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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2018–0201; Special Conditions No. 25–717A–SC]

Special Conditions: Bombardier Inc., Model BD–700–2A12 and BD–700–2A13 Series Airplanes, Flight Envelope Protection: Pitch and Roll Limiting

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Amended final special conditions; request for comments.

SUMMARY: These amended special conditions are issued for the Bombardier Inc. (Bombardier), Model BD–700–2A12 and BD–700–2A13 series airplanes. These amended special conditions change paragraphs 2 and 3 of the special conditions section based on information from Bombardier that makes changes to the novel or unusual design feature of this airplane. This airplane will have a novel or unusual design feature when compared to the state of technology envisioned in the applicable airworthiness standards for transport category airplanes. This design feature is the fly-by-wire electronic flight-control system (EFCS) that will limit pitch and roll functions to prevent the airplane from attaining certain pitch attitudes and roll angles. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: This action is effective on Bombardier Inc. on July 31, 2018. Send comments on or before September 14, 2018.

ADDRESSES: Send comments identified by docket number FAA–2018–0201 using any of the following methods:

☐ *Federal eRegulations Portal:* Go to *http://www.regulations.gov/* and follow the online instructions for sending your comments electronically.

☐ *Mail:* Send comments to Docket Operations, M–30, U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.

☐ *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

☐ *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: The FAA will post all comments it receives, without change, to *http://www.regulations.gov/,* including any personal information the commenter provides. Using the search function of the docket website, anyone can find and read the electronic form of all comments received into any FAA docket, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). DOT's complete Privacy Act Statement can be found in the **Federal Register** published on April 11, 2000 (65 FR 19477–19478).

Docket: Background documents or comments received may be read at *http://www.regulations.gov/* at any time. Follow the online instructions for accessing the docket or go to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Joe Jacobsen, FAA, Airplane and Flight Crew Interface Section, AIR–671, Transport Standards Branch, Policy and Innovation Division, Aircraft Certification Service, 2200 South 216th Street, Des Moines, Washington 98198; telephone 206–231–3158; email *Joe.Jacobsen@faa.gov.*

SUPPLEMENTARY INFORMATION: The FAA has determined that notice of, and opportunity for prior public comment on, these amended special conditions is impracticable because these procedures would significantly delay issuance of the design approval and thus delivery of the affected airplane. Additionally, the substance of these special conditions has been published in the **Federal Register** for public comment in several prior instances with no substantive comments received. Therefore, the FAA has determined that prior public notice and comment are impracticable and unnecessary, and finds that, for the same reasons, good cause exists for adopting these special conditions upon publication in the **Federal Register**.

Comments Invited

We invite interested people to take part in this rulemaking by sending written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data.

We will consider all comments we receive by the closing date for comments. We may change these special conditions based on the comments we receive.

Background

On May 30, 2012, Bombardier applied for an amendment to Type Certificate No. T00003NY to include the new Models BD–700–2A12 and BD–700–2A13 series airplanes. The BD–700–2A12 and BD–700–2A13 series airplanes, are derivatives of the BD–700 currently approved under Type Certificate No. T00003NY, and are business jets with a maximum certified passenger capacity of 19. The maximum takeoff weight of Model BD–700–2A12 airplane is 106,250 lbs. and 104,800 lbs. for the Model BD–700–2A13 airplane.

Type Certification Basis

Under the provisions of title 14, Code of Federal Regulations (14 CFR) 21.101, Bombardier must show that the Model BD–700–2A12 and BD–700–2A13 series airplanes meet the applicable provisions of the regulations listed in Type Certificate No. T00003NY or the applicable regulations in effect on the date of application for the change except for earlier amendments as agreed upon by the FAA.

If the Administrator finds that the applicable airworthiness regulations (*i.e.,* 14 CFR part 25) do not contain adequate or appropriate safety standards for the Model BD–700–2A12 and BD–700–2A13 series airplanes because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same novel or unusual design feature, or should any other model already included on the same type certificate be modified to incorporate the same novel or unusual design feature, these special conditions would also apply to the other model under § 21.101.

In addition to the applicable airworthiness regulations and special conditions, the Bombardier Model BD–700–2A12 and BD–700–2A13 series airplanes must comply with the fuel-vent and exhaust-emission requirements of 14 CFR part 34, and the noise-certification requirements of 14 CFR part 36.

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with § 11.38, and they become part of the type certification basis under § 21.101.

Novel or Unusual Design Features

The Model BD–700–2A12 and BD–700–2A13 series airplanes will incorporate the following novel or unusual design features:

Fly-by-wire EFCS that will limit pitch and roll functions to prevent the airplane from attaining certain pitch attitudes and roll angles greater than plus or minus 65 degrees, and introduce positive spiral stability introduced for roll angles greater than 30 degrees at speeds below V_{MO}/M_{MO}. This system generates the actual surface commands that provide for stability augmentation and flight control for all three airplane axes (longitudinal, lateral, and directional).

Discussion

Part 25 of title 14 of the CFR does not specifically relate to flight characteristics associated with fixed attitude limits. Bombardier proposes to implement on the airplanes pitch and roll attitude-limiting functions via the EFCS normal mode. This will prevent the airplane from attaining certain pitch attitudes and roll angles greater than plus or minus 65 degrees. In addition, positive spiral stability, introduced for roll angles greater than 30 degrees at speeds below V_{MO}/M_{MO}, and spiral stability characteristics, must not require excessive pilot strength to achieve bank angles up to the bank-angle limit.

Bombardier requested this amendment, in order to be performance-based rather than prescriptive and to more closely follow the language developed in the Aviation Rulemaking Advisory Committee (ARAC) Flight Test Harmonization Working Group (FTHWG). The FAA concurs with this request.

The basic envelope protection requirement, historically applied, is to not unduly limit the maneuver capability of the airplane, or interfere with its ability to perform maneuvers required for normal and emergency operations. Since the design details used to meet this requirement vary from airplane to airplane, this amendment recognizes and adopts that philosophy for this specific design implementation. The substance of the special conditions is unchanged, in that, for this specific design, the design details support the objective of not unduly limiting the maneuver capability, while also protecting the airplane from adverse attitudes.

These special conditions are in addition to the requirements of § 25.143. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

Applicability

As discussed above, these special conditions are applicable to the Model BD–700–2A12 and BD–700–2A13 series airplanes. Should Bombardier apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, these special conditions would apply to that model as well.

Conclusion

This action affects only certain novel or unusual design features on one model series of airplanes. It is not a rule of general applicability.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

Authority Citation

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40113, 44701, 44702, 44704.

The Special Conditions

■ Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for Bombardier Model BD–700–2A12 and BD–700–2A13 series airplanes:

In addition to § 25.143, the following requirements apply to the electronic flight-control system (EFCS) pitch- and roll-limiting functions:

1. The pitch-limiting function must not impede normal maneuvering for pitch angles up to the maximum required for normal maneuvering, including a normal, all-engines-operating takeoff, plus a suitable margin to allow for satisfactory speed control.

2. The pitch- and roll-limiting functions must not restrict or prevent attaining pitch attitudes necessary for emergency maneuvering, or roll angles up to 65 degrees. Spiral stability, which is introduced above 30 degrees of roll angle, must not require excessive pilot strength to achieve these roll angles. Other protections, which further limit the roll capability under certain extreme angle-of-attack, attitude, or high-speed conditions, are acceptable, as long as the airplane is able to perform coordinated turns as per § 25.143(h). A roll attitude limit of approximately 45 degrees at high angle-of-attack conditions is acceptable.

3. A reduced roll attitude limit is acceptable at extreme nose down pitch attitudes and beyond the overspeed warning to provide protection against high-speed combined pitch and roll upsets. The airplane should be able to perform operational turns at these speeds. A roll attitude limit of approximately 30 degrees at V_{df}/M_{df} is considered acceptable.

Issued in Des Moines, Washington.

Victor Wicklund,

Manager, Transport Standards Branch, Policy and Innovation Division, Aircraft Certification Service.

[FR Doc. 2018–16360 Filed 7–30–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0630; Product Identifier 2018–NE–25–AD; Amendment 39–19347; AD 2018–16–07]

RIN 2120–AA64

Airworthiness Directives; General Electric Company Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain General Electric Company (GE) GEnx–1B54, –1B58, –1B64, –1B67, –1B70, –1B54/P1, –1B58/P1, –1B64/P1, –1B67/

P1, –1B70/P1, –1B54/P2, –1B58/P2, –1B64/P2, –1B67/P2, –1B70/P2, –1B70C/P1, –1B70/72/P1, –1B70/75/P1, –1B74/75/P1, –1B75/P1, –1B70C/P2, –1B70/72/P2, –1B70/75/P2, –1B74/75/P2, –1B75/P2, –1B76/P2, –1B76A/P2, –1B78/P2, –2B67, –2B67B, and –2B67/P turbofan engines. This AD requires removal of affected high-pressure turbine (HPT) stator cases (HPT cases) from service and their replacement with a part eligible for installation. This AD was prompted by the discovery of a quality escape at a manufacturing facility. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective August 15, 2018.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of August 15, 2018.

We must receive comments on this AD by September 14, 2018.

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

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

For service information identified in this final rule, contact General Electric Company, GE Aviation, Room 285, 1 Neumann Way, Cincinnati, OH 45215; phone: 513–552–3272; email: *aviation.fleetsupport@ge.com.* You may view this service information at the FAA, Engine and Propeller Standards Branch, 1200 District Avenue, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7759. It is also available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0630.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0630; 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 street address for the Docket Operations (phone: 800–647–5527) is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Herman Mak, Aerospace Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7147; fax: 781–238–7199; email: *herman.mak@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We learned from GE of a quality escape at one of their suppliers. This supplier was performing welds on newly-manufactured components to correct errors introduced in their manufacturing process. These welds were not reviewed or approved by either GE or the FAA. GE's review of manufacturing records determined that these parts include HPT cases installed on GEnx engines. These HPT cases are life limited. The unapproved repairs reduced the material capability of these cases which requires their removal prior to reaching their published Airworthiness Limitation Section life limit. This condition, if not addressed, could result in failure of the HPT case, engine fire, and damage to the airplane. We are issuing this AD to address the unsafe condition on these products.

Related Service Information Under 1 CFR Part 51

We reviewed GE Service Bulletin (SB) GEnx–1B S/B 72–0424, Revision 03, dated June 29, 2018 and GEnx–2B S/B 72–0360, Revision 03, dated June 29, 2018. The SBs describe procedures for removing the affected HPT cases from the engine. GE SB GEnx–1B S/B 72–0424 is effective for GEnx–1B engines with the serial numbers of HPT cases listed in that SB. GE SB GEnx–2B S/B 72–0360 is effective for GEnx-2B engines with the serial numbers of HPT cases listed in that SB. 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.

Other Related Service Information

We reviewed Inspection 001, Subtask 72–52–01–230–001 of GEnx–1B Cleaning, Inspection, and Repair Manual GEK112862, Rev 27, dated April 30, 2018, and GEnx–2B Cleaning, Inspection, and Repair Manual GEK114120, Rev 20, dated April 30, 2018. These manuals provide guidance for conducting Class A fluorescent penetrant inspections.

FAA's Determination

We are issuing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

AD Requirements

This AD requires removal of the affected HPT cases from service and their replacement with a part eligible for installation.

FAA's Justification and Determination of the Effective Date

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption. The FAA has found that the risk to the flying public justifies waiving notice and comment prior to adoption of this rule because the compliance time for the required action is shorter than the time necessary for the public to comment and for us to publish the final rule. Therefore, we find good cause that notice and opportunity for prior public comment are impracticable. In addition, for the reason stated above, we find that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

This AD is a final rule that involves requirements affecting flight safety and was not preceded by notice and an opportunity for public comment. However, we invite you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under the **ADDRESSES** section. Include the docket number FAA–2018–0630 and Product Identifier 2018–NE–25–AD at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this final rule. We will consider all comments received by the closing date and may amend this final rule because of those comments.

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

Costs of Compliance

We estimate that this AD affects 13 engines installed on airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Replacement of HPT case	0 work-hours × $85 per hour = $0	$362,400	$362,400	$4,711,200

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.

We are 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 engines, propellers, and associated appliances to the Manager, Engine and Propeller Standards Branch, Policy and Innovation 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) Is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

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

(4) 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):

2018–16–07 General Electric Company: Amendment 39–19347; Docket No. FAA–2018–0630; Product Identifier 2018–NE–25–AD.

(a) Effective Date

This AD is effective August 15, 2018.

(b) Affected ADs

None.

(c) Applicability

This AD applies to General Electric Company (GE) GEnx–1B54, –1B58, –1B64, –1B67, –1B70, –1B54/P1, –1B58/P1, –1B64/P1, –1B67/P1, –1B70/P1, –1B54/P2, –1B58/P2, –1B64/P2, –1B67/P2, –1B70/P2, –1B70C/P1, –1B70/72/P1, –1B70/75/P1, –1B74/75/P1, –1B75/P1, –1B70C/P2, –1B70/72/P2, –1B70/75/P2, –1B74/75/P2, –1B75/P2, –1B76/P2, –1B76A/P2, –1B78/P2, –2B67, –2B67B, and –2B67/P turbofan engines with a high-pressure turbine (HPT) stator case (HPT case), part number (P/N) 2302M90G04 installed, and with any serial number (S/N) listed in Table 1, 2, or 3, in the Planning Information section of GE Service Bulletin (SB) GEnx–2B S/B 72–0360, Revision 03, dated June 29, 2018, or GEnx–1B S/B 72–0424, Revision 03, dated June 29, 2018, installed.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by the discovery of a quality escape at a manufacturing facility involving unapproved welds on HPT cases. We are issuing this AD to prevent failure of the HPT case. The unsafe condition, if not addressed, could result in engine fire and damage to the airplane.

(f) Compliance

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

(g) Required Actions

(1) For HPT cases listed in Planning Information, Table 1 or 2, of GE SBs GEnx–2B S/B 72–0360, Revision 03, dated June 29, 2018 and GEnx–1B S/B 72–0424, Revision 03, dated June 29, 2018, determine the lesser of the following: Cycles since new (CSN) or cycles since Class A fluorescent penetrant inspection (CSFPI) of the entire HPT case.

(2) Using the determination made in paragraph (g)(1) of this AD, remove from service the HPT case after the effective date of this AD as specified in Table 1 to paragraph (g) of this AD. Replace the removed HPT case with a part eligible for installation.

Table 1 to Paragraph (g) of this AD – Compliance Times

CSN or CSFPI of HPT case	Remove from Service (cycles after the effective date of this AD)
Less than 1000	150 cycles
1000 to 2000	125 cycles
2001 to 3000	100 cycles
3001 to 4000	75 cycles
4001 to 5000	50 cycles
5001 or more	25 cycles

(3) Remove from service HPT cases listed in Planning Information, Table 3, of GE SBs GEnx–2B S/B 72–0360, Revision 03, dated June 29, 2018 or GEnx–1B S/B 72–0424, Revision 03, dated June 29, 2018, prior to exceeding 10 cycles after the effective date of this AD or exceeding the CSN limits listed in Table 3, whichever comes later. Replace the removed HPT case with a part eligible for installation.

(h) Installation Prohibition

(1) After the effective date of this AD, do not install any affected HPT case onto any engine.

(2) After the effective date of this AD, HPT cases listed in Planning Information, Table 3, in GE SB GEnx–2B S/B 72–0360, Revision 03, dated June 29, 2018 or GEnx–1B S/B 72–0424, Revision 03, dated June 29, 2018, and any higher level assemblies with these parts installed, may not be removed from a GEnx–2B engine and installed on a GEnx–1B engine or removed from a GEnx–1B engine and installed on a GEnx–2B engine.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, ECO 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. You may email your request to: *ANE-AD-AMOC@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.

(j) Related Information

For more information about this AD, contact Herman Mak, Aerospace Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7147; fax: 781–238–7199; email: *herman.mak@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) General Electric Company (GE) Service Bulletin (SB) GEnx–2B S/B 72–0360, Revision 03, dated June 29, 2018.

(ii) GE SB GEnx–1B S/B 72–0424, Revision 03, dated June 29, 2018.

(3) For GE service information identified in this AD, contact General Electric Company, GE Aviation, Room 285, 1 Neumann Way, Cincinnati, OH 45215; phone: 513–552–3272; email: *aviation.fleetsupport@ge.com.*

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

(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, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Burlington, Massachusetts, on July 25, 2018.

Karen M. Grant,

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DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 40

[Docket No. RM18–2–000; Order No. 848]

Cyber Security Incident Reporting Reliability Standards

AGENCY: Federal Energy Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Federal Energy Regulatory Commission (Commission) directs the North American Electric Reliability Corporation (NERC) to develop and submit modifications to the NERC Reliability Standards to augment the mandatory reporting of Cyber Security Incidents, including incidents that might facilitate subsequent efforts to harm the reliable operation of the bulk electric system (BES).

DATES: This rule will become effective October 1, 2018.

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SUPPLEMENTARY INFORMATION:

Order No. 848—Final Rule (Issued July 19, 2018)

1. Pursuant to section 215(d)(5) of the Federal Power Act (FPA), the Commission directs the North American Electric Reliability Corporation (NERC) to develop and submit modifications to

the NERC Reliability Standards to augment the mandatory reporting of Cyber Security Incidents, including incidents that might facilitate subsequent efforts to harm the reliable operation of the BES.[1] The Commission directs NERC to develop and submit modifications to the Reliability Standards to require the reporting of Cyber Security Incidents that compromise, or attempt to compromise, a responsible entity's Electronic Security Perimeter (ESP) or associated Electronic Access Control or Monitoring Systems (EACMS).[2]

2. In the NOPR, the Commission observed that Cyber Security Incidents are presently reported by responsible entities in accordance with Reliability Standard CIP–008–5 (Cyber Security—Incident Reporting and Response Planning).[3] However, under the definition of Reportable Cyber Security Incident in Reliability Standard CIP–008–5, responsible entities must only report Cyber Security Incidents if they have ''compromised or disrupted one or more reliability tasks.'' The Commission explained that the current reporting threshold may understate the true scope of cyber-related threats facing the Bulk-Power System, particularly given the lack of any reportable incidents in 2015 and 2016. To improve awareness of existing and future cyber security threats and potential vulnerabilities, the Commission proposed to direct that NERC develop and submit modifications to the existing Reliability Standards to augment the reporting of Cyber Security Incidents, including incidents that might facilitate subsequent efforts to harm the reliable operation of the BES.

3. As discussed in detail below, the Commission adopts the NOPR proposal. The Commission's directive in this Final Rule consists of four elements intended to augment the current Cyber Security Incident reporting requirement: (1) Responsible entities must report Cyber Security Incidents that compromise, or attempt to compromise, a responsible entity's ESP or associated EACMS; (2) required information in Cyber Security Incident reports should include certain minimum information to improve the quality of reporting and allow for ease of comparison by ensuring that each report includes specified fields of information; (3) filing deadlines for Cyber Security Incident reports should be established once a compromise or disruption to reliable BES operation, or an attempted compromise or disruption, is identified by a responsible entity; and (4) Cyber Security Incident reports should continue to be sent to the Electricity Information Sharing and Analysis Center (E–ISAC), rather than the Commission, but the reports should also be sent to the Department of Homeland Security (DHS) Industrial Control Systems Cyber Emergency Response Team (ICS–CERT). Further, NERC must file an annual, public, and anonymized summary of the reports with the Commission.

4. As discussed below, after considering the comments submitted in response to the NOPR, we conclude that the proposed directive to augment the current reporting requirement for Cyber Security Incidents is appropriate to carry out FPA section 215. As NERC recognizes in its NOPR comments, ''[b]roadening the mandatory reporting of Cyber Security Incidents would help enhance awareness of cyber security risks facing entities[,] . . . would create a more extensive baseline understanding of the nature of cyber security threats and vulnerabilities[,] . . . [and] is consistent with recommendations in NERC's 2017 State of Reliability Report.'' [4] Our directive is intended to result in a measured broadening of the existing reporting requirement in Reliability Standard CIP–008–5, consistent with NERC's recommendation, rather than a wholesale change in cyber incident reporting that supplants or otherwise chills voluntary reporting, as some commenters maintain. Indeed, as NERC contends, we believe that the new ''baseline understanding, coupled with the additional context from voluntary reports received by the E–ISAC, [will] allow NERC and the E–ISAC to share that information broadly through the electric industry to better prepare entities to protect their critical infrastructure.'' [5]

5. We address in the discussion below concerns raised by commenters regarding elements of the Commission's directive and the burdens the directive might impose if NERC develops requirements that are overly broad. At the outset, we agree with NERC that ''because certain requirements in the CIP Reliability Standards already require entities to track data on compromises or attempts to compromise the ESP or EACMS, the additional burden to report that data appears reasonable.'' [6] And we do not believe that complying with the augmented reporting requirements that we direct here would be any more burdensome to industry than the alternative, responding to a perpetual data or information request to collect the same information pursuant to Section 1600 of the NERC Rules of Procedure. To ensure that the burden is reasonable with respect to including EACMS in the augmented reporting requirement, NERC should develop requirements based on the function of the EACMS and the nature of the attempted compromise or successful intrusion. Similarly, as discussed below, NERC should develop reporting timelines for Cyber Security Incidents that are commensurate with the adverse or attempted adverse impact to the BES that loss, compromise, or misuse of those BES Cyber Systems could have on the reliable operation of the BES.[7] Prioritizing incident reporting will allow responsible entities to devote resources to reporting the most significant Cyber Security Incidents faster than less significant events. With this guidance, we believe that the standard drafting team, in the first instance, is in the best position to develop the specific elements of the directed Reliability Standard requirements.

6. We have considered comments submitted by NERC and others recommending that broadened Cyber Security Incident reporting should be implemented through a request for information or data pursuant to Section 1600 of the NERC Rules of Procedure instead of through Reliability Standard requirements. However, on balance, we

[1] 16 U.S.C. 824o(d)(5). The NERC Glossary of Terms Used in NERC Reliability Standards (June 12, 2018) (NERC Glossary) defines a Cyber Security Incident as ''A malicious act or suspicious event that: Compromises, or was an attempt to compromise, the Electronic Security Perimeter or Physical Security Perimeter or, Disrupts, or was an attempt to disrupt, the operation of a BES Cyber System.''

[2] The NERC Glossary defines ''ESP'' as ''[t]he logical border surrounding a network to which BES Cyber Systems are connected using a routable protocol.'' The NERC Glossary defines ''EACMS'' as ''Cyber Assets that perform electronic access control or electronic access monitoring of the Electronic Security Perimeter(s) or BES Cyber Systems. This includes Intermediate Systems.''

[3] *Cyber Security Incident Reporting Reliability Standards,* Notice of Proposed Rulemaking, 82 FR 61499 (Dec. 28, 2017), 161 FERC ¶ 61,291, P 1 (2017) (NOPR).

[4] NERC Comments at 4.

[5] *Id.*

[6] *Id.* at 8 (citing Reliability Standard CIP–005–5 (Cyber Security—Electronic Security Perimeter(s)) and Reliability Standard CIP–007–6 (Cyber Security—System Security Management)).

[7] The NERC Glossary defines BES Cyber System as ''[o]ne or more BES Cyber Assets logically grouped by a responsible entity to perform one or more reliability tasks for a functional entity.'' Glossary of Terms Used in NERC Reliability Standards (NERC Glossary). Reliability Standard CIP–002–5.1a (Cyber Security System Categorization) provides a ''tiered'' approach to cybersecurity requirements, based on classifications of high, medium and low impact BES Cyber Systems.

believe that broadened mandatory reporting pursuant to Reliability Standard requirements as opposed to a standing data request is more aligned with the seriousness and magnitude of the current threat environment, and more likely to improve awareness of existing and future cyber security threats and potential vulnerabilities. Four main reasons inform our decision. First, a new or modified Reliability Standard will ensure that the desired goals of our directive are met because the Commission will have the ability to review and ultimately approve the standard, as opposed to the opportunity for informal review that the Commission would have of a data request under ROP Section 1600. Second, the Commission has well-defined authority and processes under section 215(e) of the FPA to audit and enforce compliance with a Reliability Standard. Third, we do not anticipate that there will be a need to change the parameters of the Cyber Security Incident report for EACMS because the parameters that we direct below are based on five static functions of EACMS and are not technology specific, so the potential flexibility provided by a Section 1600 data request may not be significantly beneficial. Finally, collecting data through a Reliability Standard is consistent with existing practices; responsible entities are currently required to maintain the types of information that would lead to a reportable Cyber Security Incident pursuant to Reliability Standard CIP–007–6, Requirement R4.1. Nonetheless, should future events require an expedited change in data collection or should NERC desire to collect data outside the scope of the proposed Reliability Standard, NERC could then use the Section 1600 process to supplement information reported under a mandatory Reliability Standard.

7. Accordingly, pursuant to section 215(d)(5) of the FPA, we adopt the NOPR proposal and direct NERC to develop modifications to the Reliability Standards to include the mandatory reporting of Cyber Security Incidents that compromise, or attempt to compromise, a responsible entity's ESP or associated EACMS, as well as modifications to specify the required information in Cyber Security Incident reports, their dissemination, and deadlines for filing reports. We direct NERC to submit the directed modifications within six-months of the effective date of this Final Rule.

I. Background

A. Section 215 and Mandatory Reliability Standards

8. Section 215 of the FPA requires a Commission-certified Electric Reliability Organization (ERO) to develop mandatory and enforceable Reliability Standards, subject to Commission review and approval. Reliability Standards may be enforced by the ERO, subject to Commission oversight, or by the Commission independently.[8] Pursuant to section 215 of the FPA, the Commission established a process to select and certify an ERO,[9] and subsequently certified NERC.[10]

B. Notice of Proposed Rulemaking

9. On December 21, 2017, the Commission issued a NOPR proposing to direct that NERC develop enhanced Cyber Security Incident reporting requirements. Specifically, pursuant to section 215(d)(5) of the FPA, the NOPR proposed to direct NERC to develop modifications to the Reliability Standards to require the reporting of Cyber Security Incidents that compromise, or attempt to compromise, a responsible entity's ESP or associated EACMS. The proposed directive was based in part on a lack of Reportable Cyber Security Incidents in 2015 and 2016, and NERC's assessment in the 2017 State of Reliability Report that ''[w]hile there were no reportable cyber security incidents during 2016 and therefore none that caused a loss of load, this does not necessarily suggest that the risk of a cyber security incident is low.'' [11] In addition, the NOPR stated that it agreed with the recommendation by NERC in the 2017 State of Reliability Report to ''redefine reportable incidents to be more granular and include zero-consequence incidents that might be precursors to something more serious.'' [12]

10. In justifying the proposed inclusion of ESPs and associated EACMS within the scope of the enhanced Cyber Security Incident requirement, the NOPR stated that the purpose of an ESP is to manage electronic access to BES Cyber Systems to support the protection of the BES Cyber Systems against compromise that could lead to misoperation or instability in the BES.[13] In addition, the NOPR explained that EACMS, which include, for example, firewalls, authentication servers, security event monitoring systems, intrusion detection systems and alerting systems, control electronic access into the ESP and play a significant role in the protection of high and medium impact BES Cyber Systems.[14] The NOPR indicated further that, once an EACMS is compromised, an attacker could more easily enter the ESP and effectively control the BES Cyber System or Protected Cyber Asset.

11. The NOPR discussed the scope of the present Cyber Security Incident reporting requirement. The NOPR observed that Reliability Standard CIP–008–5, Requirement R1.2 currently requires that each responsible entity shall document one or more Cyber Security Incident Plan(s) with one or more processes to determine if an identified Cyber Security Incident is a Reportable Cyber Security Incident. And where a Cyber Security Incident is determined to qualify as a Reportable Cyber Security Incident, the NOPR explained that responsible entities are required to notify the E–ISAC with initial notification within one hour from the determination of a Reportable Cyber Security Incident. The NOPR stated, however, that the NERC Glossary defines a Reportable Cyber Security Incident as ''[a] Cyber Security Incident that has compromised or disrupted one or more reliability tasks of a functional entity.'' The NOPR indicated that the definition of Reportable Cyber Security Incident, insofar as it excludes unsuccessful attempts to compromise or disrupt a responsible entity's core activities, is thus more narrow than the definition of ''cybersecurity incident'' in FPA section 215(a)(8), which encompasses ''a malicious act or suspicious event that disrupts, or was an attempt to disrupt, the operation of those programmable electronic devices and communication networks including hardware, software and data that are essential to the reliable operation of the bulk power system.'' [15]

12. The NOPR stated that altering the Cyber Security Incident reporting

[8] *Id.*

[9] *Rules Concerning Certification of the Electric Reliability Organization; and Procedures for the Establishment, Approval, and Enforcement of Electric Reliability Standards,* Order No. 672, FERC Stats. & Regs. ¶ 31,204, *order on reh'g,* Order No. 672–A, FERC Stats. & Regs. ¶ 31,212 (2006).

