317).

(2) Develop and document procedures for completion of new and updated bridge load ratings. Load ratings must be completed as soon as practical, but no later than 3 months after the initial inspection and when a change is identified that warrants a re-rating, such as, but not limited to, changes in condition, reconstruction, new construction, or changes in dead or live loads.

(3) Analyze routine and special permit loads for each bridge that these loads cross to verify the bridge can safely carry the load.

(j) *Load posting.* (1) Implement load posting for a bridge in accordance with Section 6, AASHTO Manual (incorporated by reference, see § 650.317), when the maximum unrestricted legal loads or State routine permit loads exceed that allowed under the operating rating, legal load rating, or permit load analysis.

(2) Develop and document procedures for timely load posting based upon the load capacity and characteristics such as average daily traffic (ADT), average daily truck traffic (ADTT), and loading conditions. Posting shall be made as soon as possible but not later than 30 days after a valid load rating determines a need for such posting. Implement load posting in accordance with these procedures.

(k) *Closed bridges.* Develop and document criteria for closing a bridge which considers condition and load carrying capacity for each legal vehicle. Bridges that meet the criteria must be closed immediately. Bridges must be closed when the gross live load capacity is less than 3 tons.

(l) *Bridge files.* Prepare and maintain bridge files in accordance with Section 2.1, AASHTO Manual (incorporated by reference, *see* § 650.317).

(m) *Scour.* (1) Perform a scour appraisal for all bridges over water. The appraisal shall be based upon the least stable of either the evaluation process or observed scour condition.

(2) For bridges which are determined to be scour critical or have unknown foundations, prepare a plan of action for deployment of scour countermeasures for known and potential deficiencies and to address safety concerns. The plan of action must address a schedule for repairing or installing physical and/or hydraulic scour countermeasures, and/or the use of monitoring countermeasures that includes, inspecting, closing, and opening of each applicable bridge to traffic prior to, during and after flood events to protect the traveling public.

(3) Execute action in accordance with the plan.

(n) *Quality control and quality assurance.* (1) Assure systematic quality control (QC) and quality assurance (QA) procedures identified in Section 1.4,

AASHTO Manual (incorporated by reference, see § 650.317) are used to maintain a high degree of accuracy and consistency in the inspection program.

(2) Document the extent, interval, and responsible party for the review of inspection teams in the field, inspection reports, NBI data, and computations, including scour appraisal and load ratings. QA reviews should not be performed by the personnel who completed the original work.

(3) Perform QC/QA reviews and document the results of the QC/QA process, including the tracking and completion of actions identified in the procedures.

(4) Address the findings of the QC/QA reviews.

(o) *Critical findings.* (1) Document procedures to address critical findings in a timely manner. Procedures must:

(i) Define critical findings considering the magnitude, location and consequence of a deficiency. Deficiencies include, but are not limited to scour, impact, corrosion, section loss, settlement, cracking, deflection, distortion, delamination, loss of bearing, and invalid or missing load posting signs. At a minimum, include findings which result in the following:

(A) Full or partial closure of any bridge;

(B) A program manager recommendation for full or partial closure of any bridge;

(C) A nonredundant member with any quantity in condition state 4, as defined in the AASHTO MBEI (incorporated by reference, *see* § 650.317);

(D) Superstructure or substructure condition rating of serious (3) or worse;

(E) Immediate load restriction or posting, or immediate repair work to a bridge, including shoring, in order to remain open; and

(F) Missing required load posting signage.

(ii) Develop and document timeframes to address critical findings identified in paragraph (o)(1)(i) of this section.

(2) Periodically, or as requested, provide written reports to FHWA for all critical findings and actions taken to resolve or monitor critical findings. Notification and reporting procedures are as follows:

(i) State transportation departments, Federal agencies, and tribal governments must report, or cause to be reported, to the FHWA within 24 hours of discovery of any critical finding that involves:

(A) Full or partial closure of any bridge;

(B) Program manager recommends full or partial closure of any bridge; or

(C) A National Highway System (NHS) bridge with a nonredundant member with any quantity in condition state 4, as defined in the AASHTO MBEI.