[10] *North American Electric Reliability Corp.,* 116 FERC ¶ 61,062, *order on reh'g and compliance,* 117 FERC ¶ 61,126 (2006), *aff'd sub nom. Alcoa, Inc.* v. *FERC,* 564 F.3d 1342 (D.C. Cir. 2009).

[11] NOPR, 161 FERC ¶ 61,291 at P 28 (citing 2017 NERC State of Reliability Report at 4).

[12] *Id.* P 29 (citing 2017 NERC State of Reliability Report at 4).

[13] *See id.* P 33 (citing Reliability Standard CIP–005–5 (Cyber Security—Electronic Security Perimeter(s)).

[14] *See id.* (citing Reliability Standard CIP–002–5.1 (Cyber Security—BES Cyber System Categorization), Background at 6; Reliability Standard CIP–007–6 (Cyber Security—System Security Management), Background at 4).

[15] 16 U.S.C. 824o(a)(8).

threshold to require reporting of attempts to compromise, instead of only successful compromises, is consistent with information already logged by registered entities pursuant to current monitoring requirements in the Reliability Standards. The NOPR explained that Reliability Standard CIP–007–6, Requirement R4.1, mandates logging of detected successful login attempts, detected failed access attempts, and failed login attempts, and the Guidelines and Technical Basis for Requirement R4.1 states that events should be logged even if access attempts were blocked or otherwise unsuccessful.[16]

13. In addition to modifying the reporting threshold, the NOPR proposed to direct NERC to modify the Reliability Standards to specify the required information in Cyber Security Incident reports to improve the quality of reporting and allow for ease of comparison by ensuring that each report includes specified fields of information, as well as the deadlines for submitting a report. Specifically, the NOPR proposed that the minimum set of attributes to be reported should include: (1) The functional impact, where possible, that the Cyber Security Incident achieved or attempted to achieve; (2) the attack vector used to achieve or attempt to achieve the Cyber Security Incident; and (3) the level of intrusion achieved or attempted by the Cyber Security Incident. The NOPR explained that knowledge of these attributes regarding a specific Cyber Security Incident will improve awareness of cyber threats to BES reliability. The NOPR also noted that the proposed attributes are the same as attributes already used by DHS for its multi-sector reporting and summarized by DHS in an annual report.[17]

14. The NOPR also proposed to continue to require that Cyber Security Incident reports be sent to the E–ISAC instead of the Commission, but the NOPR proposed to require that such reports also be sent to ICS–CERT and that NERC file with the Commission an annual, public, and anonymized summary of such reports.

15. Finally, the NOPR sought comment on potential alternatives to modifying the mandatory reporting requirements in the NERC Reliability Standards. Specifically, the NOPR sought comment on whether a request for data or information pursuant to Section 1600 of the NERC Rules of Procedure would effectively address the reporting gap and current lack of awareness of cyber-related incidents among NERC, responsible entities and the Commission, and satisfy the goals of the proposed directive.

II. Discussion

16. Pursuant to section 215(d)(5) of the FPA, we adopt the NOPR proposal and direct NERC to develop and submit modifications to the NERC Reliability Standards to augment current mandatory reporting of Cyber Security Incidents, including incidents that might facilitate subsequent efforts to harm the reliable operation of the BES. We direct NERC, subject to the discussion below, to develop and submit Reliability Standard requirements that: (1) Require responsible entities to report Cyber Security Incidents that compromise, or attempt to compromise, a responsible entity's ESP or associated EACMS; (2) specify the required information in Cyber Security Incident reports; (3) establish deadlines for filing Cyber Security Incident reports that are commensurate with incident severity; and (4) require that Cyber Security Incident reports be sent to ICS–CERT, in addition to E–ISAC, and that NERC file with the Commission an annual, public, and anonymized summary of such reports.

17. Below, we discuss the following matters: (A) The need for broadened mandatory Cyber Security Incident reporting; (B) the threshold for a reportable Cyber Security Incident; (C) the appropriate procedural approach to augment Cyber Security Incident reporting, *i.e.,* new or modified Reliability Standards versus a NERC data request to applicable entities; (D) the content and timing of Cyber Security Incident reports; and (E) other issues.

A. Need for Broadened Mandatory Cyber Security Incident Reporting

1. NOPR

18. In the NOPR, the Commission indicated that cyber-related event reporting is currently addressed in Reliability Standard CIP–008–5, Requirement R1.2, which requires that each responsible entity shall document one or more Cyber Security Incident Plan(s) with one or more processes to determine if an identified Cyber Security Incident is a Reportable Cyber Security Incident. The NOPR noted that a Cyber Security Incident is defined in the NERC Glossary as: ''A malicious act or suspicious event that: (1) compromises, or was an attempt to compromise, the Electronic Security Perimeter or Physical Security Perimeter or (2) disrupts, or was an attempt to disrupt, the operation of a BES Cyber System.''

19. The Commission further explained that where a cyber-related event is determined to qualify as a Reportable Cyber Security Incident, responsible entities are required to notify the E–ISAC with initial notification to be made within one hour from the determination of a Reportable Cyber Security Incident.[18] However, the NOPR observed that a Reportable Cyber Security Incident is defined more narrowly in the NERC Glossary than a Cyber Security Incident because the former requires that the incident result in the compromise or disruption of one or more reliability tasks of a functional entity. As the Commission explained, in order for a cyber-related event to be considered reportable under the existing CIP Reliability Standards, it must compromise or disrupt a core activity (*e.g.,* reliability task) of a responsible entity that is intended to maintain BES reliability.[19] Therefore, under these definitions, unsuccessful attempts to compromise or disrupt a responsible entity's core activities are not subject to the current reporting requirements in Reliability Standard CIP–008–5 or elsewhere in the CIP Reliability Standards.

20. The NOPR explained that recent NERC State of Reliability Reports indicate that there were no Reportable Cyber Security Incidents in 2015 and 2016. The NOPR also highlighted NERC's conclusion that ''[w]hile there were no reportable cyber security incidents during 2016 and therefore none that caused a loss of load, this does not necessarily suggest that the risk of a cyber security incident is low.'' [20] The NOPR contrasted the results reported in the NERC reports with the 2016 annual summary of the Department of Energy's (DOE) Electric

[16] *See* Reliability Standard CIP–007–6 (Cyber Security—Systems Security Management), Requirement R4.1.

[17] NOPR, 161 FERC ¶ 61,291 at P 38 (citing 2016 ICS–CERT Year in Review, *https://ics-cert.us-cert.gov/Year-Review-2016*).

[18] *See* Reliability Standard CIP–008–5 (Cyber Security—Incident Reporting and Response Planning), Requirement R1, Part 1.2. This requirement pertains to high impact BES Cyber Systems and medium impact BES Cyber Systems.

[19] The NERC Functional Model ''describes a set of Functions that are performed to ensure the reliability of the Bulk Electric System. Each Function consists of a set of related reliability Tasks. The Model assigns each Function to a functional entity, that is, the entity that performs the function. The Model also describes the interrelationships between that functional entity and other functional entities (that perform other Functions).'' NERC, Reliability Functional Model: Function Definitions and Functional Entities, Version 5 at 7 (November 2009), *http://www.nerc.com/pa/Stand/Functional%20Model%20Archive%201/Functional_Model_V5_Final_2009Dec1.pdf.*

[20] 2017 NERC State of Reliability Report at 4.

Disturbance Reporting Form OE–417, which contained four cybersecurity incidents reported in 2016; two suspected cyber attacks and two actual cyber attacks.[21] Moreover, the NOPR noted that ICS–CERT responded to fifty-nine cybersecurity incidents within the Energy Sector in 2016.[22]

21. Based on the comparison of information reported by NERC, DOE, and ICS–CERT, the NOPR concluded that the current reporting threshold in Reliability Standard CIP–008–5 may not reflect the true scope and scale of cyber-related threats facing responsible entities. In particular, the NOPR raised a concern that the disparity in the reporting of cyber-related incidents under existing reporting requirements, in particular the lack of any incidents reported to NERC in 2015 and 2016, suggests a gap in the current reporting requirements. The NOPR highlighted the fact that this concern is echoed in the 2017 NERC State of Reliability Report, which includes a recommendation that NERC and industry should ''redefine reportable incidents to be more granular and include zero-consequence incidents that might be precursors to something more serious.'' [23] Agreeing with NERC's recommendation in the 2017 State of Reliability report, the NOPR proposed to direct NERC to address the apparent gap in cyber incident reporting.

2. Comments

22. NERC supports improving the reporting of Cyber Security Incidents, stating that ''[b]roadening the mandatory reporting of Cyber Security Incidents would help enhance awareness of cyber security risks facing entities.'' [24] NERC maintains that enhanced reporting ''would create a more extensive baseline understanding of the nature of cyber security threats and vulnerabilities.'' [25] NERC notes that broadening the scope of Cyber Security Incident reporting ''is consistent with recommendations in NERC's 2017 State of Reliability Report.'' [26] While NERC recognizes the need for enhanced Cyber Security Incident reporting, as discussed in the following sections, NERC does not support all aspects of the NOPR, including requiring enhanced cyber incident reporting through a modified Reliability Standard.

23. BPA, ITC, IRC, NYPSC, and NRG also support the NOPR proposal to direct NERC to address the gap in reporting Cyber Security Incidents. As noted by BPA, the current definition of Reportable Cyber Security Incident only addresses successful attempts to compromise or disrupt operations and, therefore, ''a broader definition of a Reportable Cyber Security incident is warranted'' because ''information about certain attempts to compromise will likely better assist the industry in preventing successful cyber attacks.'' [27] BPA, ITC, and IRC raise concerns, however, regarding the risk of over-reporting. IRC states that the proposed requirement to report all attempts to compromise an ESP or associated EACMS ''needs further clarification.'' [28] BPA states that any new reporting requirement ''must ensure that the information reported is useful and does not result in under and over reporting of information.'' [29] NRG recommends that the term ''attempt'' should be clarified (*i.e.,* as a more serious risk than a port scan) and ''should be provided in technical guidance or glossary definition relating to the context of [the] existing NERC glossary term: Cyber Security Incident.'' [30]

24. EEI/NRECA, Trade Associations, APS, Chamber, EnergySec, Eversource, Idaho Power, and LPPC do not support the NOPR proposal to direct NERC to address the gap in reporting Cyber Security Incidents. EEI/NRECA, Trade Associations, and Chamber suggest that the Commission support existing voluntary reporting practices as opposed to mandating the reporting of Cyber Security Incidents through the CIP Reliability Standards. EEI/NRECA state that ''[s]ignificant resources from responsible entities and government are engaged in [. . .] partnerships'' to share threat and vulnerability information.[31] EEI/NRECA argue that ''[m]andating such sharing will overlap with these voluntary efforts and may harm the partnerships and ability of the programs to enhance cybersecurity for the electric grid.'' [32] In addition, EEI/NRECA state that mandating Cyber Security Incident reporting ''may weaken the ability of electric companies to participate in these [voluntary reporting] programs by shifting their focus to compliance activity.'' [33] Eversource states that the NOPR proposal would ''introduce new technical and administrative challenges that will likely impact responsible entities' ability to participate in existing voluntary threat information sharing programs.'' [34] LPPC states that whatever action the Commission takes on Cyber Security Incident reporting, it ''must be done with an eye towards causing as little disruption to existing information sharing programs as possible.'' [35]

25. Trade Associations state that while improving Cyber Security Incident reporting is an appropriate objective, ''directing new or revised mandatory reliability standards is not the only tool that NERC and the Commission have for achieving that reliability objective.'' [36] Trade Associations contend that, in light of the constantly evolving state of cyber security, ''the Commission should consider and utilize the most flexible tools to achieve its reliability goals without imposing undue burden on registered entities.'' [37]

26. APS states that while it ''supports the Commission's objectives expressed in the NOPR,'' it does not agree that modifying the CIP Reliability Standards is the appropriate solution.[38] APS asserts that ''the reporting requirements that already exist under Form OE–417 meet the same objectives as the Commission is attempting to satisfy by requiring additional reporting under the CIP Standards as proposed in the NOPR.'' [39] APS instead suggests that ''the Commission . . . direct NERC to modify the CIP Standards to include a requirement for Responsible Entities to submit copies of its Form OE–417 to the E–ISAC and ICS–CERT.'' [40]

27. EnergySec states that it is ''generally in agreement with the Commission's goal of increasing the frequency and detail of incident reporting,'' but raises concerns with the specifics of the NOPR proposal.[41] EnergySec maintains that '''compromise' as used in the definition of Reportable Cybersecurity Incident does not necessarily imply harm.'' [42] Therefore, EnergySec argues that ''an incident should be considered a 'compromise' if an attacker has obtained

[21] 2016 DOE Electric Disturbance Events (OE–417) Annual Summary Archives, *https://www.oe.netl.doe.gov/OE417_annual_summary.aspx.*

[22] ICS–CERT cybersecurity incident statistics for the Energy Sector combine statistics from the electric subsector and the oil and natural gas subsector. ICS–CERT does not break out the cybersecurity incidents that only impact the electric subsector. 2016 ICS–CERT Year in Review, *https://ics-cert.us-cert.gov/Year-Review-2016.*

[23] 2017 NERC State of Reliability Report at 4.

[24] NERC Comments at 4.

[25] *Id.* at 4.

[26] *Id.* at 4.

[27] BPA Comments at 3.

[28] IRC Comments at 1.

[29] BPA Comments at 3.

[30] NRG Comments at 3.

[31] EEI/NRECA Comments at 12.

[32] *Id.* at 12.

[33] *Id.* at 14–15.

[34] Eversource Comments at 5.

[35] LPPC Comments at 4.

[36] APPA, *et al.* Comments at 3–4.

[37] *Id.* at 4.

[38] APS Comments at 5.

[39] *Id.* at 7.

[40] *Id.* at 5.

[41] EnergySec Comments at 2.

[42] *Id.* at 2.

the ability to disrupt, even if no disruption occurs.'' [43] EnergySec states further that it believes ''that a clarified understanding of the current definition of Reportable Cybersecurity Incident can sufficiently address the Commission's concerns'' since it ''can be construed to include certain non-impactful incidents, as well as incidents affecting [ESPs] and [EACMS].'' [44]

28. EnergySec also raises a concern that the NOPR proposal is too broad. EnergySec argues that determining incidents that might facilitate future cyber incidents ''would be highly subjective and could easily be construed to include systems and networks that are outside the scope of the Commission's authority.'' [45] EnergySec notes that most failed login or access attempts are benign in nature and ''the volume of such events is orders of magnitude larger than what would be an appropriate volume for mandatory reporting.'' [46] EnergySec states further that while it agrees that successful attacks against ESPs and EACMS should be reported, it does not support including attempted compromise in the reporting requirements since the ''[d]etermination of attempted compromise is highly subjective and it would therefore be difficult at best to clearly define within the standards a basis for such determinations.'' [47]

29. Eversource and Idaho Power do not support the NOPR proposal due to the anticipated increased burden that could result from increased mandatory reporting. Eversource states that ''expanding the amount of required information to be reported and increasing the number of recipients of the reports will create undue administrative burdens.'' [48] In addition, Eversource contends that ''the meaning of an attempted compromise is currently undefined and may impose significant burdens on responsible entities to identify such attempts.'' [49] Idaho Power states that even though ''additional reporting can provide some visibility into the types of threats that entities face, additional administrative burdens such as reporting requirements reduce the finite resources that entities have to monitor and defend their critical infrastructure.'' [50]

30. LPPC asserts that the NOPR proposal ''may yield a substantial quantity of unhelpful information and confusing analysis, while needlessly burdening Registered Entities.'' [51] LPPC states that it supports NERC's request for flexibility in addressing enhanced Cyber Security Incident reporting and concludes that ''a technical conference may productively explore the nature and scope of the various programs that currently exist for information sharing regarding threats and the incremental value of any new requirements.'' [52] Resilient Societies states that ''the modifications proposed to improve the reporting of cybersecurity incidents are unlikely to have any significant positive effect.'' [53] Specifically, Resilient Societies states that the proposed reporting parameters are not broad enough because ''reporting of malware infection is not necessarily within thresholds set on other criteria, such as 'compromise,' 'breach,' 'impact,' or 'disruption.' '' [54] Resilient Societies also suggests that the Commission convene a public technical conference.

3. Commission Determination

31. We adopt the NOPR proposal and, pursuant to section 215(d)(5) of the FPA, direct NERC to develop and submit modifications to the Reliability Standards to augment the mandatory reporting of Cyber Security Incidents, including incidents that might facilitate subsequent efforts to harm the reliable operation of the BES. Comments submitted by NERC and others support our determination that enhanced reporting of Cyber Security Incidents will address an existing gap in Cyber Security Incident reporting and will provide useful information on existing and future cyber security risks, as well as provide entities with better visibility into malicious activity prior to an event occurring. As noted in NERC's comments, ''[b]roadening the mandatory reporting of Cyber Security Incidents would help enhance awareness of cyber security risks facing entities.'' [55] Similarly, BPA agrees with the directive to include attempted compromises in an enhanced reporting regime, stating that ''information about certain attempts to compromise will likely better assist the industry in preventing successful cyber attacks.'' [56] Moreover, while the record reflects differing views on whether broadened Cyber Security Incident reporting should be mandatory or voluntary, there is general agreement that improved reporting is an appropriate objective.[57]

32. Some commenters contend that the directive to require mandatory reporting of Cyber Security Incidents that compromise, or attempt to compromise, a responsible entity's ESP or associated EACMS is vague and requires clarification. Recognizing this concern, NERC states that ''[t]he challenge is to scope any additional mandatory reporting requirements in a manner that collects meaningful data about security risks without creating an unduly burdensome reporting requirement.'' [58] While we address the threshold for a broadened reporting requirement issue in the next section, as a general matter, we agree with NERC that the scope of any new reporting requirement should be tailored to provide better information on cyber security threats and vulnerabilities without imposing an undue burden on responsible entities. Indeed, the NOPR proposal was not intended to be prescriptive or overly broad, but rather support NERC's efforts to enhance the reporting of Cyber Security Incidents as outlined in NERC's 2017 State of Reliability Report through the standards development process.

33. Some commenters assert that a broadened reporting requirement will overlap, duplicate or otherwise chill voluntary reporting programs, potentially diverting resources away from such programs. Other commenters, however, assert that voluntary reporting does not adequately address the gap identified in the NOPR because voluntary reporting and mandatory reporting under currently-effective Reliability Standard CIP–008–5 have not resulted in adequate reporting of cybersecurity threats to the BES.[59] As Appelbaum notes, ''[w]ithout mandatory reporting scheme a degraded threat image will result.'' [60]

34. Based on the record, we are not persuaded that our directive to augment current mandatory reporting requirements will adversely impact existing voluntary information sharing efforts. Instead, we agree with NERC's comment that the new ''baseline understanding [resulting from broadened mandatory reporting], coupled with the additional context from voluntary reports received by the E–ISAC, [will] allow NERC and the E–

[43] *Id.* at 2.

[44] *Id.* at 3.

[45] *Id.* at 3.

[46] *Id.* at 3.

[47] *Id.* at 3–4.

[48] Eversource Comments at 1.

[49] *Id.* at 6.

[50] Idaho Power Comments at 2.

[51] LPPC Comments at 1.

[52] *Id.* at 5–6.

[53] Resilient Societies Comments at 12.

[54] *Id.* at 10.

[55] NERC Comments at 4.

[56] BPA Comments at 3.

[57] *See* NERC Comments at 4, Trade Associations Comments at 3, APS Comments at 1, BPA Comments at 3, EnergySec Comments at 1, Idaho Power Comments at 2, ITC Comments at 5, IRC Comments at 1, NRG Comments at 2–3.

[58] NERC Comments at 3.

[59] *See id.* at 4–5.

[60] Appelbaum Comments at 7.

ISAC to share that information broadly through the electric industry to better prepare entities to protect their critical infrastructure.'' [61] Moreover, we do not anticipate that the incremental burden of the directed modifications will divert significant resources from other information sharing programs since responsible entities are already required to monitor and log successful login attempts, detected failed access attempts, and failed login attempts under Reliability Standard CIP–007–6, Requirement R4.1. Nor do we anticipate that the incremental burden of complying with the directed Reliability Standards modifications would be significantly more than the burden of responding to a standing data or information request under Section 1600. We also do not believe that broadened mandatory reporting is at cross-purposes with voluntary cybersecurity-related programs offered by DHS and other government agencies. We believe that voluntary programs that focus on cyber response and sharing of cyber threat information across industry are important initiatives that should be supported. However, the comments do not provide a compelling explanation why the broadening of mandatory reporting will supplant or inhibit voluntary programs.

35. While we agree with EnergySec that revisions to the current definition of Reportable Cyber Security Incident could address some aspects of our directive, a modified definition alone would not address the need to specify the required information in Cyber Security Incident reports to improve the quality of reporting and allow for ease of comparison, or establish deadlines for submitting a report to facilitate timely information sharing. Therefore, while we believe that a modified definition of Reportable Cyber Security Incident could address part of the Commission's concerns, additional modifications would be necessary to meet the full scope of our directive.

36. In addition, we do not agree with Resilient Societies that the detection of malware infecting a responsible entity's ESP or associated EACMS would fall outside the new reporting requirement. While Resilient Societies asserts that a malware infection would not meet the threshold of a compromise, breach, impact, or disruption, we believe that it would fall within the parameters of an attempted compromise. As discussed in the next section, however, we believe that it is appropriate for NERC to address the reporting threshold through the standards development process in order to weigh the diverse technical opinions on how to identify the appropriate assets and the level of attempted compromise that warrants reporting. Accordingly, we are not persuaded to convene a technical conference. Rather, persons interested in the development of appropriate detailed parameters of the augmented reporting requirements should participate in the NERC standards development process.

37. In sum, we conclude that the record supports our determination that directing NERC to develop and submit modifications to the Reliability Standards to require the reporting of Cyber Security Incidents that compromise, or attempt to compromise, a responsible entity's ESP, as well as associated EACMS, is appropriate to carry out FPA section 215. Therefore, pursuant to FPA section 215(d)(5), we direct NERC to develop and submit modifications to the Reliability Standards to include the mandatory reporting of Cyber Security Incidents that compromise, or attempt to compromise, a responsible entity's ESP or associated EACMS. As noted above, we direct NERC to submit the directed modifications within six-months of the effective date of this Final Rule.

B. Threshold for a Reportable Cyber Security Incident

1. NOPR

38. The NOPR proposed to direct NERC to modify the Reliability Standards to include the mandatory reporting of Cyber Security Incidents that compromise, or attempt to compromise, a responsible entity's ESP or associated EACMS. The NOPR explained that reporting attempts to compromise, instead of only successful compromises, is consistent with current monitoring requirements in Reliability Standard CIP–007–6, Requirement R4.1, which mandates logging of detected successful login attempts, detected failed access attempts and failed login attempts.[62] In addition, the NOPR identified other reporting regimes that include attempts within the general definition of a ''cyber incident.'' Specifically, DHS defines a ''cyber incident'' as ''attempts (either failed or successful) to gain unauthorized access to a system or its data. . . .'' [63] The E–ISAC defines a ''cyber incident'' as including unauthorized access through the electronic perimeter as well as ''a detected effort . . . without obvious success.'' [64] And ICS–CERT defines a ''cyber incident'' as an ''occurrence that actually or potentially results in adverse consequences. . . .'' [65]

39. As noted above, an ESP is defined in the NERC Glossary as the ''logical border surrounding a network to which BES Cyber Systems are connected using a routable protocol.'' The purpose of an ESP is to manage electronic access to BES Cyber Systems to support the protection of the BES Cyber Systems against compromise that could lead to misoperation or instability in the BES. The NOPR explained that since an ESP is intended to protect BES Cyber Systems, it is reasonable to establish the compromise of, or attempt to compromise, an ESP as the minimum reporting threshold.

40. In addition, the NOPR identified an ESP's associated EACMS as another threshold for a Reportable Cyber Security Incident. As explained in the NOPR, EACMS are defined in the NERC Glossary as ''Cyber Assets that perform electronic access control or electronic access monitoring of the Electronic Security Perimeter(s) or BES Cyber Systems. This includes Intermediate Systems.'' More specifically, EACMS include, for example, firewalls, authentication servers, security event monitoring systems, intrusion detection systems and alerting systems.

41. While the Commission proposed to include EACMS within the scope of the proposed directive, the Commission also sought comment on the possibility of excluding EACMS from the scope of the proposed directive.

2. Comments

42. NERC supports the NOPR proposal to limit the scope of Cyber Security Incident reporting to incidents that compromise or attempt to compromise a responsible entity's ESP or associated EACMS. NERC explains that any new reporting requirements ''need to be scoped in a manner that provides for meaningful reporting of cyber security risks but does not unduly burden entities.'' [66] Specifically, NERC states:

> Because the ESP protects some of the most important Cyber Assets and the EACMS control or monitor access to those Cyber

[61] NERC Comments at 4.

[62] *See* Reliability Standard CIP–007–6 (Cyber Security—Systems Security Management), Requirement R4.1.

[63] *See* United States Computer Emergency Readiness Team (US–CERT) Incident Definition: *https://www.us-cert.gov/government-users/compliance-and-reporting/incident-definition.*

[64] *See* E–ISAC Incident Reporting Fact Sheet document: *http://www.nerc.com/files/Incident-Reporting.pdf.*

[65] *See* ICS–CERT Published ''Common Cyber Security Language'' document: *https://ics-cert.us-cert.gov/sites/default/files/documents/Common%20Cyber%20Language_S508C.pdf.*

[66] NERC Comments at 6.

Assets, NERC agrees that reporting on attempts to compromise these security measures would provide valuable data while also imposing a reasonable burden on entities given the limited traffic they should experience.[67]

NERC notes that some EACMS devices ''may provide important early indicators of future compromise'' and, therefore, NERC states that it ''supports including EACMS in the reporting threshold in addition to the ESP and notes that logging attempts to compromise the ESP and some EACMS devices does not impose an unreasonable burden on entities.'' [68]

43. While NERC supports adopting the compromise or attempt to compromise a responsible entity's ESP or an EACMS associated with an ESP as a threshold for Cyber Security Incident reporting, NERC explains that ''there is still a need to refine the scope of the proposed directive to ensure that it would provide meaningful data without overburdening entities.'' [69] Specifically, NERC states that there is a need to ''outline the parameters of an 'attempt to compromise' in order to issue a precise data request.'' [70] In particular, NERC states that it ''would consider the common understanding of adverse activities that are early indicators of compromise, such as campaigns against industrial control systems, to help refine the parameters.'' [71] In addition, NERC notes that EACMS, as defined in the NERC Glossary, include a wide variety of devices that perform control and monitoring functions. NERC states further that it ''needs to consider whether to define the reporting threshold to differentiate between the various types of EACMS for reporting purposes.'' [72] Therefore, NERC requests that the Commission provide flexibility in refining the threshold for Cyber Security Incident reporting.

44. Trade Associations, APS, BPA, EnergySec, Resilient Societies, IRC, ITC, and NYPSC generally support the reporting threshold proposed in the NOPR, but caution that any new or modified requirements should be properly scoped. Trade Associations state that the NOPR proposal ''is potentially overbroad and could result in unduly burdensome reporting requirements that *reduce* awareness of significant cyber threats.'' [73] Trade Associations also contend that a new or revised Reliability Standard ''should not include the proposed generic threshold of reporting *any* incidents that compromise or attempt to compromise an ESP or EACMS.'' [74] Instead, Trade Associations recommend that the Commission ''give NERC sufficient flexibility to define appropriate reporting thresholds for attempted compromises of an ESP or EACMS.'' [75]

45. APS asserts that, given the differences among EACMS, it does not support the inclusion of all EACMS or the exclusion of all EACMS from an enhanced reporting requirement. APS states that while it ''concurs that the incidents impacting the ESP should certainly be in scope of reporting, it is concerned that the exclusion of EACMS (which includes [Electronic Access Points (EAP)]) results in a likely compromise scenario going unreported.'' [76] Specifically, APS notes that ''a user's credentials to an Intermediate System, which includes/can be classified as an EAP(s) and/or EACMS, could be compromised.'' [77] APS contends that such a compromise would not implicate the ESP, but could impact or attempt to impact a BES Cyber Asset or System. APS states, however, that ''there are numerous EACMS for which a compromise scenario would not be critical or allow potential access to an ESP.'' [78] Therefore, APS maintains that an evaluation of the functions of various EACMS is needed before they can be included in any reporting requirement.