(ii) The initial report must include the owner, NBI structure number, date of discovery of the critical finding, and a description.

(iii) State transportation departments, Federal agencies, and tribal governments must submit a monthly status report to FHWA for all critical finding as identified in paragraph (o)(1)(i) of this section. The report must contain:

(A) Owner;

(B) National Bridge Inventory Structure Number;

(C) Date of finding;

(D) Description and photos (if available) of critical finding;

(E) Description of completed, temporary and/or planned corrective actions to address critical finding;

(F) Status of corrective actions: Active/Completed;

(G) Estimated date of completion if corrective actions are active; and

(H) Date of completion if corrective actions are completed.

(iv) All critical findings must remain on the monthly report until permanently resolved.

(p) *Review of compliance.* Provide information annually or as required in cooperation with any FHWA review of compliance with the NBIS.

§ 650.315 Inventory.

(a) Each State transportation department, Federal agency, or tribal government must prepare and maintain an inventory of all bridges subject to the NBIS. Inventory data must be collected, updated, and retained by the responsible State transportation department, Federal agency, or tribal government and submitted to FHWA on an annual basis or whenever requested. Specifications for collecting and reporting this data are contained in the ''Specifications for the National Bridge Inventory'' (incorporated by reference in § 650.317) together with subsequent interim changes or the most recent version. Inventory data must include element level bridge inspection data for bridges on the NHS.

(b) For all inspection types, enter changes to the inventory data into the State transportation department, Federal agency, or tribal government inventory within three months of when the field portion of the inspection is completed.

(c) For modifications to existing bridges that alter previously recorded inventory data and for newly constructed bridges, enter the inventory data into the State transportation department, Federal agency, or tribal government inventory within three months after opening to traffic.

(d) For changes in load restriction or closure status, enter the revised inventory data into the State transportation department, Federal agency, or tribal government inventory within three months after the change in load restriction or closure status of the bridge is implemented.

(e) Each State transportation department, Federal agency, or tribal government must establish and document a process that ensures the time constraint requirements of paragraphs (b) through (d) of this section are fulfilled.

§ 650.317 Reference manuals.

Certain material is incorporated by reference (IBR) into this subpart with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at the Department of Transportation Library, 1200 New Jersey Avenue SE, Washington, DC 20590 in Room W12–300 and may be obtained from the sources listed in paragrahs (a) and (b) of this section. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of these documents at NARA email *fedreg.legal@nara.gov* or go to */www.archives.gov/federal-register/cfr/ibr-locations.html.*

(a) American Association of State Highway and Transportation Officials (AASHTO), Suite 249, 444 N Capitol Street NW, Washington, DC 20001. Tel: 1–800–231–3475, *https://bookstore.transportation.org.*

(1) AASHTO Manual: ''Manual for Bridge Evaluation,'' Second Edition, 2011, IBR approved for §§ 650.305 and 650.313. The Manual includes the following interim revisions:

(i) 2011 Interim Revisions.

(ii) 2013 Interim Revisions.

(iii) 2014 Interim Revisions.

(iv) 2015 Interim Revisions.

(v) 2016 Interim Revisions.

(2) AASHTO MBEI: ''Manual for Bridge Element Inspection,'' First Edition, 2014, including 2015 Interim Revisions, IBR approved for § 650.313.

(b) The following documents are available from the Federal Highway Administration, 1200 New Jersey Avenue SE, Washington, DC 20590, tel: 202–366–4000, *http://www.fhwa.dot.gov/bridge/nbi.cfm.*

(1) ''Specifications for the National Bridge Inventory,'' FHWA, 2019 IBR approved for §§ 650.305 and 650.315.

(2) [Reserved]

Subpart D—[Removed and Reserved]

■ 3. Remove and reserve subpart D.

Subpart G—[Removed and Reserved]

■ 4. Remove and reserve Subpart G.

[FR Doc. 2019–23929 Filed 11–8–19; 8:45 am]

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