46. BPA states that a broader definition of a Reportable Cyber Security Incident is necessary since the current definition only addresses actual compromises. BPA avers that ''information about certain attempts to compromise will likely better assist the industry in preventing successful cyber attacks.'' [79] BPA states that the current definition of a Cyber Security Incident is a good starting point for a revision since it includes attempts to compromise or disrupt. BPA cautions, however, that the current definition of Cyber Security Incident ''may be too broad and result in overreporting of information.'' [80]

47. EnergySec states that it ''generally agree[s] that successful attacks against ESPs and EACMS should be within the scope of reporting; [but] disagree[s] with the proposal to include attempted compromise in the reporting requirements.'' [81] In addition, EnergySec suggests that monitoring-only systems be excluded from any reporting requirement, stating that ''[a]lthough compromise of monitoring systems could assist an attack, such a compromise would not directly permit access.'' [82] Resilient Societies states that ''[e]xcluding [EACMS] from the Commission directive could exempt reporting of attempted compromises.'' [83] IRC states that ''adding EACMS to the requirement for mandatory reporting would be beneficial, not only because of their role as a boundary point, but also because EACMS perform other roles that support the BES Cyber Systems.'' [84] IRC cautions, however, that ''[w]ithout providing further definitions or criteria, the NOPR's proposal to require reporting of all 'attempts to compromise' the ESP or EACMS is unclear and potentially unachievable.'' [85]

48. While ITC generally supports the NOPR proposal, ITC ''requests that the Commission refrain from including unsuccessful attempts to compromise an ESP-associated EACMS in the revised definition of a Cyber Security Incident.'' [86] ITC notes that responsible entity systems with publicly-visible IP addresses ''sustain a regular stream of denial of service attempts, phishing emails, attempted firewall breaches, untargeted and targeted malware, and other common cybersecurity threats for which countermeasures are well-established and which pose a miniscule chance of success.'' [87] ITC states that including ''attempted compromises of ESP-associated EACMS would appear to require reporting for a sizeable number of these common events.'' [88] Therefore, ITC states that while it ''supports expanding the definition of Reportable Cyber Incidents to include incidents that compromise, or attempt to compromise, a responsible entity's ESP, ITC would urge the Commission to direct NERC to include only actual breaches of a responsible entity's ESP-associated EACMS, and not attempted-but-unsuccessful compromises.'' [89] NYPSC notes that ''[f]ailed cyber attacks occur on a continuous basis, all the time. . .'' and, therefore, ''[a] reporting requirement of every attempted security

[67] *Id.* at 7.

[68] *Id.* at 8.

[69] *Id.* at 9.

[70] *Id.* at 9.

[71] *Id.* at 9.

[72] *Id.* at 9.

[73] APPA, *et al.* Comments at 5 (emphasis in original).

[74] *Id.* (emphasis in original).

[75] *Id.* at 5.

[76] APS Comments at 9.

[77] *Id.*

[78] *Id.*

[79] BPA Comments at 3.

[80] *Id.* at 3.

[81] EnergySec Comments at 3–4.

[82] *Id.* at 4.

[83] Resilient Societies Comments at 14.

[84] IRC Comments at 5.

[85] *Id.* at 3–4.

[86] ITC Comments at 5.

[87] *Id.* at 5.

[88] *Id.* at 5.

[89] *Id.* at 5.

attack may be overly burdensome for reporting entities.'' [90] NYPSC ''suggests FERC consider developing clear criteria of the required reporting based on its review of the comments and recommendations from reporting entities.'' [91]

49. Idaho Power states that ''additional reporting requirements do not increase cyber security.'' [92] Idaho Power contends that ''additional administrative burdens such as reporting requirements reduce the finite resources that entities have to monitor and defend their critical infrastructure.'' [93] In addition, Idaho Power states that EACMS ''should be excluded from any additional requirements and only BES Cyber Systems and associated devices should be included in any further reporting requirements.'' [94]

50. Other commenters support expanding the enhanced reporting requirement beyond what was proposed in the NOPR. NRG supports the NOPR proposal to direct NERC to develop modifications to the CIP Reliability Standards to improve the reporting of Cyber Security Incidents. NRG also supports including EACMS as a threshold for reporting. In addition, NRG ''recommends that the scope of the NOPR avoid limiting the requirement to High and Medium Impact BES Cyber Systems.'' [95] Specifically, NRG notes that the NOPR proposal ''would limit the requirement to High and Medium Impact BES Cyber Systems as ESPs and EACMS are not required establishments at Low Impact BES Cyber Systems.'' [96] Therefore, NRG states that ''any modification to the referenced CIP Reliability Standards should be applicable to all BES Cyber Systems with External Routable Communications.'' [97]

51. Appelbaum supports the NOPR proposal to include the attempted or actual compromise of an ESP or EACMS in the mandatory reporting requirement. However, Appelbaum ''propose[s] the Commission consider adding Physical Security Perimeters and Physical Access Control Systems (PACS) as well.''[98] Simon supports the NOPR proposal, but encourages the Commission to broaden the directive to include low impact BES Cyber Systems. Specifically, Simon states that ''[o]mission of mandatory reporting for the disruption, or an attempt to disrupt, the operation of electronic access controls for BES assets with low impact BES Cyber Systems leaves a large blind spot in the Commission's effort to learn of efforts to harm the reliable operation of the bulk electric system.'' [99] Isologic does not support limiting Cyber Security Incident reporting to situations involving an entity's ESP or associated EACMS. Isologic states that ''there are few CIP standards for 'secure perimeters' and for the mass of BES Low Impact Facilities, (substations), security is at the fence line, not in ESPs.'' [100]

3. Commission Determination

52. The record in this proceeding supports establishing the compromise or attempted compromise of an ESP as the appropriate threshold for a Reportable Cyber Security incident. In addition, with exceptions, the comments support including EACMS associated with an ESP as part of the reporting threshold. As NERC notes, an ''ESP protects some of the most important Cyber Assets and the EACMS control or monitor access to those Cyber Assets.'' [101] While we believe that ESPs and EACMS should be within the scope of a broadened reporting requirement, the comments, correctly in our view, point to the need to establish an appropriate scope for reporting. As NERC states, ''there is still a need to refine the scope of the proposed directive to ensure that it would provide meaningful data without overburdening entities.'' [102] This concern is reflected in a number of comments, pointing to the need to identify the appropriate assets to monitor (for example, only EACMS associated with an ESP) and to clearly define an ''attempt to compromise.'' [103]

53. The comments generally support the view that NERC should have the flexibility to establish an appropriate reporting threshold. We recognize the need for a certain level of flexibility and believe that it is appropriate for NERC to address the specific reporting threshold through the standards development process. However, as discussed further below, we provide guidance on certain aspects of how NERC should identify EACMS for reporting purposes and what types of attempted compromise must be reported.

54. With regard to identifying EACMS for reporting purposes, NERC's reporting threshold should encompass the functions that various electronic access control and monitoring technologies provide. Those functions must include, at a minimum: (1) Authentication; (2) monitoring and logging; (3) access control; (4) interactive remote access; and (5) alerting.[104] Reporting a malicious act or suspicious event that has compromised, or attempted to compromise, a responsible entity's EACMS that perform any of these five functions would meet the intended scope of the directive by improving awareness of existing and future cyber security threats and potential vulnerabilities. Since responsible entities are already required to monitor and log system activity under Reliability Standard CIP–007–6, the incremental burden of reporting of the compromise or attempted compromise of an EACMS that performs the identified functions should be limited, especially when compared to the benefit of the enhanced situational awareness that such reporting will provide.

55. With regard to the definition of ''attempted compromise'' for reporting purposes, we consider attempted compromise to include an unauthorized access attempt or other confirmed suspicious activity. ITC raises a concern that including unsuccessful attempts to compromise an EACMS associated with an ESP would require reporting a significant number of events. We note, however, that limiting the reporting threshold to only EACMS that are associated with an ESP should limit the reporting burden since these assets should be located apart from the responsible entity's broader business IT networks. Moreover, as discussed in the next section, we also believe that a flexible reporting timeline that reflects the severity of a Cyber Security Incident could also help address the potential burden of reporting attempted compromises.

56. With regard to BPA's suggestion that a revised definition of Reportable Cyber Security Incident is necessary, as discussed above, revisions to the current definition of Reportable Cyber Security

[90] NYPSC Comments at 5–6.

[91] *Id.* at 6.

[92] Idaho Power Comments at 2.

[93] *Id.*

[94] *Id.*

[95] NRG Comments at 5.

[96] *Id.* at 2.

[97] *Id.*

[98] Appelbaum Comments at 7.

[99] Simon Comments at 4.

[100] Isologic Comments at 7.

[101] NERC Comments at 7.

[102] *Id.* at 9.

[103] *See* NERC Comments at 9, APPA, *et al.* Comments at 5, APS Comments at 9, BPA Comments at 3, EnergySec Comments at 3, IRC Comments at 3–4, ITC Comments at 5, NYPSC Comments at 6.

[104] *See* NERC Glossary of Terms definition of EACMS. *See also* Reliability Standard CIP–006–6, Requirement R1.5 (Physical Security Plan) at 10 (''[i]ssue an alarm or alert in response to detected unauthorized access'' to certain High and Medium Impact BES Cyber Systems and associated EACMS); Reliability Standard CIP–007–6, Requirement R4.2 (Security Event Monitoring) at 16; and Reliability Standard CIP–007–6, Requirement R5.7 (System Access Control) at 25.

Incident could address certain aspects of the NOPR proposal, although a modified definition alone would not address the need to specify the required information in cyber security incident reports to improve the quality of reporting and allow for ease of comparison, or establish deadlines for submitting a report to facilitate timely information sharing. Therefore, although we believe that a modified definition of Reportable Cyber Security Incident could address part of the Commission's concerns, additional modifications to the Reliability Standards would be necessary to meet the security objective of the directives discussed herein.

57. A number of commenters request that we expand the directive to include a broader scope of assets, including low impact BES Cyber Systems. However, we decline to expand the scope of Cyber Security Incident reporting beyond the ESP and associated EACMS at this time. The focus on ESPs and associated EACMS is intended to provide threat information on BES Cyber Systems that have the greatest impact on BES reliability while imposing a reasonable reporting burden on responsible entities. Nevertheless, the Commission could revisit this issue if there is demonstrated need for expanded Cyber Security Incident reporting.

58. Therefore, we adopt the NOPR proposal and conclude that the compromise, or attempt to compromise, a responsible entity's ESP or associated EACMS is a reasonable threshold for augmented Cyber Security Incident reporting.

C. Appropriate Procedural Approach To Augment Cyber Security Incident Reporting

1. NOPR

59. The NOPR proposed to direct NERC to modify the CIP Reliability Standards to augment the mandatory reporting of Cyber Security Incidents, while also seeking comment on whether a request for data or information pursuant to Section 1600 of the NERC Rules of Procedure would effectively address the reporting gap.

2. Comments

60. While NERC supports broadened mandatory Cyber Security Incident reporting, NERC does not support the NOPR proposal to direct a modification to the Reliability Standards. Instead, NERC requests flexibility to determine the appropriate reporting procedure. Specifically, NERC proposes to ''use the [Rules of Procedure] Section 1600 process for gathering data used for system performance.'' [105] NERC maintains that it has ''successfully shifted to using Section 1600 for other data collection efforts, such as the collection of reports on Protection System Misoperation.'' [106] NERC explains further that the Section 1600 process would be used to ''supplement the existing voluntary reporting of cyber security threats to E–ISAC.'' [107]

61. NERC states that the Section 1600 process ''provides many of the same benefits as Reliability Standards,'' such as stakeholder and Commission staff input.[108] NERC also states that, similar to Reliability Standards, compliance with Section 1600 is mandatory. NERC explains that if a responsible entity does not respond to a Section 1600 data request, ''NERC has the authority under the [Rules of Procedure] to take such action as NERC deems appropriate to address a situation where a Rule of Procedure cannot practically be complied with or has been violated.'' [109] NERC explains that the Section 1600 data request process provides the flexibility to revise or update the data request, if necessary, as well as ''the flexibility to determine the appropriate timeline for submitting the data.'' [110] NERC states that while it may continue to use the Reliability Standards for data collection for evidence of compliance or to facilitate sharing of information between entities for BES operations, it ''has found the [Rules of Procedure] Section 1600 process to be effective for data collection to assess system performance.'' [111] NERC cites a standing Section 1600 data request for entities to submit quarterly data on Protection System Misoperations as an example.

62. LPPC supports the use of the Section 1600 process to facilitate enhanced Cyber Security Incident reporting. LPPC states that it ''supports a more flexible approach to collection of actionable information through the data request process outlined in NERC ROP Section 1600.'' [112] LPPC asserts that the data request approach offers flexibility that the standards development process does not. Specifically, LPPC states that ''compliance with a NERC data request is mandatory for applicable entities, while the data request procedures specified under [Rules of Procedure] Section 1600 also provide a more efficient process to update or revise a data request as needed to respond to rapidly-changing security threats.'' [113] Finally, LPPC opines that ''it seems appropriate to remove the data collection process from the enforcement process associated with mandatory Reliability Standards.'' [114]

63. APS, BPA, Resilient Societies, IRC, and NRG oppose the use of the Section 1600 process to facilitate enhanced Cyber Security Incident reporting. APS asserts that a request for data pursuant to Section 1600 would not effectively address the reporting gap and current lack of awareness of cyber-related incidents. Specifically, APS argues that a data request would create an independent, redundant reporting obligation to NERC or a regional entity and would subject the provisions of reported information to the confidentiality and data sharing processes set forth in Rules of Procedure Section 1500, unnecessarily delaying sharing and distribution of information.[115] APS states further that the Section 1600 process ''adds significant additional administrative burden for all involved entities, which is inefficient and unnecessary and presents a potential obstacle to the very sharing and distribution that is a critical part of the Commission's objectives set forth in the NOPR.'' [116]

64. BPA comments that a data request is not an effective means of obtaining information about cyber security incidents. BPA explains that Section 1600 data requests ''are one time requests for existing data, and [. . .] not the appropriate vehicle for ensuring ongoing reporting necessary to make data about Cyber Security Incidents effective.'' [117] Resilient Societies states that ''[e]xamination of NERC Rules of Procedure Section 1600 shows the intent of [the] rule is to facilitate one-time requests for data.'' [118] Therefore, Resilient Societies asserts that the Section 1600 reporting procedures ''would be a poor fit for a standing order for data on cybersecurity incidents that occur continually.'' [119] NRG opposes the use of the Section 1600 data request process asserting that a request for data or information would neither address the current lack of awareness of cyber-related incidents, nor satisfy the goals of the proposed directive.

65. APS, as discussed above, suggests adopting the DOE Electric Disturbance

[105] NERC Comments at 10.

[106] *Id.*

[107] *Id.*

[108] *Id.*

[109] *Id.* at 11.

[110] *Id.* at 12–13.

[111] *Id.* at 12.

[112] LPPC Comments at 6–7.

[113] *Id.* at 7.

[114] *Id.*

[115] APS Comments at 16.

[116] *Id.* at 16–17.

[117] BPA Comments at 4.

[118] Resilient Societies Comments at 15.

[119] *Id.*

Events, Form OE–417 as the primary reporting tool for Cyber Security Events. EnergySec, for its part, suggests that the Commission could direct NERC to require entities to develop and implement an information sharing plan.[120] According to EnergySec, such an approach should provide broad discretion to entities and ensure that compliance oversight efforts cannot result in second-guessing of decisions regarding which information to share, when, or with whom. IRC suggests, alternatively, that the Commission allow entities to comply with the reporting requirements by participating in the Cyber Risk Information Sharing program. IRC explains that the program allows entities to automatically report information to E–ISAC for analysis against classified information. IRC states that responsible entities that ''automatically report indicators of compromise through these systems will share information at machine speed, and this should be considered superior to manual reporting, which requires much slower decision-making.'' [121]

3. Commission Determination

66. As discussed above, we adopt the NOPR proposal and direct NERC to develop modifications to the NERC Reliability Standards to improve mandatory reporting of Cyber Security Incidents, including incidents that might facilitate subsequent efforts to harm the reliable operation of the BES. We have considered the arguments raised in the comments for using Reliability Standards, Section 1600 information and data requests, and other vehicles to implement augmented Cyber Security Incident reporting. On balance, we conclude that broadened mandatory reporting pursuant to Reliability Standard requirements is more aligned with the seriousness and magnitude of the current threat environment and the more effective approach to improve awareness of existing and future cyber security threats and potential vulnerabilities.

67. First, the development of a Reliability Standard provides the Commission with an opportunity to review and ultimately approve a new or modified Reliability Standard, ensuring that the desired goals of the directive are met. Moreover, the Reliability Standards development process allows for the collaboration of industry experts in developing a draft standard and also gives interested entities broader opportunity to participate and comment on any proposal that is developed. In contrast, NERC's process for developing a Section 1600 data request provides for less stakeholder input and only informal review of a draft data request by Commission staff. Thus, in this circumstance, the standards development process is preferable for the development of augmented cyber incident reporting requirements that satisfy the scope of the Commission's directive.

68. Second, the development of a Reliability Standard provides better assurance of accurate, complete, and verifiable reporting of cyber security incidents. The Commission has well-defined authority and processes under section 215(e) of the FPA to audit and enforce compliance with a Reliability Standard. While NERC notes that a responsible entity must respond to a NERC Section 1600 data request, NERC cannot impose sanctions on registered entities who fail to respond to such data requests. Rather, a failure to comply would be a violation of the Commission's regulations,[122] requiring a referral to the Commission for action. Such a process would be a departure from the clearly defined processes used to enforce compliance with the Reliability Standards. Moreover, it is unclear how NERC would even learn of such a failure since, unlike mandatory Reliability Standards, compliance with Section 1600 data requests are not subject to regular audit. Accordingly, given the importance of accurate, complete, and verifiable cyber security incident reporting, we find that the more robust and well-established compliance and enforcement processes associated with mandatory Reliability Standards are desirable in this instance.

69. Third, we are not persuaded by NERC's assertion that a Section 1600 data request is preferable in this instance because it allows for flexibility and faster modification should a need arise for future revisions to the collection of cyber incident reporting data. We do not anticipate that there would be a need to change the parameters of the event report, given that the anticipated reporting requirements should not be technology-specific, but rather, broad enough to capture basic data even as the nature of cyber security incidents evolve. Specifically, the NOPR proposed that the minimum set of attributes to be reported should include: (1) The functional impact, where possible to determine, that the Cyber Security Incident achieved or attempted to achieve; (2) the attack vector that was used to achieve or attempted to achieve the Cyber Security Incident; and (3) the level of intrusion that was achieved or attempted as a result of the Cyber Security Incident. Since these attributes are general in nature and not technology specific, they would not need to be refined as the underlying cyber threats evolve, nor would they need to be refined quickly.

70. In a similar vein, the assets (*i.e.,* EACMS) subject to the enhanced reporting requirements should be identified based on function, as opposed to a specific technology that could require a modification in the reporting requirements should the underlying technology change. As discussed above, those functions must include, at a minimum: (1) Authentication; (2) monitoring and logging; (3) access control; (4) interactive remote access; and (5) alerting. Finally, since the level of attempted compromise that warrants reporting should reflect unauthorized access attempts and other confirmed suspicious activity, we do not anticipate that a modification would be required in the future. Nevertheless, should the situation demand a more timely change in data collection or should NERC desire to collect additional information that is outside the scope of the proposed Reliability Standard, NERC could use the Section 1600 data request process to supplement information reported under a mandatory Reliability Standard.

71. Finally, requiring a data collection in a Reliability Standard is consistent with existing practices since responsible entities are currently required to maintain the types of information that would lead to a reportable Cyber Security Incident pursuant to Reliability Standard CIP–007–6, Requirement R4.1.

72. While we recognize that NERC could likely develop a Section 1600 data request more quickly than a mandatory Reliability Standard, given the potential complexity of considering reporting requirements for the various EACMS, we believe that the technical depth of a standard development process is more appropriate for this case. Although NERC states that it has successfully used ROP Section 1600 to collect data on system performance, in this circumstance the information being reported relates to threats and potential compromises that may require immediate or near-term action as opposed to retrospective reporting on Misoperations, as Section 1600 has been used.

73. We also do not support adopting the DOE Form OE–417 as the primary

[120] EnergySec Comments at 6.

[121] IRC Comments at 7.

[122] 18 CFR 39.2(b) (2017) (''All entities subject to the Commission's reliability jurisdiction . . . shall comply with applicable Reliability Standards, the Commission's regulations, and applicable Electric Reliability Organization and Regional Entity Rules made effective under this part.'').

reporting tool for reporting Cyber Security Incidents, as suggested by some commenters. The reporting criteria in our directive are distinguishable and more aligned with a risk management approach than the information requested in the DOE Form OE–417. Specifically, the DOE Form OE–417 has twelve generic criteria for filing a report to the DOE, of which only two reflect the criteria outlined in the NOPR proposal, which are discussed in the following section. The DOE Form OE–417 does not address factors such as attack vector, functional impact and level of intrusion. In addition, the definition of a ''Cyber Event'' in the DOE Form OE–417 filing instructions does not align with the definition of Cyber Security Incident in the NERC Glossary of Terms, let alone a Reportable Cyber Security Incident.[123] Nor does the DOE Form OE–417 require reporting to E–ISAC or ICS–CERT as our directive requires.

74. In sum, we conclude that modifications to the NERC Reliability Standards to improve mandatory reporting of Cyber Security Incidents, including incidents that might facilitate subsequent efforts to harm the reliable operation of the BES, is the appropriate approach to improve Cyber Security Incident reporting.

D. Content and Timing of a Cyber Security Incident Report

1. NOPR

75. The NOPR proposed to direct that NERC modify the CIP Reliability Standards to specify the required content in a Cyber Security Incident report. Specifically, the NOPR proposed that the minimum set of attributes to be reported should include: (1) The functional impact, where possible, that the Cyber Security Incident achieved or attempted to achieve; (2) the attack vector that was used to achieve or attempt to achieve the Cyber Security Incident; and (3) the level of intrusion that was achieved or attempted as a result of the Cyber Security Incident. The NOPR noted that the proposed attributes are the same as attributes already used by DHS for its multi-sector reporting and summarized by DHS in an annual report. The NOPR stated that specifying the required content should improve the quality of reporting by ensuring that basic information is provided; and allowing for ease of comparison across reports by ensuring that each report includes specified fields of information. The NOPR sought comment on the proposed attributes and, more generally, the appropriate content for Cyber Security Incident reporting to improve awareness of existing and future cyber security threats and potential vulnerabilities.

76. In addition, the NOPR proposed to direct NERC to establish requirements outlining deadlines for filing a report once a compromise or disruption to reliable BES operation, or an attempted compromise or disruption, is identified by a responsible entity. The NOPR stated that the reporting timeline should reflect the actual or potential threat to reliability, with more serious incidents reported in a more timely fashion. The NOPR explained that a reporting timeline that takes into consideration the severity of a Cyber Security Incident should minimize potential burdens on responsible entities.

77. The NOPR also proposed that the reports submitted under the enhanced mandatory reporting requirements would be provided to E–ISAC, similar to the current reporting scheme under Reliability Standard CIP–008–5, as well as ICS–CERT or any successor organization. While the NOPR stated that the detailed incident report would not be submitted to the Commission, the NOPR proposed to direct NERC to file publicly an annual report reflecting the Cyber Security Incidents reported to NERC during the previous year. Specifically, the NOPR proposed to direct NERC to file annually an anonymized report providing an aggregated summary of the reported information, similar to the ICS–CERT annual report.[124]

2. Comments

78. NERC supports the minimum set of reporting attributes proposed in the NOPR, stating that ''this level of detail regarding each reported Cyber Security Incident will not only help NERC understand the specific threat but also help NERC understand trends in threats over time.'' [125] NERC also does not oppose either filing an annual, anonymized summary of the reports with the Commission, or submitting the reports of U.S.-based entities to the ICS–CERT in addition to E–ISAC. Finally, while NERC supports the concept of imposing a deadline for entities to submit full reports of Cyber Security Incidents, NERC requests flexibility to determine the appropriate timeframe. Specifically, NERC states that it ''will determine an appropriate deadline for reports so that NERC can use the data for awareness and early indicators of potential compromise but also consider whether reporting for historical analysis can provide insight to the trends and effectiveness of industry's security controls.'' [126]

79. ITC, IRC, and NRG support the minimum set of reporting attributes proposed in the NOPR. ITC states that the NOPR proposal reflects ''a reasonable set of baseline requirements for reporting.'' [127] While ITC raises a concern that the collective information in a report could potentially lead to the identification of the reporting entity, ITC states that it ''will work within the NERC stakeholder and standards development process to ensure that the Standards submitted in response to the Commission's final rule are structured to preserve anonymity to the maximum extent practicable.'' [128] IRC asserts that ''it will be beneficial for responsible entities to report indicators of compromise that are detected in potential cyberattacks against their systems in standard form.'' [129] NRG recommends that mandatory reporting include: ''content Date, Time, Duration of Incident, Origination of the attack, threat vector, targeted system (or OS), vulnerability exploited, [and] method used to stop/prevent the attack.'' [130]

80. Appelbaum, APS, EnergySec, Resilient Societies, and Idaho Power raise concerns with the minimum set of reporting attributes proposed in the NOPR. According to Appelbaum, a count by category of asset, attack vector, and impact is sufficient for the mandatory reporting. APS contends that ''because each entity's network topology, architecture, applications, and other characteristics are different, any requirement to provide the functional impact and level of intrusion as part of reporting is of very low value and should not be included as mandatory attributes of reporting.'' [131]

81. APS, however, ''agrees that information regarding attack vectors could be more relevant, actionable information to be shared.'' [132] EnergySec expresses concern that including the proposed set of reporting attributes as a requirement could be construed to require significant forensic and analysis efforts. Resilient Societies suggests that

[123] *See* Department of Energy Electric Emergency Incident and Disturbance Report—Form OE 417. Form OE–417 defines a Cyber Event as a disruption on the electrical system and/or communication system(s) caused by unauthorized access to computer software and communications systems or networks including hardware, software, and data. *https://www.oe.netl.doe.gov/oe417.aspx.*

[124] NOPR, 161 FERC ¶ 61,291 at 42.

[125] NERC Comments at 14.

[126] *Id.*

[127] ITC Comments at 6.

[128] *Id.*

[129] IRC Comments at 7.

[130] NRG Comments at 5.

[131] APS Comments at 11–12.

[132] *Id.* at 12.

the Commission leverage prior work done by the federal government as opposed to establishing new report content. Specifically, Resilient Societies suggests that the Commission adopt the US–CERT ''Federal Incident Notification Guidelines.'' Idaho Power states that a ''description of the event and the system(s) affected along with a fact pattern describing the situation and known information at the time the report is submitted should be sufficient.'' [133]

82. With regard to the timing of reports, ITC questions whether an initial report of a Cyber Security Incident would have to be submitted to ICS–CERT as well as E–ISAC. ITC opines that ''the existing one-hour reporting requirement poses a significant compliance challenge, and that requiring that the initial report also be provided to ICS–CERT would be unworkable under that timeframe.'' [134] IRC states that ''[t]he timeframe for completing a full report depends on the scale and scope of the investigation [and] FERC should consider requiring that reports be updated at a certain frequency until the full report is complete.'' [135] IRC recommends a 90-day update requirement until a report is finalized. NRG recommends that Cyber Security Incident reports should be submitted after existing industry processes have been followed relating to Incident Reporting and Response Plans. In addition, NRG recommends that the Commission consider directing NERC to file a quarterly report in addition to the annual report.

83. APS recommends aligning the timing of any mandatory reporting obligations with the timing dictated in Form OE–417. APS contends that reporting events that ''could, but didn't, cause harm to the BES and/or facilitate subsequent efforts to harm . . . should be far enough removed from the incident to not divert resources from incident response and to ensure that enough details are known about the incident to provide an accurate, thorough report.[136]

84. EnergySec agrees that clear timelines should be included in any new mandatory Cyber Security Incident requirements. EnergySec further comments that the timelines should factor in the severity of the incident and the level of effort required to complete an investigation. Resilient Societies offers that ''[i]n an ideal world, reporting of cybersecurity incidents would take place at machine speed'' and suggests that the Commission ''allow and preferably require automated reporting, at least for an initial report.'' [137] Idaho Power states that, should the Commission require timelines for reporting, it should ensure that an entity has adequate time to analyze each event before the reporting deadline.

85. Lasky supports entities being required to report Cyber Security Incidents to both E–ISAC and ICS–CERT, and states that ''it would be prudent to report all incidents to the United States Cyber Emergency Response Team (US–CERT)'' as well.[138]

3. Commission Determination

86. As discussed below, we adopt the NOPR proposal on minimum reporting attributes and timing, in response to the commenters' concerns, but we also leave discretion to NERC to develop the reporting timelines in the standards development process by considering several factors so that the timelines provide for notice based upon the severity of the event and the risk to BES reliability, with updates to follow initial reports.

87. The comments generally support the proposed minimum set of reporting attributes. For example, NERC supports the proposed content for a Cyber Security Incident report, while requesting flexibility to determine the appropriate reporting timeframe. As noted by ITC, the NOPR proposal reflects ''a reasonable set of baseline requirements for reporting.'' [139] Certain comments do raise concerns with the proposed reporting attributes, especially in the case of attempts versus actual compromises.

88. In our view, a new or revised Cyber Security Incident report should include, at a minimum, the information outlined in the NOPR proposal, where available. Specifically, the minimum set of attributes to be reported should include: (1) The functional impact, where possible, that the Cyber Security Incident achieved or attempted to achieve; (2) the attack vector that was used to achieve or attempted to achieve the Cyber Security Incident; and (3) the level of intrusion that was achieved or attempted or as a result of the Cyber Security Incident. In addition, we agree that any reporting requirement should not take away from efforts to mitigate a potential compromise.

89. With regard to timing, we conclude that NERC should establish reporting timelines for when the responsible entity must submit Cyber Security Incident reports to the E–ISAC and ICS–CERT based on a risk impact assessment and incident prioritization approach to incident reporting.[140] This approach would establish reporting timelines that are commensurate with the adverse impact to the BES that loss, compromise, or misuse of those BES Cyber Systems could have on the reliable operation of the BES. Higher risk incidents, such as detecting malware within the ESP and associated EACMS or an incident that disrupted one or more reliability tasks, could trigger the report to be submitted to the E–ISAC and ICS–CERT within a more urgent timeframe, such as within one hour, similar to the current reporting deadline in Reliability Standard CIP–008–5.[141] For lower risk incidents, such as the detection of attempts at unauthorized access to the responsible entity's ESP or associated EACMS, an initial reporting timeframe between eight and twenty-four hours would provide an early indication of potential cyber attacks.[142] For situations where a responsible entity identifies other suspicious activity associated with an ESP or associated EACMS, a monthly report could, as NERC states, assist in the analysis of trends in activity over time.[143]

90. With regard to the appropriate recipients for Cyber Security Incident reports, we determine that the reports should be provided to E–ISAC, similar to the current reporting scheme under Reliability Standard CIP–008–5, as well as ICS–CERT or its successor.[144]

[133] Idaho Power Comments at 3.

[134] ITC Comments at 7.

[135] IRC Comments at 8.

[136] APS Comments at 13.

[137] Resilient Societies Comments at 15.

[138] Lasky Comments at 1.

[139] ITC Comments at 6.

[140] Similar to the Cyber Incident Severity Schema in DHS's National Cyber Incident Response Plan, Annex D (Reporting Incidents to the Federal Government) at 41 (2016), *https://www.us-cert.gov/sites/default/files/ncirp/National_Cyber_Incident_Response_Plan.pdf.*

[141] An example of incident categories is the Chairman of the Joint Chiefs of Staff Manual, Cyber Incident Handling Program, Enclosure B, Appendix A to Enclosure B (Cyber Incident and Reportable Cyber Event Categorization) (2012), *http://www.jcs.mil/Portals/36/Documents/Library/Manuals/m651001.pdf?ver=2016-02-05-175710-897.*

[142] *See* Department of Energy Electric Emergency Incident and Disturbance Report, Form OE–417 (six-hour reporting deadline for cyber events that could potentially impact electric power system reliability) found at: *https://www.oe.netl.doe.gov/docs/OE417_Form_05312021.pdf;* Nuclear Regulatory Commission Regulatory Guide 5.71 (four-hour reporting deadline for cyber events that could have caused an adverse impact) found at: *https://www.nrc.gov/docs/ML0903/ML090340159.pdf; see also* Reliability Standard EOP–004–3 (Event Reporting), Requirement R2 (requiring a report within twenty-four hours for an events that impact or may impact BES reliability).

[143] *See* NERC Comments at 14.

[144] The DHS ICS–CERT is undergoing a reorganization and rebranding effort. In the event

Continued

Reporting directly to E–ISAC and ICS–CERT will result in cyber threat information being provided to the organizations best suited to analyze and, to the extent necessary, timely inform responsible entities of cyber threats. In addition, reporting directly to E–ISAC and ICS–CERT addresses the concerns discussed above regarding the confidentiality of reported Cyber Security Incident information. We also find that it is reasonable for NERC to file annually an anonymized report providing an aggregated summary of the reported information, similar to the ICS–CERT annual report. The annual report will provide the Commission, NERC, and the public a better understanding of any Cyber Security Incidents that occurred during the prior year without releasing information on specific responsible entities or Cyber Security Events.

91. Therefore, we conclude that the minimum set of attributes to be reported should include: (1) The functional impact, where possible, that the Cyber Security Incident achieved or attempted to achieve; (2) the attack vector that was used to achieve or attempted to achieve the Cyber Security Incident; and (3) the level of intrusion that was achieved or attempted or as a result of the Cyber Security Incident. NERC may augment the list should it determine that additional information would benefit situational awareness of cyber threats. As discussed above, we also conclude that NERC should establish a reporting timeline that provides for notice based upon the severity of the event and the risk to BES reliability, with updates to follow initial reports. We also support the adoption of an online reporting tool to streamline reporting and reduce burdens on responsible entities to the extent the option is available.[145]

E. Other Issues

1. Comments

92. NYPSC supports the NOPR proposal, but notes that if the Commission adopts the NOPR proposal, ''the only additional information that state entities would gain is an annual compilation of incidents reported to federal entities.'' [146] NYPSC claims that an annual report would not provide states with sufficient information on a timely basis so that they can ensure that corrective actions can be taken. Therefore, NYPSC argues that appropriate state entities should also be provided with the cyber reporting information when it is filed with the ''federal authorities.''

93. Microsoft raises a concern that the NOPR proposal is not clear as to whether the modified CIP Reliability Standards would apply to responsible entities that use a commercial cloud service to operate cloud-based BES Cyber Systems. Specifically, Microsoft requests that the Commission ''confirm that cloud service providers that provide services to Registered Entities are not required to register with NERC based on their provision of [cloud-based] services, and . . . are not responsible for compliance with the CIP Reliability Standards.'' [147] Microsoft asserts that clarifying the status of cloud service providers is important to foster technical innovation.

2. Commission Determination

94. While we appreciate NYPSC's interest in receiving Cyber Security Incident reports when reported to E–ISAC and ICS–CERT, state entities will have access to the same information that is reported to the Commission (*i.e.,* the annual, anonymized summary). Should a state entity determine that it requires additional information from a responsible entity under its jurisdiction, the state entity can work within its own jurisdiction to procure additional information. Our directive is intended to enhance the quality of information received by E–ISAC and ICS–CERT, and directing additional sharing with state entities is outside the scope of this proceeding.

95. We decline to grant Microsoft's requested clarification regarding the potential registration status of cloud service providers because it is outside the scope of this proceeding. Specifically, Microsoft's requested clarification addresses a question regarding registration of cloud service providers under the NERC functional model, as opposed to the specifics of enhanced Cyber Security Incident reporting. The purpose of this proceeding is not to make a determination regarding the registration status of cloud service providers and we have not received input from other interested entities.

III. Information Collection Statement

96. The FERC–725 information collection requirements contained in this Final Rule are subject to review by the Office of Management and Budget (OMB) under section 3507(d) of the Paperwork Reduction Act of 1995.[148] OMB's regulations require approval of certain information collection requirements imposed by agency rules.[149] Upon approval of a collection of information, OMB will assign an OMB control number and expiration date. Respondents subject to the filing requirements of this rule will not be penalized for failing to respond to these collections of information unless the collections of information display a valid OMB control number. The Commission solicits comments on the Commission's need for this information, whether the information will have practical utility, the accuracy of the burden estimates, ways to enhance the quality, utility, and clarity of the information to be collected or retained, and any suggested methods for minimizing respondents' burden, including the use of automated information techniques.

97. The Commission will submit these proposed reporting requirements to OMB for its review and approval under section 3507(d) of the PRA because the Final Rule results in nonsubstantive/non-material changes in paperwork burden. The Final Rule directs NERC to make Cyber Security reporting changes across all applicable Reliability Standards. These proposed changes will be covered by the FERC–725 information collection (Certification of Electric Reliability Organization; Procedures for Electric Reliability Standards) [OMB Control No. 1902–0225]). FERC–725 includes the ERO's overall responsibility for developing Reliability Standards to include any Reliability Standards that relate to Cyber Security Incident reporting. There will be no change to the Public Reporting Burden as it affects the FERC–725 information collection.

98. Comments are solicited on the Commission's need for the information proposed to be reported, whether the information will have practical utility, ways to enhance the quality, utility, and clarity of the information to be collected, and any suggested methods for minimizing the respondent's burden, including the use of automated information techniques.

99. Internal review: The Commission has reviewed the approved changes and has determined that the changes are necessary to ensure the reliability and integrity of the Nation's Bulk-Power System.

100. Interested persons may obtain information on the reporting requirements by contacting the

that ICS–CERT no longer exists, its successor will assume the role as incident report recipient.

[145] An online reporting tool will streamline the effort and allow for direct input into a database for a faster turnaround to those that may need to know about the information. For example, *see https://www.us-cert.gov/forms/report*.

[146] NYPSC Comments at 4–5.

[147] Microsoft Comments at 1.

[148] 44 U.S.C. 3507(d) (2012).

[149] 5 CFR 1320.11 (2017).

following: Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426 [Attention: Ellen Brown, Office of the Executive Director, email: *DataClearance@ferc.gov,* phone: (202) 502–8663, fax: (202) 273–0873].

101. For submitting comments concerning the collection(s) of information and the associated burden estimate(s), please send your comments to the Commission, and to the Office of Management and Budget, Office of Information and Regulatory Affairs, 725 17th Street NW, Washington, DC 20503 [Attention: Desk Officer for the Federal Energy Regulatory Commission, phone: (202) 395–8528, fax: (202) 395–7285]. For security reasons, comments to OMB should be submitted by email to: *oira_submission@omb.eop.gov.* Comments submitted to OMB should include Docket Number RM18–2–000 and OMB Control Number 1902–0225.

IV. Regulatory Flexibility Act Analysis

102. The Regulatory Flexibility Act of 1980 (RFA) [150] generally requires a description and analysis of final rules that will have significant economic impact on a substantial number of small entities.

103. By only proposing to direct NERC, the Commission-certified ERO, to develop modified Reliability Standards for Cyber Security Incident reporting, this Final Rule will not have a significant or substantial impact on entities other than NERC. Therefore, the Commission certifies that this Final Rule will not have a significant economic impact on a substantial number of small entities.

104. Any Reliability Standards proposed by NERC in compliance with this rulemaking will be considered by the Commission in future proceedings. As part of any future proceedings, the Commission will make determinations pertaining to the Regulatory Flexibility Act based on the content of the Reliability Standards proposed by NERC.

V. Environmental Analysis

105. The Commission is required to prepare an Environmental Assessment or an Environmental Impact Statement for any action that may have a significant adverse effect on the human environment.[151] The Commission has categorically excluded certain actions from this requirement as not having a significant effect on the human environment. Included in the exclusion are rules that are clarifying, corrective, or procedural or that do not substantially change the effect of the regulations being amended.[152] The actions proposed herein to augment current reporting requirements fall within this categorical exclusion in the Commission's regulations.

VI. Document Availability

106. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) and in the Commission's Public Reference Room during normal business hours (8:30 a.m. to 5:00 p.m. Eastern time) at 888 First Street NE, Room 2A, Washington, DC 20426.

107. From the Commission's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number of this document, excluding the last three digits, in the docket number field. User assistance is available for eLibrary and the Commission's website during normal business hours from the Commission's Online Support at (202) 502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov.*

VII. Effective Date and Congressional Notification

108. The Final Rule is effective October 1, 2018. The Commission has determined that this Final Rule imposes no substantial effect upon either NERC or NERC registered entities [153] and, with the concurrence of the Administrator of the Office of Information and Regulatory Affairs of OMB, that this rule is not a ''major rule'' as defined in section 351 of the Small Business Regulatory Enforcement Fairness Act of 1996. This Final Rule is being submitted to the Senate, House, and Government Accountability Office.

By the Commission.

Issued: July 19, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

Note: The following appendix will not appear in the Code of Federal Regulations.

Appendix Commenters

Jonathan Appelbaum (Appelbaum)
American Public Power Association, Electricity Consumers Resource Council, and Transmission Access Policy Study Group (Trade Associations)
Applied Control Solutions (ACS)
Arizona Public Service Company (APS)
Bonneville Power Administration (BPA)
Edison Electric Institute and National Rural Electric Cooperative Association (EEI/NRECA)
Douglas E. Ellsworth (Ellsworth)
Energy Sector Security Consortium (EnergySec)
Eversource Energy Service Company (Eversource)
Foundation for Resilient Societies (Resilient Societies)
Frank Gaffney (Gaffney)
Idaho Power Company (Idaho Power)
International Transmission Company (ITC)
ISO/RTO Council (IRC)
Isologic LLC (Isologic)
Jerry Ladd (Ladd)
Large Public Power Council (LPPC)
Mary D. Lasky (Lasky)
Michael Mabee (Mabee)
Garland T. McCoy (McCoy)
Microsoft Corporation (Microsoft)
New York Public Service Commission (NYPSC)
North American Electric Reliability Corporation (NERC)
NRG Energy (NRG)
Fred Reitman (Reitman)
Preston L. Schleinkofer (Schleinkofer)
Mark S. Simon (Simon)
Karen Testerman (Testerman)
U.S. Chamber of Commerce (Chamber)

[FR Doc. 2018–16242 Filed 7–30–18; 8:45 am]

BILLING CODE 6717–01–P

POSTAL REGULATORY COMMISSION

39 CFR Part 3020

[Docket Nos. MC2010–21 and CP2010–36]

Update to Product Lists

AGENCY: Postal Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Commission is updating the product lists. This action reflects a publication policy adopted by Commission order. The referenced policy assumes periodic updates. The updates are identified in the body of this document. The product lists, which are re-published in its entirety, include these updates.

DATES: *Effective Date:* July 31, 2018. For applicability dates, see **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6800.

SUPPLEMENTARY INFORMATION:

Applicability Dates: April 2, 2018, First-Class Package Service Contract 92

[150] 5 U.S.C. 601–612.

[151] *Regulations Implementing the National Environmental Policy Act of 1969,* Order No. 486, FERC Stats. & Regs. ¶ 30,783 (1987).

[152] 18 CFR 380.4(a)(2)(ii) (2017).

[153] 5 U.S.C 804(3)c.

(MC2018–133 and CP2018–189); April 3, 2018, Priority Mail Contract 426 (MC2018–134 and CP2018–190); April 17, 2018, Priority Mail & First-Class Package Service Contract 77 (MC2018–136 and CP2018–197); April 17, 2018, Priority Mail Contract 427 (MC2018–139 and CP2018–200); April 17, 2018, Priority Mail Express, Priority Mail & First-Class Package Service Contract 33 (MC2018–137 and CP2018–198); April 17, 2018, Priority Mail Express & Priority Mail Contract 64 (MC2018–138 and CP2018–199); April 18, 2018, Priority Mail Contract 429 (MC2018–141 and CP2018–202); April 18, 2018, Priority Mail Express & First-Class Package Service Contract 3 (MC2018–135 and CP2018–196); April 18, 2018, Priority Mail Contract 428 (MC2018–140 and CP2018–201); April 18, 2018, Priority Mail Contract 430 (MC2018–142 and CP2018–203); April 24, 2018, Priority Mail Contract 431 (MC2018–143 and CP2018–205); April 30, 2018, Priority Mail Contract 432 (MC2018–144 and CP2018–207); May 3, 2018, Priority Mail & First-Class Package Service Contract 78 (MC2018–145 and CP2018–208); May 3, 2018, Priority Mail & First-Class Package Service Contract 79 (MC2018–146 and CP2018–209); May 8, 2018, Priority Mail Express, Priority Mail & First-Class Package Service Contract 34 (MC2018–147 and CP2018–211); May 18, 2018, Priority Mail Express, Priority Mail & First-Class Package Service Contract 35 (MC2018–148 and CP2018–214); May 23, 2018, Priority Mail Express & Priority Mail Contract 65 (MC2018–151 and CP2018–217); May 23, 2018, Priority Mail Express, Priority Mail & First-Class Package Service Contract 36 (MC2018–153 and CP2018–219); May 23, 2018, Priority Mail & First-Class Package Service Contract 80 (MC2018–152 and CP2018–218); May 29, 2018, Priority Mail Express, Priority Mail & First-Class Package Service Contract 37 (MC2018–154 and CP2018–223); May 30, 2018, Priority Mail Contract 433 (MC2018–149 and CP2018–215); May 30, 2018, First-Class Package Service Contract 93 (MC2018–155 and CP2018–224); June 7, 2018, Priority Mail Contract 435 (MC2018–157 and CP2018–226); June 7, 2018, Priority Mail Contract 434 (MC2018–156 and CP2018–225); June 13, 2018, Priority Mail Express Contract 62 (MC2018–158 and CP2018–228); June 13, 2018, Priority Mail Contract 438 (MC2018–161 and CP2018–231); June 13, 2018, Priority Mail Contract 436 (MC2018–159 and CP2018–229); June 13, 2018, Priority Mail Contract 437 (MC2018–160 and CP2018–230); June 19, 2018, Priority Mail Contract 440 (MC2018–163 and CP2018–234); June 19, 2018, Priority Mail Contract 441 (MC2018–164 and CP2018–235); June 19, 2018, Priority Mail Contract 439 (MC2018–162 and CP2018–233); June 20, 2018, Priority Mail Express & Priority Mail Contract 66 (MC2018–165 and CP2018–236); June 20, 2018, Priority Mail Contract 442 (MC2018–166 and CP2018–238); June 21, 2018, Priority Mail Express & Priority Mail Contract 67 (MC2018–167 and CP2018–239); June 21, 2018, Priority Mail Contract 443 (MC2018–168 and CP2018–240); June 21, 2018, Priority Mail Express & Priority Mail Contract 68 (MC2018–169 and CP2018–241); June 21, 2018, Priority Mail Contract 444 (MC2018–170 and CP2018–242); June 21, 2018, Priority Mail Contract 445 (MC2018–171 and CP2018–243); June 22, 2018, Priority Mail Express, Priority Mail & First-Class Package Service Contract 38 (MC2018–172 and CP2018–244); June 22, 2018, First-Class Package Service Contract 94 (MC2018–173 and CP2018–245); June 25, 2018, Priority Mail & First-Class Package Service Contract 81 (MC2018–174 and CP2018–246); June 25, 2018, Priority Mail & First-Class Package Service Contract 82 (MC2018–175 and CP2018–247); June 25, 2018, Priority Mail Contract 447 (MC2018–177 and CP2018–249); June 25, 2018, Priority Mail Contract 446 (MC2018–176 and CP2018–248); June 26, 2018, Parcel Select Contract 31 (MC2018–179 and CP2018–251); June 26, 2018, Priority Mail Contract 448 (MC2018–178 and CP2018–250); June 26, 2018, Priority Mail Express, Priority Mail & First-Class Package Service Contract 39 (MC2018–180 and CP2018–252); June 28, 2018, Priority Mail Express Contract 63 (MC2018–181 and CP2018–255); June 28, 2018, Priority Mail Contract 449 (MC2018–182 and CP2018–256); June 28, 2018, Priority Mail Contract 450 (MC2018–183 and CP2018–257).

This document identifies updates to the market dominant and the competitive product lists, which appear as 39 CFR Appendix A to Subpart A of Part 3020—Market Dominant Product List and 39 CFR Appendix B to Subpart A of Part 3020—Competitive Product List, respectively. Publication of the updated product lists in the **Federal Register** is addressed in the Postal Accountability and Enhancement Act (PAEA) of 2006.

Authorization. The Commission process for periodic publication of updates was established in Docket Nos. MC2010–21 and CP2010–36, Order No. 445, April 22, 2010, at 8.

Changes. The product lists are being updated by publishing replacements in their entirety of 39 CFR Appendix A to Subpart A of Part 3020—Market Dominant Product List and 39 CFR Appendix B to Subpart A of Part 3020—Competitive Product List. The following products are being added, removed, or moved within the product lists:

Competitive Product List

1. First-Class Package Service Contract 92 (MC2018–133 and CP2018–189) (Order No. 4561), added April 2, 2018.
2. Priority Mail Contract 426 (MC2018–134 and CP2018–190) (Order No. 4564), added April 3, 2018.
3. Priority Mail & First-Class Package Service Contract 77 (MC2018–136 and CP2018–197) (Order No. 4579), added April 17, 2018.
4. Priority Mail Contract 427 (MC2018–139 and CP2018–200) (Order No. 4580), added April 17, 2018.
5. Priority Mail Express, Priority Mail & First-Class Package Service Contract 33 (MC2018–137 and CP2018–198) (Order No. 4581), added April 17, 2018.
6. Priority Mail Express & Priority Mail Contract 64 (MC2018–138 and CP2018–199) (Order No. 4582), added April 17, 2018.
7. Priority Mail Contract 429 (MC2018–141 and CP2018–202) (Order No. 4584), added April 18, 2018.
8. Priority Mail Express & First-Class Package Service Contract 3 (MC2018–135 and CP2018–196) (Order No. 4585), added April 18, 2018.
9. Priority Mail Contract 428 (MC2018–140 and CP2018–201) (Order No. 4586), added April 18, 2018.
10. Priority Mail Contract 430 (MC2018–142 and CP2018–203) (Order No. 4587), added April 18, 2018.
11. Priority Mail Contract 431 (MC2018–143 and CP2018–205) (Order No. 4590), added April 24, 2018.
12. Priority Mail Contract 432 (MC2018–144 and CP2018–207) (Order No. 4597), added April 30, 2018.
13. Priority Mail & First-Class Package Service Contract 78 (MC2018–145 and CP2018–208) (Order No. 4600), added May 3, 2018.
14. Priority Mail & First-Class Package Service Contract 79 (MC2018–146 and CP2018–209) (Order No. 4601), added May 3, 2018.
15. Priority Mail Express, Priority Mail & First-Class Package Service Contract 34 (MC2018–147 and CP2018–211) (Order No. 4603), added May 8, 2018.
16. Priority Mail Express, Priority Mail & First-Class Package Service Contract 35 (MC2018–148 and CP2018–214) (Order No. 4609), added May 18, 2018.
17. Priority Mail Express & Priority Mail Contract 65 (MC2018–151 and

CP2018–217) (Order No. 4615), added May 23, 2018.

18. Priority Mail Express, Priority Mail & First-Class Package Service Contract 36 (MC2018–153 and CP2018–219) (Order No. 4616), added May 23, 2018.

19. Priority Mail & First-Class Package Service Contract 80 (MC2018–152 and CP2018–218) (Order No. 4617), added May 23, 2018.

20. Priority Mail Express, Priority Mail & First-Class Package Service Contract 37 (MC2018–154 and CP2018–223) (Order No. 4625), added May 29, 2018.

21. Priority Mail Contract 433 (MC2018–149 and CP2018–215) (Order No. 4626), added May 30, 2018.

22. First-Class Package Service Contract 93 (MC2018–155 and CP2018–224) (Order No. 4627), added May 30, 2018.

23. Priority Mail Contract 435 (MC2018–157 and CP2018–226) (Order No. 4637), added June 7, 2018.

24. Priority Mail Contract 434 (MC2018–156 and CP2018–225) (Order No. 4638), added June 7, 2018.

25. Priority Mail Express Contract 62 (MC2018–158 and CP2018–228) (Order No. 4642), added June 13, 2018.

26. Priority Mail Contract 438 (MC2018–161 and CP2018–231) (Order No. 4643), added June 13, 2018.

27. Priority Mail Contract 436 (MC2018–159 and CP2018–229) (Order No. 4644), added June 13, 2018.

28. Priority Mail Contract 437 (MC2018–160 and CP2018–230) (Order No. 4645), added June 13, 2018.

29. Priority Mail Contract 440 (MC2018–163 and CP2018–234) (Order No. 4650), added June 19, 2018.

30. Priority Mail Contract 441 (MC2018–164 and CP2018–235) (Order No. 4651), added June 19, 2018.

31. Priority Mail Contract 439 (MC2018–162 and CP2018–233) (Order No. 4653), added June 19, 2018.

32. Priority Mail Express & Priority Mail Contract 66 (MC2018–165 and CP2018–236) (Order No. 4656), added June 20, 2018.

33. Priority Mail Contract 442 (MC2018–166 and CP2018–238) (Order No. 4657), added June 20, 2018.

34. Priority Mail Express & Priority Mail Contract 67 (MC2018–167 and CP2018–239) (Order No. 4662), added June 21, 2018.

35. Priority Mail Contract 443 (MC2018–168 and CP2018–240) (Order No. 4663), added June 21, 2018.

36. Priority Mail Express & Priority Mail Contract 68 (MC2018–169 and CP2018–241) (Order No. 4664), added June 21, 2018.

37. Priority Mail Contract 444 (MC2018–170 and CP2018–242) (Order No. 4665), added June 21, 2018.

38. Priority Mail Contract 445 (MC2018–171 and CP2018–243) (Order No. 4666), added June 21, 2018.

39. Priority Mail Express, Priority Mail & First-Class Package Service Contract 38 (MC2018–172 and CP2018–244) (Order No. 4667), added June 22, 2018.

40. First-Class Package Service Contract 94 (MC2018–173 and CP2018–245) (Order No. 4668), added June 22, 2018.

41. Priority Mail & First-Class Package Service Contract 81 (MC2018–174 and CP2018–246) (Order No. 4671), added June 25, 2018.

42. Priority Mail & First-Class Package Service Contract 82 (MC2018–175 and CP2018–247) (Order No. 4672), added June 25, 2018.

43. Priority Mail Contract 447 (MC2018–177 and CP2018–249) (Order No. 4673), added June 25, 2018.

44. Priority Mail Contract 446 (MC2018–176 and CP2018–248) (Order No. 4674), added June 25, 2018.

45. Parcel Select Contract 31 (MC2018–179 and CP2018–251) (Order No. 4676), added June 26, 2018.

46. Priority Mail Contract 448 (MC2018–178 and CP2018–250) (Order No. 4677), added June 26, 2018.

47. Priority Mail Express, Priority Mail & First-Class Package Service Contract 39 (MC2018–180 and CP2018–252) (Order No. 4678), added June 26, 2018.

48. Priority Mail Express Contract 63 (MC2018–181 and CP2018–255) (Order No. 4686), added June 28, 2018.

49. Priority Mail Contract 449 (MC2018–182 and CP2018–256) (Order No. 4687), added June 28, 2018.

50. Priority Mail Contract 450 (MC2018–183 and CP2018–257) (Order No. 4688), added June 28, 2018.

The following negotiated service agreements have expired, or have been terminated early, and are being deleted from the Competitive Product List:

1. Priority Mail Express Contract 16 (MC2014–12 and CP2014–16) (Order No. 1941).

2. Priority Mail Express Contract 23 (MC2015–16 and CP2015–20) (Order No. 2296).

3. Priority Mail Contract 94 (MC2014–48 and CP2014–84) (Order No. 2209).

4. Priority Mail Contract 110 (MC2015–29 and CP2015–38) (Order No. 2354).

5. Priority Mail Contract 119 (MC2015–39 and CP2015–50) (Order No. 2393).

6. Priority Mail Contract 121 (MC2015–43 and CP2015–54) (Order No. 2428).

7. Priority Mail Contract 291 (MC2017–85 and CP2017–114) (Order No. 3784).

8. Parcel Select Contract 18 (MC2017–65 and CP2017–93) (Order No. 3724).

9. Priority Mail & First-Class Package Service Contract 2 (MC2015–24 and CP2015–32) (Order No. 2347).

10. Priority Mail & First-Class Package Service Contract 41 (MC2017–48 and CP2017–74) (Order No. 3698).

The following negotiated service agreements have expired, or have been terminated early, and are being deleted from the Market Dominant Product List:

1. PHI Acquisitions, Inc. Negotiated Service Agreement (MC2014–21 and R2014–6) (Notice of Termination of Agreement).

Updated product lists. The referenced changes to the product lists are incorporated into 39 CFR Appendix A to Subpart A of Part 3020—Market Dominant Product List and 39 CFR Appendix B to Subpart A of Part 3020—Competitive Product List.

List of Subjects in 39 CFR Part 3020

Administrative practice and procedure, Postal Service.

For the reasons discussed in the preamble, the Postal Regulatory Commission amends chapter III of title 39 of the Code of Federal Regulations as follows:

PART 3020—PRODUCT LISTS

■ 1. The authority citation for part 3020 continues to read as follows:

Authority: 39 U.S.C. 503; 3622; 3631; 3642; 3682.

■ 2. Revise Appendix A to Subpart A of Part 3020 and Appendix B to Subpart A of Part 3020 to read as follows:

Appendix A to Subpart A of Part 3020—Market Dominant Product List

(An asterisk (*) indicates an organizational class or group, not a Postal Service product.)

Part A—Market Dominant Products

1000 Market Dominant Product List

First-Class Mail *

Single-Piece Letters/Postcards
Presorted Letters/Postcards
Flats
Outbound Single-Piece First-Class Mail International
Inbound Letter Post

USPS Marketing Mail (Commercial and Nonprofit) *

High Density and Saturation Letters
High Density and Saturation Flats/Parcels
Carrier Route
Letters
Flats
Parcels
Every Door Direct Mail—Retail

Periodicals *

In-County Periodicals
Outside County Periodicals

Package Services *

Alaska Bypass Service
Bound Printed Matter Flats
Bound Printed Matter Parcels
Media Mail/Library Mail

Special Services *

Ancillary Services
International Ancillary Services
Address Management Services
Caller Service
Credit Card Authentication
International Reply Coupon Service
International Business Reply Mail Service
Money Orders
Post Office Box Service
Customized Postage
Stamp Fulfillment Services

Negotiated Service Agreements *

Domestic *
International *
- Inbound Market Dominant Multi-Service Agreements with Foreign Postal Operators 1
- Inbound Market Dominant Exprés Service Agreement 1
- Inbound Market Dominant Registered Service Agreement 1
- Inbound Market Dominant PRIME Tracked Service Agreement

Nonpostal Services *

Alliances with the Private Sector to Defray Cost of Key Postal Functions
Philatelic Sales
Market Tests *

Appendix B to Subpart A of Part 3020—Competitive Product List

(An asterisk (*) indicates an organizational class or group, not a Postal Service product.)

Part B—Competitive Products

2000 Competitive Product List

Domestic Products *

Priority Mail Express
Priority Mail
Parcel Select
Parcel Return Service
First-Class Package Service
USPS Retail Ground

International Products *

Outbound International Expedited Services
Inbound Parcel Post (at UPU rates)
Outbound Priority Mail International
International Priority Airmail (IPA)
International Surface Air List (ISAL)
International Direct Sacks—M-Bags
Outbound Single-Piece First-Class Package International Service

Negotiated Service Agreements *

Domestic *
- Priority Mail Express Contract 26
- Priority Mail Express Contract 27
- Priority Mail Express Contract 28
- Priority Mail Express Contract 29
- Priority Mail Express Contract 30
- Priority Mail Express Contract 31
- Priority Mail Express Contract 32
- Priority Mail Express Contract 34
- Priority Mail Express Contract 35
- Priority Mail Express Contract 36
- Priority Mail Express Contract 37
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- Parcel Return Service Contract 5
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Outbound International *

Global Expedited Package Services (GEPS) Contracts
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GEPS 8
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Global Bulk Economy (GBE) Contracts
Global Plus Contracts
Global Plus 1C
Global Plus 1D
Global Plus 1E
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Global Reseller Expedited Package Services 1
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Global Reseller Expedited Package Services 3
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Global Expedited Package Services (GEPS)—Non-Published Rates
Global Expedited Package Services (GEPS)—Non-Published Rates 2
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Competitive International Merchandise Return Service Agreements with Foreign Postal Operators 1
Competitive International Merchandise Return Service Agreements with Foreign Postal Operators 1
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Alternative Delivery Provider (ADP) Contracts
ADP 1
Alternative Delivery Provider Reseller (ADPR) Contracts

ADPR 1

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International Business Reply Service Competitive Contract 1
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Inbound EMS
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Inbound Air Parcel Post (at non-UPU rates)
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Address Enhancement Services
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International Money Transfer Service—Outbound
International Money Transfer Service—Inbound
Premium Forwarding Service
Shipping and Mailing Supplies
Post Office Box Service
Competitive Ancillary Services

Nonpostal Services *

Advertising
Licensing of Intellectual Property other than Officially Licensed Retail Products (OLRP)
Mail Service Promotion
Officially Licensed Retail Products (OLRP)
Passport Photo Service
Photocopying Service
Rental, Leasing, Licensing or other Non-Sale Disposition of Tangible Property
Training Facilities and Related Services
USPS Electronic Postmark (EPM) Program

Market Tests *

Customized Delivery
Global eCommerce Marketplace (GeM)

Ruth Ann Abrams,

Acting Secretary.

[FR Doc. 2018–16267 Filed 7–30–18; 8:45 am]

BILLING CODE 7710–FW–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2016–0603; FRL–9981–45—Region 5]

Air Plan Approval; Minnesota; PSD Infrastructure SIP Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving elements of a state implementation plan (SIP) submission from Minnesota regarding the infrastructure requirements of section 110 of the Clean Air Act (CAA) relating to Prevention of Significant Deterioration (PSD) for the 1997 ozone, 1997 fine particulate ($PM_{2.5}$), 2006 $PM_{2.5}$, 2008 lead (Pb), 2008 ozone, 2010 nitrogen dioxide (NO_2), 2010 sulfur dioxide (SO_2), and 2012 $PM_{2.5}$ National Ambient Air Quality Standards (NAAQS). The Minnesota Pollution Control Agency (MPCA) submitted the SIP revision to EPA on October 4, 2016.

DATES: This final rule is effective on August 30, 2018.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R05–OAR–2016–0603. All documents in the docket are listed on the *www.regulations.gov* website. Although listed in the index, some information is not publicly available, *i.e.,* Confidential Business Information (CBI) 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 through *www.regulations.gov* or at the Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. This facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. We recommend that you telephone Eric Svingen, Environmental Engineer, at (312) 353–4489 before visiting the Region 5 office.

FOR FURTHER INFORMATION CONTACT: Eric Svingen, Environmental Engineer, Attainment Planning and Maintenance Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 353–4489, *svingen.eric@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA. This supplementary information section is arranged as follows:

I. What is the background of this SIP submission?

This rulemaking approves a SIP submission from MPCA dated October 4, 2016, which addresses infrastructure requirements relating to PSD for the 1997 ozone, 1997 $PM_{2.5}$, 2006 $PM_{2.5}$, 2008 Pb, 2008 ozone, 2010 NO_2, 2010 SO_2, and 2012 $PM_{2.5}$ NAAQS.

The requirement for states to make infrastructure SIP submissions arises out of CAA section 110(a)(1). Pursuant to CAA section 110(a)(1), states must make SIP submissions ''within 3 years (or such shorter period as the Administrator may prescribe) after the promulgation of a national primary ambient air quality standard (or any revision thereof),'' and these SIP submissions are to provide for the ''implementation, maintenance, and enforcement'' of such NAAQS. The statute directly imposes on states the duty to make these SIP submissions, and the requirement to make the submissions is not conditioned upon EPA's taking any action other than promulgating a new or revised NAAQS. CAA section 110(a)(2) includes a list of specific elements that ''[e]ach such plan'' submission must address.

EPA has historically referred to these SIP submissions made for the purpose of satisfying the requirements of CAA section 110(a)(1) and (2) as ''infrastructure SIP'' submissions. Although the term ''infrastructure SIP'' does not appear in the CAA, EPA uses the term to distinguish this particular type of SIP submission from submissions that are intended to satisfy other SIP requirements under the CAA. This specific rulemaking is only taking action on the infrastructure SIP elements relating to PSD, provided at CAA sections 110(a)(2)(C), 110(a)(2)(D)(i)(II), 110(a)(2)(D)(ii), and 110(a)(2)(J).

In previous rulemakings, EPA addressed Minnesota's infrastructure obligations under the various NAAQS. On July 13, 2011 (76 FR 41075), EPA approved most elements of Minnesota's infrastructure SIP submittal for the 1997 ozone and 1997 $PM_{2.5}$ NAAQS. On October 29, 2012 (77 FR 65478), EPA approved most elements of Minnesota's

infrastructure SIP submittal for the 2006 $PM_{2.5}$ NAAQS. On July 16, 2014 (79 FR 41439), EPA approved most elements of Minnesota's infrastructure SIP submittal for the 2008 Pb NAAQS. Finally, on October 20, 2015 (80 FR 63436), EPA approved most elements of Minnesota's infrastructure SIP submittal for the 2008 ozone, 2010 NO_2, 2010 SO_2, and 2012 $PM_{2.5}$ NAAQS. However, because Minnesota did not have an approved PSD program at the time of these rulemakings, EPA generally disapproved infrastructure SIP elements relating to PSD in the rulemakings.[1]

MPCA's submission dated October 4, 2016, requested that EPA approve into its SIP Minnesota Rule 7007.3000, which incorporates by reference the Federal PSD rules at 40 CFR 52.21. On July 10, 2017 (82 FR 31741), EPA proposed to approve this request, and on September 26, 2017 (82 FR 44734), EPA finalized approval; the change became effective on October 26, 2017. Therefore, Minnesota is now implementing its own SIP-approved PSD program.

In this rulemaking, as requested by Minnesota, EPA is finding that Minnesota has satisfied all infrastructure SIP elements relating to PSD, at CAA sections 110(a)(2)(C), 110(a)(2)(D)(i)(II), 110(a)(2)(D)(ii), and 110(a)(2)(J), for the 1997 ozone, 1997 $PM_{2.5}$, 2006 $PM_{2.5}$, 2008 Pb, 2008 ozone, 2010 NO_2, 2010 SO_2, and 2012 $PM_{2.5}$ NAAQS.

II. What guidance is EPA using to evaluate this SIP submission?

EPA's guidance relating to infrastructure SIP submissions can be found in a guidance document entitled ''Guidance on SIP Elements Required Under Sections 110(a)(1) and (2) for the 1997 8-hour Ozone and $PM_{2.5}$ [2] National Ambient Air Quality Standards'' (2007 Guidance).[3] Further guidance is provided in a September 13, 2013, document entitled ''Guidance on Infrastructure State Implementation Plan (SIP) Elements under CAA Sections 110(a)(1) and (2)'' (2013 Guidance).[4]

III. What is the result of EPA's review of this SIP submission?

Pursuant to CAA section 110(a), states must provide reasonable notice and opportunity for public hearing for all infrastructure SIP submissions. MPCA commenced a public comment period on June 20, 2016, and closed the public comment period on July 20, 2016. Minnesota received three comments, and provided a response to comments in its submittal.

Minnesota provided a synopsis of how its SIP meets each of the applicable requirements in CAA sections 110(a)(2)(C), 110(a)(2)(D)(i)(II), 110(a)(2)(D)(ii), and 110(a)(2)(J) for the 1997 ozone, 1997 $PM_{2.5}$, 2006 $PM_{2.5}$, 2008 Pb, 2008 ozone, 2010 NO_2, 2010 SO_2, and 2012 $PM_{2.5}$ NAAQS, as applicable.

On May 17, 2018 (83 FR 22913), EPA published a proposed rule that would approve this submission into Minnesota's SIP. This proposed rule contained a detailed evaluation of how Minnesota's submission satisfies certain requirements under CAA section 110. Two comments were received; neither is relevant to this rulemaking. Therefore, EPA is finalizing this rule as proposed.

IV. What action is EPA taking?

EPA is approving the submission from Minnesota certifying that its current SIP is sufficient to meet the infrastructure SIP requirements relating to PSD, at CAA sections 110(a)(2)(C), 110(a)(2)(D)(i)(II), 110(a)(2)(D)(ii), and 110(a)(2)(J), for the 1997 ozone, 1997 $PM_{2.5}$, 2006 $PM_{2.5}$, 2008 Pb, 2008 ozone, 2010 NO_2, 2010 SO_2, and 2012 $PM_{2.5}$ NAAQS. EPA is also making some consistency and clarification edits to Minnesota's infrastructure SIP table in 40 CFR 52.1220.

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 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, 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 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
- 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).

In addition, 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).

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

[1] States may develop and implement their own PSD programs, which are evaluated against EPA's requirements for each component. States may alternatively decline to develop their own program, but instead directly implement Federal PSD rules. At the time of the infrastructure rulemakings referenced above, Minnesota had chosen to implement the federally promulgated PSD rules at 40 CFR 52.21, and EPA had delegated to Minnesota the authority to implement these regulations. The federally promulgated rules satisfied all infrastructure requirements relating to PSD. However, as a delegated program, these infrastructure elements were not approved into the Minnesota SIP.

[2] $PM_{2.5}$ refers to particles with an aerodynamic diameter of less than or equal to 2.5 micrometers, oftentimes referred to as ''fine'' particles.

[3] *https://www3.epa.gov/ttn/naaqs/aqmguide/collection/cp2/20071002_harnett_110(a)_sip_guidance.pdf.*

[4] *https://www3.epa.gov/airquality/urbanair/sipstatus/docs/Guidance_on_Infrastructure_SIP_Elements_Multipollutant_FINAL_Sept_2013.pdf.*

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 October 1, 2018. 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, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: July 17, 2018.

Cathy Stepp,

Regional Administrator, Region 5.

40 CFR part 52 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.*

■ 2. In § 52.1220, the table in paragraph (e) is amended by:

■ i. Removing the entry for ''CAA 110(a)(2)(D)(i) SIP-Interstate Transport''.

■ ii. Revising the entries for ''Section 110(a)(2) Infrastructure Requirements for the 1997 8-hour ozone NAAQS''; ''Section 110(a)(2) Infrastructure Requirements for the 1997 $PM_{2.5}$ NAAQS''; ''Section 110(a)(2) Infrastructure Requirements for the 2006 24-Hour $PM_{2.5}$ NAAQS''; ''Section 110(a)(2) Infrastructure Requirements for the 2008 lead (Pb) NAAQS''; ''Section 110(a)(2) Infrastructure Requirements for the 2008 ozone NAAQS''; ''Section 110(a)(2) Infrastructure Requirements for the 2010 nitrogen dioxide (NO_2) NAAQS''; ''Section 110(a)(2) Infrastructure Requirements for the 2010 sulfur dioxide (SO_2) NAAQS''; and ''Section 110(a)(2) Infrastructure Requirements for the 2012 fine particulate matter ($PM_{2.5}$) NAAQS''.

The revisions reads as follows:

§ 52.1220 Identification of plan.

* * * * *

(e) * * *

EPA-APPROVED MINNESOTA NONREGULATORY PROVISIONS

Name of nonregulatory SIP provision	Applicable geographic or nonattainment area	State submittal date/ effective date	EPA approved date	Comments
*	*	* *	*	* *
Section 110(a)(2) Infrastructure Requirements for the 1997 8-Hour Ozone NAAQS.	Statewide	10/23/2007, 11/29/2007, 5/26/2016 and 10/4/2016.	7/31/2018, [insert **Federal Register** citation].	Fully approved for all CAA elements.
Section 110(a)(2) Infrastructure Requirements for the 1997 $PM_{2.5}$ NAAQS.	Statewide	10/23/2007, 11/29/2007, 5/26/2016 and 10/4/2016.	7/31/2018, [insert **Federal Register** citation].	Fully approved for all CAA elements.
Section 110(a)(2) Infrastructure Requirements for the 2006 24-Hour $PM_{2.5}$ NAAQS.	Statewide	5/23/2011, 5/26/2016 and 10/4/2016.	7/31/2018, [insert **Federal Register** citation].	Fully approved for all CAA elements except (D)(i)(I), which has been remedied with a FIP, and the visibility protection requirements of (D)(i)(II).
Section 110(a)(2) Infrastructure Requirements for the 2008 lead (Pb) NAAQS.	Statewide	6/19/2012, 5/26/2016 and 10/4/2016.	7/31/2018, [insert **Federal Register** citation].	Fully approved for all CAA elements.
Section 110(a)(2) Infrastructure Requirements for the 2008 ozone NAAQS.	Statewide	6/12/2014, 5/26/2016 and 10/4/2016.	7/31/2018, [insert **Federal Register** citation].	Fully approved for all CAA elements except the visibility protection requirements of (D)(i)(II).
Section 110(a)(2) Infrastructure Requirements for the 2010 nitrogen dioxide (NO_2) NAAQS.	Statewide	6/12/2014, 5/26/2016 and 10/4/2016.	7/31/2018, [insert **Federal Register** citation].	Fully approved for all CAA elements except the visibility protection requirements of (D)(i)(II).
Section 110(a)(2) Infrastructure Requirements for the 2010 sulfur dioxide (SO_2) NAAQS.	Statewide	6/12/2014, 5/26/2016 and 10/4/2016.	7/31/2018, [insert **Federal Register** citation].	Fully approved for all CAA elements except (D)(i)(I) and the visibility protection requirements of (D)(i)(II).
Section 110(a)(2) Infrastructure Requirements for the 2012 fine particulate matter ($PM_{2.5}$) NAAQS.	Statewide	6/12/2014, 5/26/2016 and 10/4/2016.	7/31/2018, [insert **Federal Register** citation].	Fully approved for all CAA elements except (D)(i)(I) and the visibility protection requirements of (D)(i)(II).

[FR Doc. 2018–16256 Filed 7–30–18; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2017–0535; FRL–9981–46—Region 5]

Air Plan Approval; Indiana; Air Quality Standards Update for the 2015 Ozone Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a September 7, 2017, request by the Indiana Department of Environmental Management (IDEM) to revise the Indiana state implementation plan (SIP) for ozone. IDEM revised its ozone standard in order to be consistent with EPA's 2015 revisions to the 8-hour national ambient air quality standards (NAAQS). IDEM also revised references to the monitoring test methods in its rules to be consistent with the current EPA test methods. EPA is also approving administrative revisions to regulations addressing other ambient air quality standards.

DATES: This final rule is effective on August 30, 2018.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R05–OAR–2017–0535. All documents in the docket are listed on the *www.regulations.gov* website. Although listed in the index, some information is not publicly available, *i.e.,* Confidential Business Information (CBI) 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 through *www.regulations.gov* or at the Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. This facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. We recommend that you telephone Matt Rau, Environmental Engineer, at (312) 886–6524 before visiting the Region 5 office.

FOR FURTHER INFORMATION CONTACT: Matt Rau, Environmental Engineer, Control Strategies Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–6524, *rau.matthew@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA. This supplementary information section is arranged as follows:

I. Background

On October 26, 2015 (80 FR 65291), EPA revised the primary and secondary ozone NAAQS from 0.075 to 0.070 parts per million (ppm), daily maximum 8-hour concentration, codified at 40 CFR 50.19. EPA also revised the monitoring test methods for ozone, which are codified at 40 CFR part 50, appendices D and U, and at 40 CFR part 53.

On April 11, 2017, IDEM revised its ambient air quality primary and secondary standards for ozone to be consistent with EPA's 2015 revision, and codified that revision at 326 Indiana Administrative Code (IAC) 1–3–4, Ambient Air Quality Standards. IDEM revised 326 IAC 1–3–4(4)(B) to update its references to the Federal monitoring test methods. Indiana also made administrative revisions throughout 326 IAC 1–3–4 for ambient air quality standards other than ozone. This includes changing ''shall represent'' to ''represents'' and ''shall'' to ''must.''

On September 7, 2017, IDEM submitted the revisions of 326 IAC 1–3–4 to EPA and requested their approval into the Indiana SIP. EPA proposed approving 326 IAC 1–3–4, as revised, on May 2, 2018 (83 FR 19194).

II. Public Comment

A public comment period was provided in the May 2, 2018 (83 FR 19194) proposed rule. The comment period closed on June 1, 2018. Two comments were submitted during the comment period. Both comments raised issues outside the scope of this rulemaking.

III. What action is EPA taking?

EPA is approving revisions related to Indiana's ambient air quality standards in 326 IAC 1–3–4 into the Indiana SIP. The revisions to 326 IAC 1–3–4 include making IDEM's ozone standard consistent with the 2015 8-hour ozone NAAQS, as codified at 40 CFR part 50, and making IDEM's monitoring test methods for ozone consistent with the methods codified at 40 CFR part 50 and 40 CFR part 53. Further, administrative revisions were made to IDEM's other ambient air quality standards in 326 IAC 1–3–4. IDEM submitted the SIP revision request on September 7, 2017.

IV. 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 of the Indiana Regulations described in the amendments to 40 CFR part 52 set forth below. EPA has made, and will continue to make, these documents generally available through *www.regulations.gov,* and at the EPA Region 5 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). Therefore, these materials 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.[1]

V. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Clean Air Act and applicable Federal regulations. 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 Clean Air Act. 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

[1] 62 FR 27968 (May 22, 1997).

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 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 Clean Air Act; 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).

In addition, 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).

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 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 October 1, 2018. 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, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides.

Dated: July 17, 2018.

Cathy Stepp,

Regional Administrator, Region 5.

40 CFR part 52 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.*

■ 2. In § 52.770, the table in paragraph (c) is amended by revising the entry for ''1–3–4'' under ''Article 1. General Provisions'' ''Rule 3. Ambient Air Quality Standards'' to read as follows:

§ 52.770 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED INDIANA REGULATIONS

Indiana citation	Subject	Indiana effective date	EPA approval date	Notes
Article 1. General Provisions				
*	*	*	*	*
Rule 3. Ambient Air Quality Standards				
*	*	*	*	*
1–3–4	Ambient air quality standards	8/11/2017	7/31/2018, [Insert **Federal Register** citation].	
*	*	*	*	*

* * * * *

[FR Doc. 2018–16247 Filed 7–30–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R10–OAR–2018–0001; FRL–9981–50-Region 10]

Air Plan Approval; Washington; Regional Haze Progress Report

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a revision to the regional haze State Implementation Plan (SIP) submitted by Washington on November 6, 2017. Washington submitted its Regional Haze Progress Report (''progress report'' or ''report'') and a negative declaration stating that further revision of the existing regional haze SIP is not needed at this time.

Washington submitted both the progress report and the negative declaration in the form of implementation plan revisions as required by federal regulations. The progress report addresses the federal Regional Haze Rule requirements under the Clean Air Act to submit a report describing progress in achieving reasonable progress goals established for regional haze and a determination of the adequacy of the state's existing plan addressing regional haze.

DATES: This final rule is effective August 30, 2018.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R10–OAR–2018–0001. 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.,* CBI or other information the disclosure of which is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and is publicly available only in hard copy form. Publicly available docket materials are available at *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: Jeff Hunt at (206) 553–0256, or *hunt.jeff@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document wherever ''we,'' ''us,'' or ''our'' is used, it is intended to refer to the EPA.

I. Background Information

On May 31, 2018, the EPA proposed to approve Washington's Regional Haze Progress Report (83 FR 24954). An explanation of the Clean Air Act requirements, a detailed analysis of the submittal, and the EPA's reasons for proposing approval were provided in the notice of proposed rulemaking, and will not be restated here. The public comment period for the proposal ended July 2, 2018.

II. Response to Comments

We received six comments on the rulemaking. After reviewing the comments, we have determined that four of the comments are outside the scope of our proposed action and fail to identify any material issue necessitating a response. The fifth and sixth comments, submitted by TransAlta Centralia Generation LLC (TransAlta) and an anonymous commenter, are described below.

Comment 0012: In its comment, TransAlta stated: ''We write to comment on the future operations of TransAlta's Centralia Power Plant in the Regional Haze 5-Year Progress Report. The Progress Report and its supporting documents describe the 'retirement' or 'closure' of TransAlta's Centralia Power Plant in reference to reducing emissions and impacts. However, TransAlta and a number of other parties have always anticipated that when the Centralia Power Plant ceases coal-fired operations, it would likely convert one or both boilers to use gas instead of coal. Rather than shuttering the plant, TransAlta envisions retrofitting the facility to accommodate fuel-switching to natural gas as a means to supply power for Washington State until renewable energy is reliably sufficient. TransAlta estimates a reduction in emissions as a result of this fuel-switching, but does not anticipate ceasing operations or closing the Centralia Power Plant.'' TransAlta then requested that the EPA make specific wording changes to the narrative text of the state's progress report, and supporting documents, to reflect this position.

Comment 0013: Purportedly in response to TransAlta's Comment 0012, an anonymous commenter stated: ''The agreement to close a plant means that it is CLOSED. The last minute attempt to re-engineer the plant to burn a different type of fossil fuel is a contradiction of the plan.''

Response: Under the Clean Air Act the EPA has the authority to approve or disapprove SIP revisions submitted by the states. We do not have the authority to modify the narrative text of state submissions, or supporting documents, other than disapproval or partial disapproval. To the extent TransAlta believes that Washington's narrative description of the existing best available retrofit technology (BART) Order 6426 (order) is ambiguous or incorrect regarding facility operation after 2020 and 2025, this comment could have been submitted during the state public comment period. In reviewing *Appendix G. Ecology's Responses to Comments Received during the Public Comment Period,* we see no evidence of TransAlta requesting changes or commenting on this issue during the state public comment period.[1]

As discussed in the proposal for this action, the primary purpose of the progress report is to evaluate whether the existing regional haze plan is adequate for meeting the reasonable progress goals (RPGs) established for the first regional haze planning period, ending in 2018. The TransAlta BART order, as approved into the SIP states, ''Coal units BW21 and BW22 will permanently cease burning coal and be decommissioned as follows: (4.1) One coal fired unit must permanently cease burning coal no later than December 31, 2020. (4.2) The second coal fired unit must permanently cease burning coal no later than December 31, 2025.'' To the extent that TransAlta and Washington may or may not agree about the interpretation of these conditions as they relate to potential future revisions to the BART order, potential future changes under the new source review program, or potential use of the facility beyond 2020 and 2025, we note these issues are outside the scope of this action evaluating progress during the first planning period. We encourage TransAlta to resolve these issues directly with Washington as the state develops the regional haze update for the next planning period (2018–2028). In the interim, we do not believe this comment constitutes a sufficient basis for disapproving or partially disapproving Washington's progress report. As stated in our proposed approval of Washington's Regional Haze Progress Report, the progress report contained the information required by 40 CFR 51.308 and demonstrated that Washington is meeting or exceeding all reasonable progress goals for all Class I areas within Washington's borders, and implementation of the regional haze SIP has enabled other nearby states to meet RPGs for Class I areas where Washington sources are reasonably anticipated to contribute to visibility impairment. In addition, Washington's progress report contained an assessment of the status of all measures included in the SIP that were implemented during the first planning period, such as compliance with the BART emission limit for nitrogen oxides at TransAlta's Centralia Power Plant. Therefore, our position remains that the appropriate action is to approve Washington's Regional Haze Progress Report.

III. Final Action

The EPA is approving the Washington Regional Haze Progress Report, submitted on November 6, 2017, as meeting the applicable requirements of the Clean Air Act and the federal Regional Haze Rule, as set forth in 40 CFR 51.308(g). The EPA is also approving Washington's determination that the existing regional haze SIP is

[1] The EPA was sent a copy of TransAlta's December 13, 2017, letter with similar comments. This letter was written after the state public comment period closed on August 1, 2017, and also after submission of the SIP revision to the EPA on November 6, 2017.

adequate to meet the state's visibility goals established for the first planning period and requires no substantive revision at this time, as set forth in 40 CFR 51.308(h). We have also determined that Washington fulfilled the requirements in 40 CFR 51.308(i) regarding state coordination with Federal Land Managers.

IV. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Clean Air 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 Clean Air Act. 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 actions such as 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 Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because this action does not involve technical standards; and
- does not provide the 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 and is also not approved to apply in any other area where the 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).

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. 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).

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 October 1, 2018. 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, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: July 23, 2018.

Chris Hladick,

Regional Administrator, Region 10.

For the reasons set forth in the preamble, 40 CFR part 52 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 WW—Washington

■ 2. In § 52.2470(e), amend table 2 by adding the entry ''Regional Haze Progress Report'' after the entry ''Regional Haze State Implementation Plan—BP Cherry Point Refinery BART Revision'' to read as follows:

§ 52.2470 Identification of plan.

* * * * *

(e) * * *

TABLE 2—ATTAINMENT, MAINTENANCE, AND OTHER PLANS

Name of SIP provision	Applicable geographic or nonattainment area	State submittal date	EPA approval date	Explanations
* *	*	*	* *	*
Regional Haze Progress Report ...	Statewide	11/6/2017	7/31/2018, [Insert **Federal Register** citation].	
* *	*	*	* *	*

[FR Doc. 2018–16266 Filed 7–30–18; 8:45 am]
BILLING CODE 6560–50–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–HQ–ES–2016–0076; 4500030115]

RIN 1018–BC82

Endangered and Threatened Wildlife and Plants; Endangered Species Status for Five Poecilotheria Tarantula Species From Sri Lanka

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), determine endangered species status under the Endangered Species Act of 1973, as amended, for the following five tarantula species from Sri Lanka: *Poecilotheria fasciata, P. ornata, P. smithi, P. subfusca,* and *P. vittata.* The effect of this regulation will be to add these species to the List of Endangered and Threatened Wildlife.

DATES: This rule becomes effective August 30, 2018.

ADDRESSES: This final rule is available on the internet at *http://www.regulations.gov* at docket number FWS–HQ–ES–2016–0076. Comments and materials we received, as well as supporting documentation we used in preparing this rule, are available for public inspection at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Don Morgan, Chief, Branch of Delisting and Foreign Species, Ecological Services, U.S. Fish and Wildlife Service, MS: ES, 5275 Leesburg Pike, Falls Church, VA 22041–3803; telephone, 703–358–2171. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish a rule. Under the Endangered Species Act of 1973, as amended (Act; 16 U.S.C. 1531 *et seq.*), a species may be protected through listing as an endangered species or threatened species if it meets the definition of an ''endangered species'' or ''threatened species'' under the Act. Listing a species as an endangered or threatened species can only be completed by issuing a rule.

What this document does. This rule will add the following five tarantula species to the List of Endangered and Threatened Wildlife in title 50 of the Code of Federal Regulations (50 CFR 17.11(h)) as endangered species: *Poecilotheria fasciata, P. ornata, P. smithi, P. subfusca, and P. vittata.*

The basis for our action. Under the Act, we use the best available scientific and commercial data to determine whether a species meets the definition of a ''threatened species'' or an ''endangered species'' because of any one or more of the following five factors or the cumulative effects thereof: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) Overutilization for commercial, recreational, scientific, or educational purposes; (C) Disease or predation; (D) The inadequacy of existing regulatory mechanisms; or (E) Other natural or manmade factors affecting its continued existence. We have determined on the basis of the best available scientific and commercial data that *P. fasciata, P. ornata, P. smithi, P. subfusca,* and *P. vittata* are in danger of extinction because of ongoing habitat loss and degradation and the cumulative effects of this and other threat factors. One species, *P. smithi,* is also in danger of extinction because of the effects of stochastic (random) processes.

Peer review and public comment. We sought comments from independent peer reviewers to ensure that our designation is based on scientifically sound data and analyses. We invited these peer reviewers to comment on our listing proposal. We also considered all comments and information received from the public during the comment period.

Previous Federal Action

We received a petition, dated October 29, 2010, from WildEarth Guardians requesting that the following 11 tarantula species in the genus *Poecilotheria* be listed under the Act as endangered or threatened: *Poecilotheria fasciata, P. formosa, P. hanumavilasumica, P. metallica, P. miranda, P. ornata, P. pederseni, P. rufilata, P. smithi, P. striata,* and *P. subfusca.* The petition identified itself as such and included the information as required by 50 CFR 424.14(a). We published a 90-day finding on December 3, 2013 (78 FR 72622), indicating that the petition presents substantial scientific and commercial information indicating that listing these 11 species may be warranted. At that time we also (1) notified the public that we were initiating a review of the status of these species to determine if listing them is warranted, (2) requested from the public scientific and commercial data and other information regarding the species, and (3) notified the public that at the conclusion of our review of the status of these species, we would issue a 12-month finding on the petition, as provided in section 4(b)(3)(B) of the Act. We published a 12-month finding and proposed rule for listing the five *Poecilotheria* species that are endemic to Sri Lanka (*Poecilotheria fasciata, P. ornata, P. pederseni, P. smithi,* and *P. subfusca*) on December 14, 2016 (81 FR 90297). In our 12-month finding and proposed rule we determined that these five species were in danger of extinction throughout their ranges and proposed listing them as endangered under the Act. We requested input from the public, range country, other interested parties, and peer reviewers during a 60-day public comment period that ended February 13, 2017.

Summary of Changes From the Proposed Rule

In preparing this final rule, we reviewed and fully considered comments from the public and peer reviewers on the proposed rule. This final rule incorporates minor changes to our proposed listing based on the comments we received (See: Summary of Comments and Recommendations).

Background

Taxonomy and Species Descriptions

Poecilotheria is a genus of arboreal spiders endemic to Sri Lanka and India. The genus belongs to the family *Theraphosidae,* often referred to as tarantulas, within the infraorder *Mygalomorphae.* As with most theraphosid genera, *Poecilotheria* is a poorly understood genus. The taxonomy has never been studied using modern DNA technology; therefore, species descriptions are based solely on morphological characteristics. Consequently, there have been several revisions, additions, and subtractions to the list of *Poecilotheria* species over the last 20 years (Nanayakkara 2014a, pp. 71–72; Gabriel *et al.* 2013, entire).

The World Spider Catalog (2017, unpaginated; 2016, unpaginated) currently recognizes 14 species of *Poecilotheria.* The Integrated Taxonomic Information System currently identifies 16 species in the genus, based on the 2011 version of the same catalog. Because the World Spider Catalog is the widely accepted authority on spider taxonomy, we consider the *Poecilotheria* species recognized by the most recent (2017) version of this catalog to be valid. Based on the World

Spider Catalog, all five of the species addressed in this rule are considered valid taxon, although *P. pederseni* is now considered a junior synonym to the currently accepted name *P. vittata.* Therefore, in the remainder of this document we refer to this species as *P. vittata.* Further, all five of these species have multiple common names (see WildEarth Guardians 2010, p. 4); thus, we refer to them by their scientific names throughout this document.

Poecilotheria species are among the largest spiders in the world, with body lengths of 4 to 9 centimeters (1.5 to 3.5 inches) and maximum adult leg spans varying from 15 to 25 centimeters (6 to 10 inches) (Nanayakkara 2014a, pp. 94–129; Molur *et al.* 2006, p. 23). They are known for their fast movements and potent venom that, in humans, typically causes extended muscle cramps and severe pain (Fuchs 2014, p. 75; Nanayakkara and Adikaram 2013, p. 53). They are hairy spiders and have striking coloration, with dorsal color patterns of gray, black, brown, and in one case, a metallic blue. Ventral coloration of either sex is typically more of the same with the exception of the first pair of legs, which in some species bear bright yellow to orange aposematic (warning) markings that are visible when the spider presents a defensive display. Mature spiders exhibit some sexual dimorphism with mature males having a more drab coloration and being significantly smaller than the adult females (Siliwal 2017, unpaginated; Nanayakkara 2014a, entire; Pocock 1899, pp. 84–86).

The primary characteristics used to distinguish *Poecilotheria* species are ventral leg markings (Gabriel 2010 p. 13, citing several authors). Some authors indicate that identification via leg markings is straightforward for most *Poecilotheria* species (Nanayakkara 2014a, pp. 74–75; Gabriel 2011a, p. 25). However, the apparent consistent leg patterns observed in adults of a species could also be a function of specimens being collected from a limited number of locations (Morra 2013, p. 129). During surveys, researchers found more variation than suggested by published species descriptions and indicated that identifying *Poecilotheria* species is not as straightforward as suggested by current descriptions (Molur *et al.* 2003, unpaginated). Immature spiders (juveniles) lack the variation in coloring found in adults. As a result, they are difficult to differentiate visually; genetic analysis may be the only way to reliably identify juveniles to species (Longhorn 2014a, unpaginated).

Captive Poecilotheria

Most captive individuals of *Poecilotheria* species are in the pet trade; few specimens of the species addressed in this rule are held in zoos (Species360 2017, unpaginated). *Poecilotheria* species are commonly bred in captivity by amateur hobbyists as well as vendors, and are available as captive-bred young in the pet trade in the United States, Europe, and elsewhere (see *Trade*). However, while rearing and keeping of captive individuals by hobbyists and vendors has provided information on life history of these species, we are not aware of any existing conservation programs for these species, including any in which specimens held or sold as pets contribute to the viability of these species within their native ranges in the wild.

Individuals of these species that are held or sold as pets hold limited conservation value to the species in the wild because they are not genetically managed for conservation purposes. Individuals in the pet trade descend from wild individuals from unknown locations, have undocumented lineages, come from limited stock (*e.g.,* see Gabriel 2012, p. 18), and are bred without knowledge or consideration of their genetics. They also likely include an unknown number of hybrid individuals resulting from intentional crosses, or unintentional crosses resulting from confusion and difficulty in species taxonomy and identification (Gabriel 2011a, pp. 25–26; Gabriel *et al.* 2005, p. 4; Gabriel 2003, pp. 89–90). Further, many are likely several generations removed from wild ancestors and thus may be adversely affected by inbreeding or maladapted to conditions in the wild. In short, captive individuals held or sold as pets do not adhere to the IUCN guidelines for reintroductions and other conservation translocations (IUCN 2013, entire). Further, we are not aware of any captive-breeding programs for *Poecilotheria* that adhere to IUCN guidelines.

Because (1) the purpose of our status assessments is to determine the status of the species in the wild, (2) we are not aware of any information indicating that captive individuals are contributing to the conservation of these species in the wild, and (3) captive individuals held or sold as pets have limited value for conservation programs or for reintroduction purposes, we place little weight on the status of captive individuals in our assessment of the status of the five *Poecilotheria* species addressed in this rule.

Tarantula General Biology

Tarantulas possess life-history traits markedly different from most spiders and other arthropods (Bond *et al.* 2006, p. 145). They are long-lived, have delayed sexual maturity, and most are habitat specialists that are extremely sedentary. They also have poor dispersal ability because their mode of travel is limited to walking, and they typically do not move far from the area in which they are born. As a result, the distribution of individuals tends to be highly clumped in suitable microhabitats (a smaller habitat within a larger habitat), populations are extremely genetically structured (genetically subdivided; gene frequencies differ across the population), and the group shows a high level of endemism (species restricted to a particular geographical location) (Ferreti *et al.* 2014, p. 2; Hedin *et al.* 2013, p. 509, citing several sources; Bond *et al.* 2006, pp. 145–146, citing several sources).

Tarantulas are primarily nocturnal and typically lead a hidden life, spending much of their time concealed inside burrows or crevices (retreats) that provide protection from predators and the elements (Foelix 2011, p. 14; Molur *et al.* 2003, unpaginated; Gallon 2000, unpaginated). They are very sensitive to vibrations and climatic conditions, and usually do not come out of their retreats in conditions like rains, wind, or excessive light, or when they detect movement outside their retreat (Molur *et al.* 2003, unpaginated). Tarantulas are generalist predators that sit and wait for passing prey near the entrance of their retreats (Gallon 2000, unpaginated). With the exception of reproductive males that wander in search of females during the breeding season, they leave their retreat only briefly for capturing prey, and quickly return to it at the slightest vibration or disturbance (Foelix 2011, p. 14; Stotley and Shillington 2009, pp. 1210–1211; Molur *et al.* 2003, unpaginated). Tarantulas generally inhabit a suitable retreat for extended periods and may use the same retreat for years (Stotley and Shilling 2009, pp. 1210–1211; Stradling 1994, p. 87). Most tarantulas are solitary, with one spider occupying a retreat (Gallon 2000, unpaginated).

The lifestyle of adult male tarantulas differs from that of adult females and juveniles. Females and juveniles are sedentary, spending most of their time in or near their retreat. Adult females are long-lived and continue to grow, molt, and reproduce for several years after reaching maturity (Ferreti *et al.* 2014, p. 2, citing several sources; Costa

and Perez-Miles 2002, p. 585, citing several sources; Gallon 2000, unpaginated). They are capable of producing one brood per year, although they do not always do so (Ferreti *et al.* 2014, p. 2; Stradling 1994, pp. 92–96). Males have shorter lifespans than females and, after reaching maturity, no longer molt and usually only live one or two breeding seasons (Costa and Perez-Miles 2002, p. 585, Gallon 2000, unpaginated). Further, on reaching maturity, males leave their retreats to wander in search of receptive females with which to mate (Stotley and Shillington 2009, pp. 1210–1211). Males appear to search the landscape for females randomly and, at short range, may be able to detect females through contact sex-pheromones on silk deposited by the female at the entrance of her retreat (Ferreti *et al.* 2013, pp. 88, 90; Janowski-Bell and Horner 1999, pp. 506, 509; Yanez *et al.* 1999, pp. 165–167; Stradling 1994, p. 96). Males may cover relatively large areas when searching for females. Males of a ground-dwelling temperate species (*Aphonopelma anax*) are reported covering search areas up to 29 ha (72 acres), though the mean size of areas searched is much smaller (1.1 ± 0.5 ha one year and 8.8 ± 2.5 ha another year) (Stotley and Shillington 2009, p. 1216).

When a male locates a receptive female, the two will mate in or near the entrance to the female's retreat. After mating, the female returns to her retreat where she eventually lays eggs within an egg-sac and tends the eggs until they hatch. Spiderlings reach maturity in one or more years (Gallon 2000, unpaginated).

Poecilotheria Biology

Limited information is available on *Poecilotheria* species in the wild. While they appear to be typical tarantulas in many respects, they differ from most tarantulas in that they are somewhat social (discussed below) and reside in trees rather than ground burrows (see Microhabitat).

Poecilotheria species are patchily distributed (Siliwal *et al.* 2008, p. 8) and prey on a variety of insects, including winged termites, beetles, grasshoppers, and moths, and occasionally small vertebrates (Das *et al.* 2012, entire; Molur *et al.* 2006, p. 31; Smith *et al.* 2001, p. 57).

We are not aware of any information regarding the reproductive success of wild *Poecilotheria* species. However, reproduction may be greatly reduced during droughts (Smith *et al.* 2001, pp. 46, 49). Additionally, given the apparently random searching for females by male tarantulas, successful mating of females likely depends on the density of males in the vicinity. In a study conducted on an arboreal tropical tarantula (*Avicularia avicularia* in Trinidad), less than half of adult females produced eggs in the same year despite the fact that they were in close proximity to each other and exhibited the same weight gain, possibly due to a failure to mate (Stradling 1994, p. 96).

Time to maturity in *Poecilotheria* species varies and is influenced by the temperature at which the young are raised and amount of food provided (Gabriel 2006, entire). Based on observations of captive *Poecilotheria,* males mature from spiderlings to adults in 11 to16 months (Gabriel 2011b, p. 101; Gabriel 2005, entire). Females mature in 14 to 48 months and generally live an additional 60 to 85 months after maturing (Cowper 2017, unpaginated; Weaver 2017, unpaginated; Gabriel 2012, p. 19; Government of Sri Lanka and Government of the United States 2000, p. 3), although they have been reported living up to 14 years (Gallon 2012, p. 69). Females lay about 50 to 100 eggs, 5 to 6 months after mating (Nanayakarra 2014a, p. 79; Gabriel 2011b, entire; Gabriel 2005, p. 101). In captivity, generation time appears to be roughly 2–3 years (see Gabriel 2011b, entire; Gabriel 2006, p. 96; Gabriel 2005, entire). While captive individuals provide some indication of potential growth, longevity, and reproductive capacity of wild individuals, these variables are likely to vary with conditions in the wild. *Poecilotheria* are ectotherms and, as such, their physiological and developmental processes including growth and reproduction are strongly influenced by body temperature and it is likely that captive-rearing of these species is primarily done under ideal environmental conditions for reproduction and growth.

Unlike most tarantulas, which are solitary, most *Poecilotheria* species display a degree of sociality. Adult females often share their retreat with their spiderlings. Eventually as the young mature, they disperse to find denning areas of their own. Occasionally young remain on their natal tree to breed, or three to four adult females will share the same retreat (Nanayakkara 2014a, pp. 74, 80). These semi-social behaviors are believed to be a response to a lack of availability of suitable habitat (trees) in which individuals can reside (Nanayakkara 2014a, pp. 74, 80; Gallon 2000, unpaginated).

Poecilotheria Habitat

Microhabitat

Poecilotheria occupy preexisting holes or crevices in trees or behind loose tree bark (Molur *et al.* 2006, p. 31; Samarawckrama *et al.* 2005; Molur *et al.* 2003 unpaginated; Kirk 1996, pp. 22–23). Individuals of some species are also occasionally found in grooves or crevices in or on other substrates such as rocks or buildings that are close to wooded areas (Samarawckrama *et al.* 2005, pp. 76, 83; Molur *et al.* 2003, unpaginated). In a survey in Sri Lanka, 89 percent (31) of *Poecilotheria* spiders were found in or on trees, while 11 percent (4) were found in or on buildings (Samarawckrama *et al.* 2005, p. 76). *Poecilotheria* species are said to have a preference for residing in old, established trees with naturally occurring burrows (Nanayakkara 2014a, p. 86). Some species also appear to prefer particular tree species (Nanayakkara 2014a, p. 84; Samarawckrama *et al.* 2005, p. 76).

Macrohabitat

Most *Poecilotheria* species occur in forested areas, although some occasionally occur in other treed habitats such as plantations (Nanayakkara 2014a, p. 86; Molur *et al.* 2006, p. 10; Molur et al 2003, entire; Smith *et al.* 2001, entire). *Poecilotheria* are less abundant in degraded forest (Molur *et al.* 2004, p. 1665). Less complex, degraded forests may contain fewer trees that provide adequate retreats for these species and less cover for protection from predators and the elements. Trees with broad, dense canopy cover likely provide *Poecilotheria* in hotter, dryer habitats protection from heat and desiccation (Siliwal 2008, pp. 12, 15). We provide additional, species-specific information on habitat below.

Sri Lanka

Sri Lanka is an island nation about 65,610 square kilometers (km^2) (25,332 square miles (mi^2)) in area (Weerakoon 2012, p. xvii), or about the size of West Virginia (Fig. 1). The variation in topography, soils, and rainfall on the island has resulted in a diversity of ecosystems with high levels of species endemism (Government of Sri Lanka (GOSL) 2014, pp. xiv–xv). Sri Lanka, together with the Western Ghats of India, is identified as a global biodiversity hotspot, and is among the eight ''hottest hotspots,'' (Myers *et al.* 2000, entire).

Sri Lanka consists of a mountainous region (central highlands), reaching 2,500 meters (8,202 feet) in elevation, in

the south-central part of the island surrounded by broad lowland plains (GOSL 2012, p. 2a–3–141) (Fig. 2). The country has a tropical climate characterized by two major monsoon periods: the southwest monsoon from May to September and the northeast monsoon from December to February (GOSL 2012, pp. 7–8).

Sri Lanka's central highlands create a rain shadow effect that gives rise to two pronounced climate zones—the wet zone and dry zone—and a less extensive intermediate zone between the two (Ministry of Environment–Sri Lanka (MOE) 2010, pp. 21–22) (Fig. 2). Small arid zones also occur on the northwestern and southeastern ends of the country (Nanayakkara 2014a, p. 22). Annual rainfall ranges from less than 1,000 millimeters (mm) (39.4 inches (in)) in the arid zone to over 5,000 mm (197 in) in the wet zone of the central highlands (Jayatillake *et al.* 2005, pp. 66–67). Mean annual temperature ranges from 27 degrees Celsius (°C) (80.6 degrees Fahrenheit (°F)) in the lowlands to 15 °C (59 ;°F) in the highlands (Eriyagama *et al.* 2010, p. 2).

The wet zone is located in the southwestern quarter of the island, where high annual rainfall is maintained throughout the year by rain received during both monsoons and during inter-monsoonal periods (MOE 2010, pp. 21–22) (Fig. 2). The wet zone is divided into low, mid, and montane regions based on altitude. The dry zone, in which most of the land area of Sri Lanka occurs, is spread over much of the lowland plains and is subjected to several months of drought (MOE 2010, pp. 21–22) (Fig. 2). Most of the rain in this zone comes from the northeast monsoon and inter-monsoonal rains (MOE 2010, pp. 21–22; Malgrem 2003, p. 1236). Characteristic forest types occur within each of the different climate zones.

Species-Specific Information

Each of the five species addressed in this finding is endemic to Sri Lanka and has a range restricted to a particular region and one or two of Sri Lanka's climate zones (Nanayakkara 2014a, pp. 84–85) (Fig. 1, Fig. 2). Due to their secretive and nocturnal habits, sensitivity to vibrations, and their occurrence in structurally complex habitat (forest), *Poecilotheria* species are difficult to detect (Molur *et al.* 2003, unpaginated). Therefore, reported ranges are possibly smaller than the actual ranges of these species. However, surveys for these species were conducted at many locations throughout the country during 2009–2012 by Nanayakkara *et al.* (2012, entire), and we consider the locations reported in Nanayakkara (2014a, entire) to reflect the best available information concerning the ranges of these species.

Historical ranges for the five species addressed in this rule are unknown. Further, information on species abundance or population dynamics is not available on any of the five species; therefore, population trends are unknown. However, based upon the multitude of threats acting on these species, especially extensive and ongoing habitat loss and degradation, experts believe populations are declining, and that these species are very likely to go extinct within the next two or three decades (Nanayakkara and Adikaram 2013, p. 54). We are not aware of any existing conservation programs for these species. All five species are categorized on the National Red List of Sri Lanka as Endangered or Critically Endangered based on their area of occupancy (Critically Endangered: less than 10 km^2; Endangered: less than 500 km^2) and distribution (Critically Endangered: severely fragmented or known to exist at only a single location; Endangered: severely fragmented or known to exist at no more than five locations), and the status (continuing decline, observed, inferred or projected, in the area, extent, or quality, or any combination of the three) of their habitat (MOE 2012, p. 55; IUCN 2001, entire).

For locations discussed in species-specific information below, see Fig. 1. For locations of the ranges of the different species, see Fig. 2.

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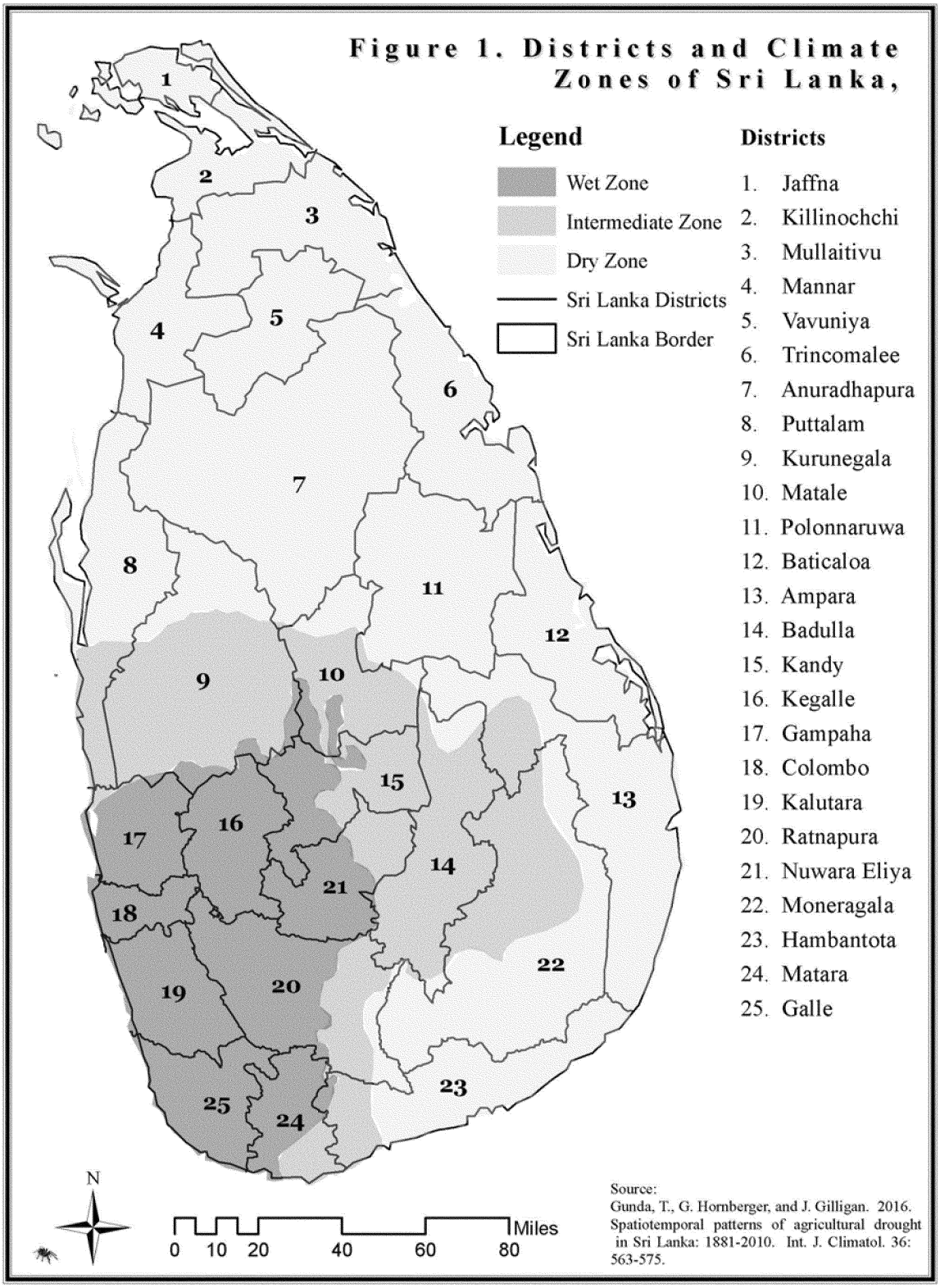
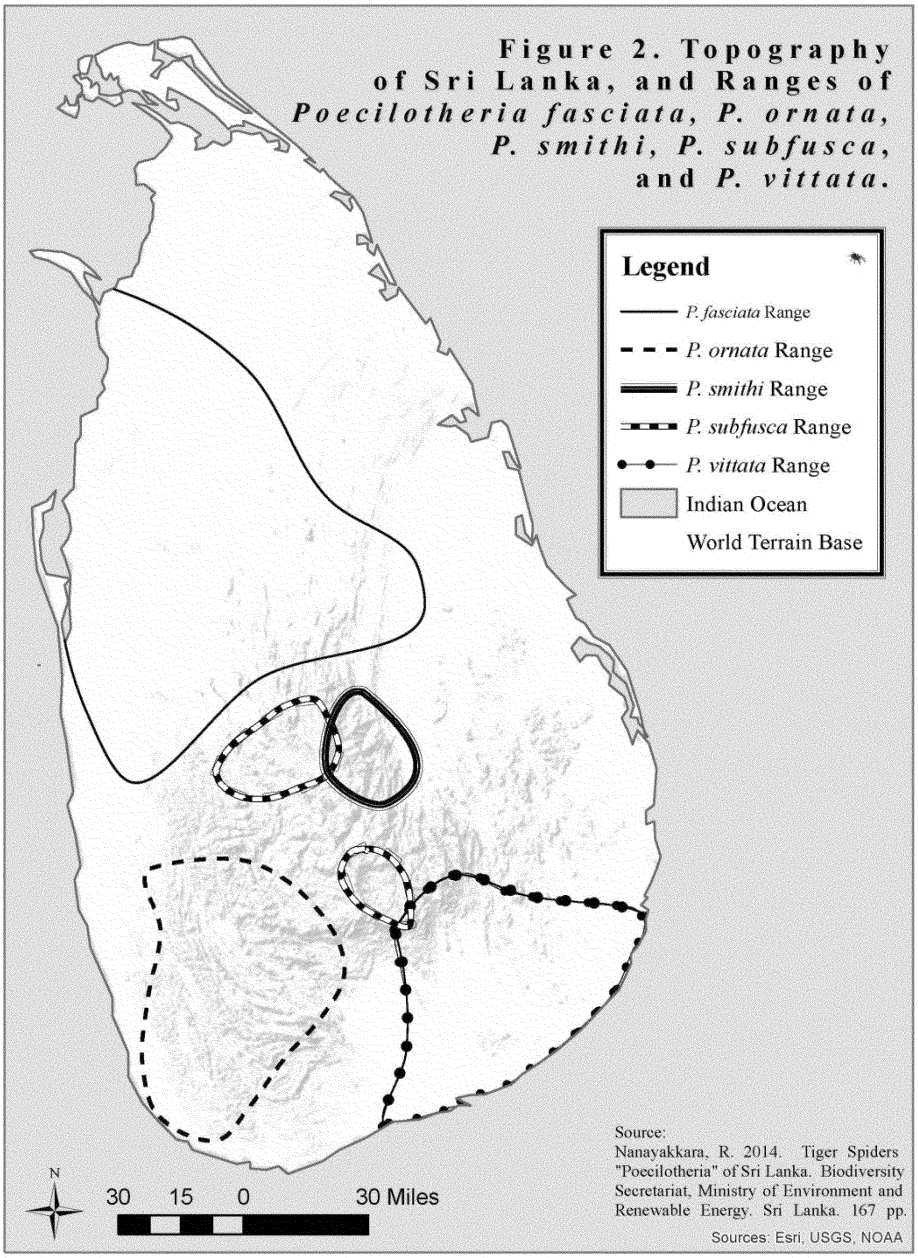


Figure 1. Districts and Climate Zones of Sri Lanka,
Legend
Wet Zone
Intermediate Zone
Dry Zone
Sri Lanka Districts
Sri Lanka Border
Districts
1. Jaffna
2. Killinochchi
3. Mullaitivu
4. Mannar
5. Vavuniya
6. Trincomalee
7. Anuradhapura
8. Puttalam
9. Kurunegala
10. Matale
11. Polonnaruwa
12. Baticaloa
13. Ampara
14. Badulla
15. Kandy
16. Kegalle
17. Gampaha
18. Colombo
19. Kalutara
20. Ratnapura
21. Nuwara Eliya
22. Moneragala
23. Hambantota
24. Matara
25. Galle
N
0 10 20 40 60 80 Miles
Source:
Gunda, T., G. Hornberger, and J. Gilligan. 2016. Spatiotemporal patterns of agricultural drought in Sri Lanka: 1881-2010. Int. J. Climatol. 36: 563-575.



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P. fasciata

Poecilotheria fasciata occurs in forests below 200-m elevation in Sri Lanka's dry and intermediate zones north of Colombo and is also sometimes found in coconut plantations in this region (Nanayakkara 2014a, p. 96; Nanayakkara 2014b, unpublished data; Smith *et al.* 2001, entire). The species has a broad but patchy distribution and is estimated to occupy less than 500 km^2 (193 mi^2) of its range (MOE 2012, p. 55; Smith *et al.* 2001, p. 48). The area, extent, or quality (or a combination thereof) of *P. fasciata*'s habitat is in continuing decline, and the species is categorized on the National Red List of Sri Lanka as Endangered (MOE 2012, p. 55).

The only detailed record of the species' occurrence is provided by Smith *et al.* (2001, entire), where *Poecilotheria fasciata* colonized a coconut plantation following a prolonged drought. While *P. fasciata* in dry and intermediate zone forests, including those surrounding the coconut plantation, were found to be emaciated and without spiderlings, those in the irrigated plantation were found to have spiderlings in their retreats and wider abdomens. Smith *et al.* argue that *P. fasciata* was able to colonize the plantation due to the occurrence of *P. fasciata* in the adjacent remnant forest, the presence of coconut trees that were infested with weevils and subsequently fed on by woodpeckers that created holes suitable for *P. fasciata* retreats, and plantation irrigation that resulted in an abundant prey base for the species. The *P. fasciata* population in the plantation was apparently established in the 1980s and persisted until at least 2000 (Smith *et al.* 2001, pp. 49, 52).

During recent surveys, *P. fasciata* were detected at nine locations—two in coconut plantations and seven in forest locations. Greater than 20 adults and 100 juveniles were found in coconut plantations, and greater than 30 adults and no juveniles were found in forest locations (Nanayakkara 2014b, unpublished data). Although no

juveniles were detected in forest habitats during these surveys, recent observations of *P. fasciata* juveniles in forest habitat have been reported (Nanayakkara 2014a, p. 96; Kumarasinghe *et al.* 2013, p. 10). Therefore, based on the observations of Smith *et al.* described above, it is possible that the lack of juveniles detected in forests during recent surveys was due to drought conditions during the survey period. As indicated above, island-wide surveys for *Poecilotheria* were conducted during 2009–2012, and droughts occurred in 2010 and 2012 in the region in which *P. fasciata* occurs (Integrated Regional Information Network 2012, unpaginated; Disaster Management Center, Sri Lanka 2010, p. 12). However, while juveniles were detected only in coconut plantations during these surveys, numbers found in coconut and forest habitat cannot be directly compared because surveys were designed for determining distribution rather than species abundance or density. For instance, juveniles may be more difficult to detect in forest habitat than in coconut plantations, or a greater area of coconut plantations may have been searched compared to forest habitat.

P. ornata

Poecilotheria ornata is found in the plains and hills of the lowland wet zone in southwestern Sri Lanka (Nanayakkara 2014a, pp. 112–113; Smith *et al.* 2002, p. 90). It is one of the few solitary species in the genus (Nanayakkara 2014a, p. 112). In recent surveys, 23 adults and no juveniles were detected at 4 locations (Nanayakkara 2014b, unpublished data). *Poecilotheria ornata* is estimated to occupy less than 500 km² (193 mi²) of its range (MOE 2012, p. 55), and the area, extent, or quality (or a combination thereof) of the species' habitat is in continuing decline. *Poecilotheria ornata* is categorized on the National Red List of Sri Lanka as Endangered (MOE 2012, p. 55).

P. smithi

Poecilotherai smithi is found in the central highlands, in Kandy and Matale districts (Nanayakkara *et al.* 2013, pp. 73–74). It was originally found in the wet zone at mid elevations (Kirk 1996, p. 23), although it is described as a montane species (Jacobi 2005, entire; Smith *et al.* 2002, p. 92). *Poecilotheria smithi* appears to be very rare (Nanayakkara *et al.* 2013, p. 73; Gabriel *et al.* 2005, p. 4) and is considered ''highly threatened'' (Nanayakkara *et al.* 2013, p. 73). The species was described in 1996, and, despite several efforts to locate the species during the past 20 years, few individuals have been found (Nanayakkara *et al.* 2013, pp. 73–74; Gabriel *et al.* 2005, pp. 6–7). In 2005, three adult females and four spiderlings were reported in the Haragama, Kandy district, an area described as severely impacted by several anthropogenic factors (Nanayakkara *et al.* 2013, p. 74; Gabriel *et al.* 2005, pp. 6–7). During surveys conducted in several areas of the country during 2003–2005, no *P. smithi* were found (Samarawckrama *et al.* 2005, entire). Finally, during recent surveys, the species was found at two locations with seven adults and nine juveniles detected (Nanayakkara 2014b, unpublished data). Prior to these recent surveys, the species was known only from the Haragama, Kandy district. However, the species was recently found about 31 km (19.3 mi) away from Haragama, in three trees within a 5-km² (1.9-mi²) area of highly disturbed habitat (Nanayakkara *et al.* 2013, p. 74).

Poecilotheria smithi was estimated to occupy less than 10 km² (3.9 mi²) of its range (MOE 2012, p. 55) but a recently reported location in Matale district increases the known area of occupancy by 5 km² (1.9 mi²). The area, extent, or quality (or a combination thereof) of the species' habitat is considered to be in continuing decline, and the species is categorized on the National Red List of Sri Lanka as Critically Endangered (MOE 2012, p. 55).

P. subfusca

Poecilotheria subfusca occurs in the wet zone of the central highlands of Sri Lanka, in two disjunct regions: the montane region above 1,500-m elevation in Nuwara Eliya and Badulla districts; and at 500 to 600 m (1,640 to 1,968 ft) elevation in Kegalla, Kandy, and Matale districts (Nanayakkara 2014a, pp. 101–102, 116; Smith *et al.* 2002, entire).

During recent surveys, *P. subfusca* was found at 10 locations, and a total of 25 adult and 56 juvenile *P. subfusca* were detected (Nanayakkara 2014b, unpublished data). The area of the range occupied by *P. subfusca* is less than 500 km² (193 mi²) (MOE 2012, p. 55). Further, the area, extent, or quality (or a combination thereof) of *P. subfusca*'s habitat is in continuing decline throughout its range, and the species is categorized on the National Red List of Sri Lanka as Endangered (MOE 2012, p. 55).

P. vittata

Poecilotheria vittata occurs in the arid, dry, and intermediate zones of Hambantota and Monaragala districts in southeastern Sri Lanka (Kekulandala and Goonatilake 2015, unpaginated; Nanayakkara 2014a, pp. 106–107). The species' preferred habitat is *Manilkara hexandra* (Palu) trees (Nanayakkara 2014a, p. 106), a dominant canopy tree species in Sri Lanka's dry forest (Gunarathne and Perera 2014, p. 15). In recent surveys, the species was found at 4 locations, and 15 adults and 7 juveniles of *P. vittata* were detected (Nanayakkara 2014b, unpublished data). *Poecilotheria vittata* is estimated to occupy less than 500 km² (193 mi²) of its range (MOE 2012, p. 55), and the area, extent, or quality (or a combination thereof) of the species' habitat is considered to be in continuing decline. *Poecilotheria vittata* is categorized on the National Red List of Sri Lanka as Endangered (MOE 2012, p. 55).

Summary of Biological Status and Threats

The Act directs us to determine whether any species is an endangered species or a threatened species because of any one or more of five factors or the cumulative effects thereof: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) Overutilization for commercial, recreational, scientific, or educational purposes; (C) Disease or predation; (D) The inadequacy of existing regulatory mechanisms; or (E) Other natural or manmade factors affecting its continued existence. In this section, we summarize the biological condition of the species and its resources, and the influences on these to assess the species' overall viability and the risks to that viability.

Habitat Loss and Degradation

Habitat loss and degradation are considered primary factors negatively affecting *Poecilotheria* species (Nanayakkara and Adikaram 2013, pp. 53–54; MOE 2012, p. 55; Molur *et al.* 2008, pp. 1–2). Forest loss and degradation are likely to negatively impact the five species addressed in this rule in several ways. First, forest loss and degradation directly eliminate or reduce the availability of trees required by *Poecilotheria* species for reproduction, foraging, and protection (Samarawckrama *et al.* 2005, p. 76; Smith *et al.* 2002, entire). Second, due to the limited ability of *Poecilotheria* species to travel, as well as their sedentary habits, forest loss and degradation are also likely to result in direct mortality of individuals or populations, via physical trauma caused by the activities that result in forest loss and degradation, or the intentional killing of these spiders when they are encountered by humans during these activities (see *Intentional Killing*). Such mortality affects these species'

abundances and distributions, and also their genetic diversity. Tarantulas have highly structured populations (See *Tarantula General Biology*) and, consequently, the loss of a local population of a species—due to habitat loss or any other factor—equates to a loss of unique genetic diversity (Bond *et al.* 2006, p. 154, citing several sources). Finally, the loss of forest also often results in fragmented habitat. Due to the limited dispersal ability of these species, forest fragmentation is likely to isolate *Poecilotheria* populations, which increases their vulnerability to stochastic processes (see *Stochastic Processes*), and may also expose wandering males and dispersing juveniles to increased mortality from intentional killing or predation when they attempt to cross between forest fragments (Bond *et al.* 2006, p. 155) (see *Intentional Killing*).

Deforestation

Forests covered almost the entire island of Sri Lanka a few centuries ago (Mattsson *et al.* 2012, p. 31). However, extensive deforestation occurred during the British colonial period (1815–1948) as a result of forest-clearing for establishment of plantation crops such as tea and coffee, and also exploitation for timber, slash-and-burn agriculture (a method of agriculture in which natural vegetation is cut down and burned to clear the land for planting), and land settlement. In 1884, about midway through the British colonial period, closed-canopy (dense) forest covered 84 percent of the country and was reduced to 44 percent by 1956 (GOSL 2012, p. 2a-3–145; Nanayakkara 1996, in Mattson *et al.* 2012, p. 31). Deforestation continued after independence as the result of timber extraction, slash-and-burn agriculture, human settlements, national development projects, and encroachment (GOSL 2012, pp. 2a-3–144–145; Perera *et al.* 2012, p. 165). As a result, dense forest cover (canopy density greater than 70 percent) declined by half in about 50 years, to 22 percent in 2010 (GOSL 2012, pp. 51, 2a-3–145; Nanayakkara 1996, in Mattson *et al.* 2012, p. 31). Open-canopy forest (canopy density less than 70 percent) covered an additional 6.8 percent of the country in 2010 for an overall forest cover of 28.6 percent (GOSL 2012, p. 51).

The extent of deforestation differed in the three climate zones of the country. The impacts of anthropogenic factors on forests in the wetter regions of the island have been more extensive due to the higher density of the human population in these regions. The human population density in the wet zone is 650 people per km² (1,684 per mi²) compared to 170 people per km² (440 per km²) in the dry zone and 329 per km² (852 per mi²) nationally (GOSL 2012, p. 8). Currently about 13 percent of the wet zone, 15 percent of the intermediate zone, and 29 percent of the dry zone are densely forested (Table 1).

Recent information on forest cover in the different climate zones is provided in three reports (GOSL 2015, GOSL 2012, and FAO 2015a), all of which provide information from the Forest Department of Sri Lanka. One report (GOSL 2015) provides a map of the change in forest cover between 1992 and 2010 and a qualitative assessment of these changes. The others (GOSL 2012 and FAO 2015a) provide quantitative information on the area of forest cover by forest type for 1992, 1999, and 2010. These latter two reports differ slightly in their presentation of information but contain identical data on natural forest cover. However, the Forest Department of Sri Lanka used different rainfall criteria to separate dry and intermediate zone forests, and different altitude criteria to separate montane and submontane forests, in different years (see climate zone and forest definitions in FAO 2015a, p. 6; GOSL 2012, p. 51; FAO 2005, p. 7; FAO 2001, pp. 16, 53). Therefore, we combined the information on intermediate and dry zone forests, and the information on montane and submontane forests (see 81 FR 90307, Table 4). We discuss the information on forest cover from the various sources by climate zone below.

Wet Zone Forest

Wet zone forests in Sri Lanka are categorized as montane, submontane, or lowland forest, based on elevation. Very little wet zone forest remains in Sri Lanka. Currently, montane and submontane forests combined covers only about 733 km² (283 mi²) and is severely fragmented (GOSL 2012, pp. 51, 2a-3–142). The area remained relatively stable from 1992 to 2010 (81 FR 90307; GOSL 2012, p. 51). More recent evidence indicates these forests are currently declining: firewood collection, cutting of trees for other domestic purposes, and gem mining are ongoing in these forests, and large areas were recently illegally cleared for vegetable cultivation (Wijesundara 2012, p. 182). While these forests are protected in Sri Lanka, administering agencies do not have sufficient resources to prevent these activities (Wijesundara 2012, p. 182).

The area of lowland wet zone forests (lowland rainforest) declined from 1992 to 2010. Remaining lowland rainforests are severely fragmented, exist primarily as small, isolated patches, and declined by 13% (183 km²)(71 mi²)) during the 18-year period, though the rate of loss slowed considerably during the latter half of this period (81 FR 90307, Table 4; GOSL 2012, p. 2a-3–142; Lindstrom *et al.* 2012, p. 681). Changes in forest cover show low levels of deforestation throughout the lowland rainforest region from 1992 to 2010, and a deforestation ''hotspot'' on the border of Kalutara and Ratnapura districts, which is within the range of *P. ornata* (Fig. 1, Fig. 2) (GOSL 2015, unpaginated).

Dry and Intermediate Zone Forests

Dry and intermediate zone forests, which include most open-canopy forest (Mattsson *et al.* 2012, p. 30), declined by 8% (1,372 km² (530 mi²)) between 1992 and 2010 (81 FR 90307, Table 4). The rate of deforestation nationwide during this period was highest in Anuradhapura and Moneragala districts, in which large portions of the ranges of *P. fasciata* and *P. vittata* occur (see Fig. 1, Fig. 2) (GOSL 2015, unpaginated). Further, deforestation hotspots have been found in other districts where these species occur, including Puttalam and Hambantota (GOSL 2015, unpaginated). Natural regeneration of dry forest species is poor, and dry zone forests are heavily degraded as a result of activities such as frequent shifting cultivation and timber logging (Perera 2012, p. 165, citing several sources).

TABLE 1—THE TOTAL AREA OF SRI LANKA'S CLIMATE ZONES, AND THE COVERAGE OF DENSE FOREST (CANOPY COVER GREATER THAN 70 PERCENT) WITHIN EACH ZONE IN 2010, BASED ON INFORMATION PROVIDED IN 81 FR 90302, TABLE 2 AND GOSL 2012, P. 51

Climate zones of Sri Lanka	Area [1] (km^2)	Area covered with dense (canopy cover greater than 70 percent) closed-canopy forest in 2010 (km^2)	Proportion (percent) with dense forest [2]
Wet Zone	15,090	1,966	13
Intermediate Zone	7,873	1,179	15
Dry Zone	39,366	[3] 11,238	29
Arid Zone	3,281	.....	.....

[1] Calculated based on proportion of land area in each climate zone as provided in 81 FR 90302, Table 2, and a total land area of 65,610 km^2.
[2] Original extent of forest cover is unknown. However, each zone was likely close to 100% forested because dense forest covered 84% of the island in 1884, following several decades of deforestation.
[3] Figure is for dry monsoon forest and riverine forest. It does not include mangrove forests.

Forest Conservation Measures

Sri Lanka has taken steps in recent decades to conserve its forests, and these efforts have contributed to the slowing of deforestation in the country (GOSL 2012, pp. 54–55). In 1990, the country imposed a moratorium on logging in all natural forests, marked most reserve boundaries to stem encroachments, and implemented management plans for forest and wildlife reserves, which became legal requirements under the Forest Ordinance Amendment Act No. 65 of 2009 and the Fauna and Flora Ordinance Amendment Act No. 22 of 2009 (GOSL 2014, p. 26). The government also encourages community participation in forest and protected area management, has implemented programs to engage residents in community forestry to reduce encroachment of cash crops and tea in the wet zone and slash-and-burn agriculture in the dry zone, and encourages use of non-forest lands and private woodlots for meeting the demands for wood and wood products (GOSL 2014, p. 26). In addition to these efforts, between 12 percent (GOSL 2015, unpaginated) and 28 percent (GOSL 2014, pp. xvi, 23) of the country's land area is reported to be under protected area status.

Although considerable efforts have been undertaken in Sri Lanka in recent years to stop deforestation and forest degradation, these processes are ongoing (see Current and Future Forest Trends). The assessment of the status of natural forests during the Species Red List assessments in 2012 indicate that, despite advances in forest conservation in the country, many existing threats continue to impact forest habitats (GOSL 2014, p. 26). While laws and regulations are in place to address deforestation, several factors inhibit their implementation (GOSL 2012, pp. 55, 2a-3–148–150). For instance, lack of financial assistance for protected area management, increasing demand for land, and unplanned, after-the-fact legalization of land encroachments, result in further loss of the forest habitat of the five species addressed in this finding (GOSL 2014, p. 22; GOSL 2011, unpaginated). Also, government agencies have poor coordination with respect to forest conservation—conservation agencies are not always adequately consulted on initiatives to develop forested land (GOSL 2014, p. 22; MOE 2010, p. 31). Finally, many protected areas within the wet zone are small, degraded, and isolated (GOSL 2014, p. 31).

Current and Future Forest Trends

The current drivers of deforestation and forest degradation in Sri Lanka include a variety of factors such as small-scale encroachments, illicit timber harvesting, forest fires, destructive mining practices, and clearing of forest for developments, settlements, and agriculture (GOSL 2012, p. 12). These stressors are exacerbated by a large, dense human population that is projected to increase from 20.7 million in 2015 to 21.5 million in 2030 (United Nations 2015, p. 22). While the majority of remaining forested areas are protected, further population growth is likely to result in reduction of forested areas because (1) Sri Lanka already has a very high human density (329 people per km^2 (852 per mi^2)), (2) increases in the population will elevate an already high demand for land, and (3) little non-forested land is available for expansion of housing, development, cash crops, or subsistence agriculture (GOSL 2012, pp. 8, 14, 58). Most (72%) of the population of Sri Lanka is rural, dependence on agriculture for subsistence is widespread, and the rate of population growth is higher in rural areas. This results in an increasing demand in the country for land for subsistence (Lindstrom *et al.* 2012, p. 680; GOSL 2011, unpaginated).

The current drivers of deforestation and forest degradation are exacerbated by high economic returns from illicit land conversions, lack of alternative livelihood opportunities for those practicing slash-and-burn agriculture and, in the dry zone, poverty and the weak implementation of land-use policy (GOSL 2012, pp. 14–15). Further, in the 30 years prior to 2009, Sri Lanka was engaged in a civil war, which was fought primarily in the dry zone of the northern and eastern regions of the country, many areas of which were inaccessible. The war, along with a reduced rate of development in the country as a whole during this period, may have helped limit deforestation rates (GOSL 2012, pp. 48, 56–57).

Overall, deforestation and forest degradation in Sri Lanka are ongoing, although recent rates of deforestation are much lower than during the mid- to late-20th century—the rate of deforestation during 1992–2010 was 71 km^2 (27.4 mi^2) per year, compared to 400 km^2 (154 mi^2) per year during 1956–1992 (GOSL 2015, unpaginated). However, since the end of Sri Lanka's civil war in 2009, the government has been implementing an extensive 10-year development plan with the goal of transforming the country into a global economic and industrial hub (Buthpitiya 2013, p. ii; Central Bank of Sri Lanka 2012, p. 67; Ministry of Finance and Planning–Sri Lanka (MOFP) 2010, entire). The plan includes large infrastructure projects throughout the country (MOFP 2010, entire). Projects include, among other things, development of seaports, airports, expressways, railways, industrial parks, power plants, and water management systems that will allow for planned

expansion of agriculture, and many of these projects have already started (Buthpitiya 2013, pp. 5–6; Central Bank of Sri Lanka 2012, p. 67; MOFP 2010, entire). They also include projects located within the ranges of all five species addressed in this finding, although the plan does not provide the amount of area that will be impacted by these projects (Fig. 2 and MOFP 2010, pp. 63, 93, 101, 202–298). For example, a new dam project within the range of *P. smithi* will submerge one of the two sites at which the species is found (Nanayakkara 2017, unpaginated). The rate of loss of natural forest (primary forest and other naturally regenerated forest) increased from 60 km² (23 mi²) per year during 2000–2010 to 86 km² (33 mi²) per year during 2010–2015 (FAO 2015b, pp. 44, 50). As post-war reconstruction and development continues in Sri Lanka, deforestation and forest degradation can be expected to rise (GOSL 2012, p. 2a–3–146).

Coconut Plantations

Coconut is grown throughout Sri Lanka. Most (57 percent) of the area under coconut cultivation is in the intermediate and wet zones north of Colombo (MOE 2011, p. 14), which overlaps with the southern portion of the range of *P. fasciata.* As indicated above, *P. fasciata* are sometimes found in coconut plantations in Sri Lanka, although the extent to which coconut plantations contribute to sustaining viable populations of these species is unknown. The ability of coconut plantations to contribute to conservation of *P. fasciata* is limited because: (1) Tarantulas are poor dispersers (see *Tarantula General Biology*); (2) colonization of coconut plantations by the species appears to depend on the occurrence of occupied natural forest in relatively close proximity to coconut plantations (Smith *et al.* 2001, entire); and (3) very little natural forest remains in the coconut-growing region in which *P. fasciata* occurs (Fig. 2 and GOSL 2015, unpaginated; MOE 2014, p. 94).

The aerial extent of coconut cultivation in Sri Lanka has varied between about 3,630 and 4,200 km² (1,402 and 1,622 mi²) since 2005 (Central Bank of Sri Lanka 2014, Statistical Appendix, Table 13), with no clear directional trend. However, due to the rising human population and resulting escalating demand for land in Sri Lanka, plantations have become increasingly fragmented due to conversion of these lands to housing (GOSL 2014, pp. 26–27). As indicated above, due to their limited dispersal ability, forest fragmentation is likely to isolate *Poecilotheria* populations, which increases their vulnerability to stochastic processes (see *Stochastic Processes*), and may also expose wandering males and dispersing juveniles to increased mortality from intentional killing or predation when they attempt to cross between forest fragments (Bond *et al.* 2006, p. 155) (see *Intentional Killing*). Thus, even though *P. fasciata* uses coconut plantations to some extent, fragmentation of this habitat is likely to isolate populations and increase their vulnerability to stochastic processes, intentional killing, and predation.

Summary

Sri Lanka has lost most of its forest cover due to a variety of factors over the past several decades. Very little (1,966 km² (759 mi²)) wet zone forest—in which the ranges of *P. ornata, P. smithi,* and *P. subfusca* occur—remains in the country. The remainder is highly fragmented and continues to be deforested. Only about 35 percent (16,872 km² (6,514 mi²)) of dense and open canopy dry and intermediate zone forests—in which the ranges of *P. fasciata* and *P. vittata* occur—remain, deforestation in these forests is ongoing, and recent rates of deforestation in the country have been highest in regions constituting large portions of the ranges of these two species. Forest cover continues to decline at a rate of 86 km² (33 mi²) per year, and the rate of loss is higher in the dry zone than the wet zone. While the current rate of forest loss is much lower than in the previous century, the rate of loss of natural forest is increasing and is anticipated to increase in the future with the country's emphasis on development and the projected population increase of 800,000 people. While coconut plantations provide additional habitat for one species (*P. fasciata*) in some areas, these plantations are becoming increasingly fragmented due to demand for housing.

Tarantulas have sedentary habits, limited dispersal ability, and highly structured populations. Therefore, loss of habitat has likely resulted in direct loss of individuals or populations and, consequently, a reduction in the distribution and genetic diversity of these species. The distribution of these species is already limited—each currently occupies less than 500 km² (193 mi²) or, for *P. smithi,* less than 10 to 15 km² (3.9 to 5.8 mi²) of its range—and deforestation continues within the ranges of all five species discussed in this finding. Further, the limited distribution of these species is likely continuing to decline with ongoing loss of habitat. We conclude that habitat loss is likely currently having significant negative impacts on the viability of these species because: (1) These species have very small distributions; (2) little forest remains in Sri Lanka; (3) remaining habitat is fragmented; and (4) deforestation is ongoing within these species' ranges.

Pesticides

Pesticides are identified as a threat to *Poecilotheria* species in Sri Lanka (Nanayakkara 2014b, unpublished data; Gabriel 2014, unpaginated). The five species addressed in this finding could potentially be exposed to pesticides via pesticide drift into forests that are adjacent to crop-growing areas; by traveling over pesticide-treated land when dispersing between forest patches; or by consuming prey that have been exposed to pesticides. Populations of these species could potentially be directly affected by pesticides through increased mortality or through sublethal effects such as reduced fecundity, fertility, and offspring viability, and changes in sex ratio, behavior, and dispersal (Nash *et al.* 2010, p. 1694, citing several sources). *Poecilotheria* species may also be indirectly affected by pesticides if pesticides reduce or deplete available prey species.

Over 100 pesticide (herbicide, fungicide, and insecticide) active ingredients are registered for use in Sri Lanka. Among the most commonly used insecticides are carbofuran, diazinon, and chloropyrifos (Padmajani *et al.* 2014, pp. 11–12). These are broad-spectrum, neurotoxic insecticides, which tend to have very negative effects on nontarget organisms (Pekar 2013, p. 415). Further, sit-and-wait predators appear to be more sensitive to insecticide applications than web-making spiders (Pekar 1999, p. 1077).

The use of pesticides in Sri Lanka has been increasing steadily since the 1950s (Selvarajah and Thiruchelvam 2007, p. 381). Pesticide imports into Sri Lanka increased by 50 percent in 2011 compared to 2006 (Padmajani *et al.* 2014, p. 11). The level of misuse and overuse of pesticides in Sri Lanka is high. Depending on region and crop species, 33 to 60 percent of Sri Lankan farmers use greater amounts, higher concentrations, or more frequent applications of pesticides (or a combination of these) than is recommended (Padmajani *et al.* 2014, pp. 13, 31, citing several sources).

The susceptibility of spiders to the direct effects of different pesticides varies with pesticide type and formulation, spider species, development stage, sex, and abiotic and biotic conditions at the time of pesticide

application (Pekar 2013, pp. 416–417). Further, different classes of pesticides can cause different sublethal effects. For instance, activities such as movement, prey capture, reproduction, development, and defense are particularly disrupted by neurotoxic formulations because they are governed by complex neural interactions. However, spiders can potentially recover from sublethal effects over several days (Pekar 2013, p. 417), although the effects are complicated by the potential for cumulative effects of multiple applications across a season (Nash *et al.* 2010, p. 1694).

We are not aware of any information on the population-level effects of pesticides on *Poecilotheria* species. However, given the large proportion of Sri Lanka's human population that is reliant on farming, the high level of misuse and overuse of pesticides in the country, and the broad-spectrum and high level of toxicity of the insecticides commonly used in the country, it is likely that the species addressed in this finding are directly or indirectly negatively affected by pesticides to some extent. Therefore, while the population-level effects of pesticides on the five species addressed in this finding are uncertain, the effects of pesticides likely exacerbate the effects of other threats acting on these species.

Climate Change

The Intergovernmental Panel on Climate Change (IPCC) concluded that warming of the climate system is unequivocal (IPCC 2013, p. 4). Numerous long-term climate changes have been observed including changes in land surface temperatures, precipitation patterns, ocean temperature and salinity, sea ice extent, and sea level (IPCC 2013, pp. 4–12). Various types of changes in climate can have direct or indirect effects on species. These effects may be positive, neutral, or negative and they may change over time, depending on the species and other relevant considerations, such as the effects of interactions of climate with other variables (*e.g.,* habitat fragmentation) (IPCC 2007, pp. 8–14, 18–19). However, a large fraction of terrestrial and freshwater species face increased extinction risk under projected climate change during and beyond the current century, especially as climate change interacts with habitat modification and other factors such as overexploitation, pollution, and invasive species (Settele *et al.* 2014, p. 275).

Maintenance of body temperature and water retention by spiders is critical to their survival. All spiders, including *Poecilotheria,* are ectotherms; therefore, their body temperature varies with that of their environment. While spiders keep body temperature within tolerable limits through behaviors such as moving into shade when temperatures rise (Pulz 1987, pp. 27, 34–35), they are susceptible to rapid fluctuations in body temperature and severe depletion of body water stores due to their relatively low body mass and high surface-to-volume ratio (Pulz 1987, p. 27).

Tropical ectotherms evolved in an environment of relatively low inter- and intra-annual climate variability, and already live near their upper thermal limits (Settele *et al.* 2014, p. 301; Deutsch *et al.* 2008, p. 6669). Their capacity to acclimate is generally low. They have small thermal safety margins, and small amounts of warming may decrease their ability to perform basic physiological functions such as development, growth, and reproduction (Deutsch *et al.* 2008, pp. 6668–6669, 6671). Evidence also indicates they may have low potential to increase their resistance to desiccation (drying out) (Schilthuizen and Kellerman 2014, p. 61, citing several sources).

The general trend in temperature in Sri Lanka over the past several decades is that of increasing temperature, although with considerable variation between locations in rates and magnitudes of change (De Costa 2008, p. 87; De Silva *et al.* 2007, p. 21, citing several sources). Over the six to ten decades prior to 2007, temperatures have increased within all climate zones of the country, although rates of increase vary from 0.065 °C (0.117 °F) per decade in Ratnapura (an increase of 0.65 °C (1.17 °F) during the 97-year period analyzed) in the lowland wet zone, to 0.195 °C (0.351 °F) per decade in Anuradhapura (an increase of 1.50 °C (2.70 °F) during the 77-year period analyzed) in the dry zone. In the montane region, temperatures increased at a rate of 0.141 °C (0.254 °F) per decade at Nuwara Eliya to 0.191 °C (0.344 °F) per decade at Badulla (increases of 1.09 and 1.47 °C (1.96 and 2.65 °F) during the 77-year period analyzed, respectively) (De Costa 2008, p. 68). The rate of warming has increased in more recent years—overall temperature in the country increased at a rate of 0.003 °C (0.005 °F) per year during 1896–1996, 0.016 °C (0.029 °F) per year during 1961–1990, and 0.025 °C (0.045 °F) per year during 1987–1996 (Eriyagama *et al.* 2010, p. 2, citing several sources). Depending on future climate scenarios, temperatures are projected to increase by 2.93 to 5.44 °C (5.27 to 9.49 °F) by the end of the current century in South Asia (Cruz *et al.* 2007, in Eriyagama *et al.* 2010, p. 6). Downscaled projections for Sri Lanka using regional climate models report increases of 2.0 to 4.0 °C (3.6 to 7.2 °F) by 2100, while statistical downscaling of global climate models report increases of 0.9 to 3 °C (1.62 to 5.4 °F) by 2100 and 1.2 to 1.3 °C (2.16 to 2.34 °F) by 2050 (Eriyagama *et al.* 2010, p. 6, citing several sources).

Trends in rainfall have been decreasing in Sri Lanka over the past several decades (see De Costa 2008, p. 87; De Silva *et al.* 2007, p. 21, citing several sources) although, according to the Climate Change Secretariat of Sri Lanka (2015, p. 19), there is no consensus on this fact. However, authors appear to agree that the intensity and frequency of extreme events such as droughts and floods have increased (Imbulana *et al.* 2016 and Ratnayake and Herath 2005, in Climate Change Secretariat of Sri Lanka 2015, p. 19).

Rainfall in Sri Lanka is highly variable from year to year, across seasons and across locations within any given year (Jayatillake *et al.* 2005, p. 70). Statistically significant declines in rainfall have been observed for the period 1869–2007 at Anuradhapura in the northern dry zone (12.92 mm (0.51 in) per decade), and Badulla, Kandy, and Nuwara Eliya (19.16, 30.50, and 51.60 mm (0.75, 1.20, and 2.03 in) per decade, respectively) in the central highlands (De Costa 2008, p. 77). Significant declines have also been observed in more recent decades at Kurunegala in western Sri Lanka's intermediate zone (120.57 mm (4.75 in) per decade during 1970–2007) and Ratnapura (41.02 mm (1.61 in) per decade during 1920–2007) (De Costa 2008, p. 77). Further, a significant trend of decreasing rainfall with increasing temperature exists at Anuradhapura, Kurunegala, and Nuwara Eliya (De Costa 2008, pp. 79–81). Patterns of future rainfall in the country are highly uncertain—studies provide variable and conflicting projections (Eriyagama *et al.* p. 6, citing several sources). However, an increased frequency of dry periods and droughts are expected (MOE 2010, p. 35).

While observed and projected changes in temperature and precipitation could potentially be within the tolerance limits of the *Poecilotheria* species addressed in this finding, it is possible that climate change could directly negatively affect these species through rising land surface temperatures, changes in the amount and pattern of precipitation, and increases in the frequency and intensity of extreme climate events such as heat waves or

droughts. It is also possible that climate change could indirectly negatively affect these species by adversely impacting populations of their insect prey, which are also tropical ectotherms. The only detailed observations of a Sri Lankan *Poecilotheria* species indicated that *P. fasciata* found in natural forest were emaciated and without spiderlings during an extended drought, while those found in an irrigated plantation had wider girths and spiderlings (see *Species-Specific Information*) (Smith *et al.* 2001, entire). The lack of reproduction in natural forest during drought may have been due to desiccation stress or lack of available prey, or both, as a result of low moisture levels.

While at least one of the species addressed in this finding (*P. fasciata*) appears to be vulnerable to drought, the responses of the five *Poecilotheria* species to observed and projected climate change in Sri Lanka are largely unknown. However, the climate in Sri Lanka has already changed considerably in all climate zones of the country, and continues to change at an increasing rate. These species evolved in specific, relatively stable climates and, because they are tropical ectotherms, may be sensitive to changing environmental conditions, particularly temperature and moisture (Deutsch *et al.* 2008, pp. 6668–6669; Schilthuizen and Kellerman 2014, pp. 59–61, citing several sources). Moreover, because they have poor dispersal ability, *Peocilotheria* are unlikely to be able to escape changing climate conditions via range shifts. Therefore, while population-level responses of the five species addressed in this finding to observed and projected changes in climate are not certain, the stress imposed on these species by increasing temperatures and changing patterns of precipitation is likely exacerbating the effects of other factors acting on these species such as stochastic events and habitat loss and degradation. This is especially the case for *P. fasciata* because (1) the frequency and intensity of droughts have increased and are expected to continue increasing, (2) the species fails to reproduce in natural forest during extended droughts, and (3) although *P. fasciata* is also known to inhabit irrigated coconut plantations, most populations have been found in natural forest.

Trade

Poecilotheria species are popular in trade due to their striking coloration and large size (Nanayakkara 2014a, p. 86; Molur *et al.* 2006, p. 23). In 2000, concerned about increasing trade in these species, Sri Lanka and the United States co-sponsored a proposal to include the genus in Appendix II of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) (Government of Sri Lanka and Government of the United States 2000, entire). However, at the 11th Conference of the Parties, the proposal was criticized as containing too little information on international trade and on the limits of the distribution of the genus. It was further noted that the genus was primarily threatened by habitat destruction, and was not protected by domestic legislation in India. Also, the delegation of Sri Lanka promised to list the genus in Appendix III if the proposal failed. No consensus was reached on the proposal and a vote failed to achieve the required two-thirds majority—there were 49 votes in favor, 30 against, and 27 abstentions—and the proposal was therefore rejected (Convention on International Trade in Endangered Species of Wild Fauna and Flora 2000, p. 50). None of the five species addressed in this rule are currently listed in the CITES Appendices (Convention on International Trade in Endangered Species of Wild Fauna and Flora 2017, p. 48).

Collection of *Poecilotheria* specimens from the wild could have significant negative impacts on *Poecilotheria* populations. Due to the patchy distributions and poor dispersal abilities of tarantulas, collection of several individuals from a single location could potentially reduce the abundance or distribution of a species, especially those with restricted distributions (Molur *et al.* 2006, p. 14; West *et al.* 2001, unpaginated). Further, because tarantula populations are highly structured, loss of individuals from a single location could result in significant loss of that species' genetic diversity (Bond 2006, p. 154). Collection of a relatively large number of individuals from a single population could also alter population demographics such that the survival of a species or population is more vulnerable to the effects of other factors, such as habitat loss.

Collection of species from the wild for trade often begins when a new species is described or when a rare species has been rediscovered. Alerted to a new or novel species, collectors arrive at the reported location and set out collecting the species from the wild (Molur *et al.* 2006, p. 15; Stuart *et al.* 2006, entire). For tarantulas, adult females may be especially vulnerable to collection pressures as collectors often attempt to capture females, which produce young that can be sold (Capannini 2003, p. 107). Collectors then sell the collected specimens or their offspring to hobbyists who captive-rear the species and provide the pet trade with captive-bred specimens (Gabriel 2014, unpaginated; Molur *et al.* 2006, p. 16). Thus, more individuals are likely to be captured from the wild during the period in which captive-breeding stocks are being established, in other words, prior to the species becoming broadly available in trade (Gabriel 2014, unpaginated).

All five of the endemic Sri Lankan species addressed in this rule are bred by hobbyists and vendors and are available in the pet trade as captive-bred individuals in the United States, Europe, and elsewhere (see Herndon 2014, *pers. comm.;* Elowsky 2014, unpaginated; Gabriel 2014, unpaginated; Longhorn 2014a, unpaginated; Longhorn 2014b, unpaginated; Mugleston 2014, unpaginated; Service 2012, *in litt.*). We are not aware of any information on numbers of these species in domestic trade within the United States or numbers solely in foreign trade outside the United States. The Service's Law Enforcement Management Information System contains information on U.S. international trade in three of these species—*P. fasciata, P. ornata,* and *P. vittata* (it does not currently collect information on *P. smithi* or *P. subfusca*). Four hundred individuals of these species were legally imported into, or exported or re-exported from, the United States during 2007–2012; 298 were imported into, and 106 were exported or re-exported from, the United States.

Captive-bred individuals appear to supply the majority of the current legal trade in these species in the United States. Of the 400 individuals legally imported into, or exported or re-exported from, the United States during 2007–2012, 392 (98 percent) were declared as captive-bred (Service 2012, *in litt.*). However, wild individuals of at least some of these species are still being collected (Nanayakkara 2014a, p. 86; Nanayakkara 2014b, unpublished data; Service 2012, *in litt.*). Two sources indicate that there is evidence of illegal smuggling from Sri Lanka, although they do not provide details (see Nanayakkara 2014, p. 85; Samarawckrama *et al.* 2005, p. 76). Further, of the 400 individuals of Sri Lankan *Poecilotheria* imported into, or exported or re-exported from, the United States during 2007–2012, 8 *P. vittata* were declared as wild-caught. It is possible that additional wild-caught individuals of the five species addressed in this rule were (or are) not included in this total because they are imported

into the United States illegally, or imported into other countries. For example, some wild-caught specimens are imported into Europe (Merzlak 2017, unpaginated; Corcoran, 2016, unpaginated), although specific information on this activity is not available.

Sri Lanka prohibits the commercial collection and exportation of all *Poecilotheria* species, under the Sri Lanka Flora and Fauna Protection (Amendment) Act, No. 22 of 2009, which is part of the Fauna and Flora Protection Ordinance No. 2 (1937) (DLA Piper 2015, p. 392; Government of Sri Lanka and Government of the United States 2000, p. 5). However, enforcement is weak and influenced by corruption (DLA Piper 2015, p. 392; GOSL 2012, p. 2a–3–149).

In sum, individuals of at least some of these species are currently being collected from the wild. However, the extent to which this activity is occurring is unknown, as is the extent to which these species have been, or are being, affected by collection. Based on the available information on U.S. imports, exports, and re-exports, a small amount of trade occurs in wild specimens of these species. However, it is likely that more wild specimens enter Europe or Asia than the United States due to the closer proximity of Sri Lanka to Europe and Asia and consequent increased ease of travel and transport of specimens. Further, even small amounts of collection of species with small populations can have a negative impact on these species. Given that collection of at least some of these species from the wild continues to occur, it is likely that collection for trade is exacerbating population effects of other factors negatively impacting these species, such as stochastic events, habitat loss, and habitat degradation.

Intentional Killing

Poecilotheria spiders are feared by humans in Sri Lanka and, as a result, are usually killed when encountered (Kekulandala and Goonatilake 2015, unpaginated; Nanayakkara 2014a, p. 86; Gabriel 2014, unpaginated; Smith *et al.* 2001, p. 49). Intentional killing of *Poecilotheria* spiders may negatively impact these five species by raising mortality rates in these species' populations to such an extent that populations decline or are more vulnerable to the effects of other factors, such as habitat loss. Adult male *Poecilotheria* are probably more vulnerable to being intentionally killed because they wander in search of females during the breeding season (see *Tarantula General Biology*) and thus are more likely to be encountered by people. Consequently, intentional killing could potentially reduce the density of males in an area. Because the mating of a female depends on a male finding her, and males search for females randomly, a reduction in the density of males could result in a reduction in the percent of females laying eggs in any given year (Stradling 1994, p. 96) and, consequently, a lower population growth rate.

We do not have any information on the number of individuals of these five species that are intentionally killed by people. However, in areas where these species occur, higher human densities are likely to result in higher human contact with these species and, consequently, higher numbers of spiders killed. The human population density in Sri Lanka is much higher in the wet zone (see *Habitat Loss and Degradation*). Therefore, it is likely that *P. ornata, P. smithi,* and *P. subfusca* are affected by intentional killing more than *P. fasciata* and *P. vittata.* Although we do not have any information indicating the numbers of individuals of these species that are intentionally killed each year, it is likely that such killing is exacerbating the negative effects of other factors on these species' populations, such as habitat loss and degradation.

Stochastic (Random) Events and Processes

Species endemic to small regions, or known from few, widely dispersed locations, are inherently more vulnerable to extinction than widespread species because of the higher risks from localized stochastic (random) events and processes, such as floods, fire, landslides, and drought (Brooks *et al.* 2008, pp. 455–456; Mangel and Tier 1994, entire; Pimm *et al.* 1988, p. 757). These problems can be further magnified when populations are very small, due to genetic bottlenecks (reduced genetic diversity resulting from fewer individuals contributing to the species' overall gene pool) and random demographic fluctuations (Lande 1988, pp. 1455–1458; Pimm *et al.* 1988, p. 757). Species with few populations, limited geographic area, and a small number of individuals face an increased likelihood of stochastic extinction due to changes in demography, the environment, genetics, or other factors, in a process described as an extinction vortex (a mutual reinforcement that occurs among biotic and abiotic processes that drives population size downward to extinction) (Gilpin and Soule´ 1986, pp. 24–25). The negative impacts associated with small population size and vulnerability to random demographic fluctuations or natural catastrophes can be further magnified by synergistic interactions with other threats.

P. smithi is known from very few widely dispersed locations and is likely very rare (see *Species-Specific Information*). Therefore, it is highly likely that *P. smithi* is extremely vulnerable to stochastic processes and that the species is highly likely negatively impacted by these processes. The remaining four species have narrow ranges within specific climate zones of Sri Lanka. It is unclear whether the range sizes of these four are so small that stochastic processes on their own are likely to have significant negative impacts on these species. However, stochastic processes may have negative impacts on these species in combination with other factors such as habitat loss, because habitat loss can further fragment and isolate populations.

Determinations

Section 4 of the Act (16 U.S.C. 1533), and its implementing regulations at 50 CFR part 424, set forth the procedures for adding species to the Federal Lists of Endangered and Threatened Wildlife and Plants. Under section 4(a)(1) of the Act, we determine whether a species meets the definition of a ''threatened species'' or an ''endangered species'' because of any one or more of the following five threat factors or the cumulative effects thereof: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) Overutilization for commercial, recreational, scientific, or educational purposes; (C) Disease or predation; (D) The inadequacy of existing regulatory mechanisms; or (E) Other natural or manmade factors affecting its continued existence.

We have carefully assessed the best scientific and commercial information available on *P. fasciata, P. ornata, P. subfusca, P. smithi,* and *P. vittata.* While information on species abundance or population dynamics is not available on these species, the best available information indicates these species' populations have experienced extensive declines in the past and their populations continue to decline. Tarantulas have limited dispersal ability and sedentary habits; therefore, the loss of habitat (Factor A) likely results in direct loss of individuals or populations and, consequently, a reduction in the distribution of the species. As a result, the extensive loss of forest (71 percent in the dry zone, 85 percent in the intermediate zone, and 87 percent in the wet zone) has reduced the amount of habitat where the species may remain,

and their populations will likely continue to decline with ongoing deforestation. Further, because these species likely have highly structured populations, reductions in these species' populations have likely resulted in coincident loss of these species' unique genetic diversities, eroding the adaptive and evolutionary potential of these species (Bond 2006, p. 154).

All five Sri Lankan *Poecilotheria* species have restricted ranges within specific regions and climates of Sri Lanka and are currently estimated to occupy areas of less than 500 km² (193 mi²), and less than 10–15 km² (4–6 mi²) for *P. smithi.* Due to the life-history traits of tarantulas—restricted range, sedentary habits, poor dispersal ability, and structured populations—these species are vulnerable to habitat loss. Extensive habitat loss (Factor A) has already occurred in all the climate zones in which these species occur, and deforestation is ongoing in the country. Further, the cumulative effects of changing climate, intentional killing, pesticides, capture for the pet trade, and stochastic processes are likely significantly exacerbating the effects of habitat loss.

Therefore, for the following reasons we conclude populations of *P. fasciata, P. ornata, P. subfusca, P. smithi,* and *P. vittata* have been and continue to be significantly reduced to the extent that the viability of each of these five species is significantly compromised:

(1) These species are closely tied to their habitats, little of their forest habitat remains, deforestation is ongoing in these habitats, and these species are vulnerable to habitat loss;

(2) these species' have poor dispersal ability, are unlikely to be able to escape changing climate conditions via range shifts, and Sri Lanka's climate is changing at increasing rates;

(3) the cumulative effects of climate change, intentional killing, pesticides, capture for the pet trade, and stochastic processes are likely significantly exacerbating the effects of habitat loss; and

(4) *P. smithi* is known from few locations, is likely rare, and very likely vulnerable to stochastic processes.

The Act defines an endangered species in section 3(6) of the Act as any species that is ''in danger of extinction throughout all or a significant portion of its range'' and a threatened species in section 3(20) of the Act as any species that is ''likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.''

Based on the factors described above and their impacts on *P. fasciata, P. ornata, P. smithi, P. subfusca,* and *P. vittata,* we find the following factors to be threats to these species (*i.e.,* factors contributing to the risk of extinction of these species): Loss of habitat (Factor A; all five species), stochastic processes (Factor E; *P. smithi*), and the cumulative effects (Factor E; all five species) of these and other threats including climate change, intentional killing, pesticide use, and capture for the pet trade. Furthermore, despite laws in place to protect these five species and the forest and other habitat they depend on, these threats continue (Factor D), in part due to lack of resources and challenges to enforcement. We consider the risk of extinction of these five species to be high because these species are vulnerable to habitat loss, this process is ongoing, and these species have limited potential to recolonize reforested areas or move to more favorable climate. We find that *P. fasciata, P. ornata, P. smithi, P. subfusca,* and *P. vittata* are presently in danger of extinction throughout their ranges based on the likely severity and immediacy of threats currently impacting these species, and we are listing these five tarantula species as endangered in accordance with sections 3(6) and 4(a)(1) of the Act. We find that a threatened species status is not appropriate for these species because of their restricted ranges, limited distributions, and vulnerability to extinction and because the threats are ongoing throughout their ranges at a level that places these species in danger of extinction now, even without the worsening of the threats, that, as discussed above, is likely.

Under the Act and our implementing regulations, a species may warrant listing if it is endangered or threatened throughout all or a significant portion of its range. Because we have determined that *P. fasciata, P. ornata, P. smithi, P. subfusca,* and *P. vittata* are endangered throughout all of their ranges, we do not need to conduct an analysis of whether there is any significant portion of their ranges where these species are in danger of extinction or likely to become so in the foreseeable future. This is consistent with the Act because when we find that a species is currently in danger of extinction throughout all of its range (*i.e.,* meets the definition of an endangered species), the species is experiencing high-magnitude threats across its range or threats are so high in particular areas that they severely affect the species across its range. Therefore, the species is in danger of extinction throughout every portion of its range and an analysis of whether there is any significant portion of the range that may be in danger of extinction or likely to become so would not result in a different outcome.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened under the Act include recognition of conservation status, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing encourages and results in public awareness and conservation actions by Federal and State governments in the United States, foreign governments, private agencies and groups, and individuals.

Section 7(a) of the Act, as amended, and as implemented by regulations at 50 CFR part 402, requires Federal agencies to evaluate their actions that are to be conducted within the United States or upon the high seas, with respect to any species that is listed as an endangered or threatened species. Because *P. fasciata, P. ornata, P. smithi, P. subfusca,* and *P. vittata* are not native to the United States, no critical habitat is being designated with this rule. Regulations implementing the interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(2) of the Act requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of a listed species or to destroy or adversely modify its critical habitat. If a proposed Federal action may adversely affect a listed species, the responsible Federal agency must enter into formal consultation with the Service. Currently, with respect to *P. fasciata, P. ornata, P. smithi, P. subfusca,* and *P. vittata,* no Federal activities are known that would require consultation.

Section 8(a) of the Act authorizes the provision of limited financial assistance for the development and management of programs that the Secretary of the Interior determines to be necessary or useful for the conservation of endangered or threatened species in foreign countries. Sections 8(b) and 8(c) of the Act authorize the Secretary to encourage conservation programs for foreign listed species, and to provide assistance for such programs, in the form of personnel and the training of personnel.

Section 9 of the Act and our implementing regulations at 50 CFR 17.21 set forth a series of general prohibitions that apply to all endangered wildlife. These

prohibitions, in part, make it illegal for any person subject to the jurisdiction of the United States to ''take'' (which includes harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect; or to attempt any of these) endangered wildlife within the United States or upon the high seas. It is also illegal to possess, sell, deliver, carry, transport, or ship any such wildlife that has been taken illegally. In addition, it is illegal for any person subject to the jurisdiction of the United States to import; export; deliver, receive, carry, transport, or ship in interstate or foreign commerce, by any means whatsoever and in the course of commercial activity; or sell or offer for sale in interstate or foreign commerce any listed species. Certain exceptions apply to employees of the Service, the National Marine Fisheries Service, other Federal land management agencies, and State conservation agencies.

We may issue permits to carry out otherwise prohibited activities involving endangered wildlife under certain circumstances. No permit is required for activities that do not constitute prohibited acts. Regulations governing permits for endangered species are codified at 50 CFR 17.22. With regard to endangered wildlife, a permit may be issued for the following purposes: For scientific purposes, to enhance the propagation or survival of the species, and for incidental take in connection with otherwise lawful activities. The Service may also register persons subject to the jurisdiction of the United States through its captive-bred-wildlife (CBW) program if certain established requirements are met under the CBW regulations. 50 CFR 17.21(g). Through a CBW registration, the Service may allow a registrant to conduct certain otherwise prohibited activities under certain circumstances to enhance the propagation or survival of the affected species: Take; export or re-import; deliver, receive, carry, transport or ship in interstate or foreign commerce, in the course of a commercial activity; or sell or offer for sale in interstate or foreign commerce. A CBW registration may authorize interstate purchase and sale only between entities that both hold a registration for the taxon concerned. The CBW program is available for species having a natural geographic distribution not including any part of the United States and other species that the Director has determined to be eligible by regulation. The individual specimens must have been born in captivity in the United States. There are also certain statutory exemptions from the prohibitions, which are found in sections 9 and 10 of the Act.

Summary of Comments and Recommendations

In the proposed rule published on December 14, 2016 (81 FR 90297), we requested that all interested parties submit written comments on the proposal by February 13, 2017. We also contacted appropriate scientific experts and organizations, and other interested parties and invited them to comment on the proposal. We did not receive any requests for a public hearing. All substantive information provided during comment periods has either been incorporated directly into this final determination or is addressed below.

Peer Reviewer Comments

In accordance with our peer review policy published on July 1, 1994 (59 FR 34270), we solicited expert opinion from four knowledgeable individuals with scientific expertise that included familiarity with *Poecilotheria* species or other tarantulas, their habitats and biological needs, and stressors acting on their populations. We received responses from two of the peer reviewers from whom we requested comments. One did not review the rule but provided additional information regarding a threat to the habitat of *P. smithi,* and we have incorporated this information into this final rule. The second peer reviewer supported our determinations based on our assessment of some threats, but disagreed with our assessment of others. This peer reviewer also provided a technical correction pertaining to our physical description of *Poecilotheria* species, and we have incorporated this information into this final rule.

We reviewed all comments received from the peer reviewers for substantive and new information regarding the listing of the five species addressed in this rule. Peer reviewer comments are addressed in the following summary and incorporated into the final rule as appropriate.

(1) Comment: Citing the taxonomic revision done by Gabriel *et al.* (2013, entire), and the World Spider Catalog, the peer reviewer states that *P. vittata* is not endemic to Sri Lanka, but rather that *P. vittata* was synonymized with the Indian species *P. striata* and recently removed from this synonymy.

Our response: Gabriel *et al.* (2013, entire) not only remove *P. vittata* from synonymy with the Indian species *P. striata,* but also show *P. vittata* to be the senior synonym of *P. pederseni.* Further, the World Spider Catalog (2017, unpaginated) recognizes this synonymy, identifying *P. pederseni* as a synonym of *P. vittata.* Therefore, in this final rule we retain the taxonomy provided in our proposed rule.

(2) Comment: The peer reviewer indicated that our conclusions regarding the effects of climate change and pesticides on these species are speculative because no studies have been conducted on the effects of these factors on *Poecilotheria* species. The peer reviewer also indicates that *Poecilotheria* are unlikely to come in direct contact with pesticides because they live in forests, which are not generally sprayed, and are nocturnal so are not active when spraying occurs. The peer reviewer indicates that studies on spiders in agroecosystems show spiders that do not have direct contact with pesticides survive. However, the peer reviewer did not provide any new information or evidence supporting her assertions.

Our response: While no studies have been carried out specifically assessing the effects of stress factors on any *Poecilotheria* species, the Act requires that we make our determination of species status based on the best scientific and commercial data available at the time of our rulemaking. In conducting our assessment of the statuses of these species, we reviewed all relevant information available to us, including information submitted to us following the initiation of the 12-month status reviews for these species. We subsequently based our conclusions regarding the factors affecting these five species on the best available information. We acknowledged in our proposed rule that the population-level effects of climate change and pesticides on these species are uncertain. However, as indicated in our proposed rule, the best available information indicates that these stressors are likely negatively affecting these species, either directly or indirectly, to some extent. Consequently, it is reasonable to conclude, as we did in our proposed rule, that pesticides and climate change likely exacerbate the effects of other stressors acting on these species. Therefore, because we based our conclusions on the best available information, and the peer reviewer provided no evidence or new information for our review, we did not revise our conclusions regarding the effects of climate change or pesticides on these five species.

We cannot assess the studies to which the reviewer refers regarding the effects of pesticides on spiders because the reviewer did not provide copies of these studies or the citations for them. Further, while we agree that some

members of these species' populations are unlikely to have direct contact with pesticides, we do not agree that is the case for all members, particularly those inhabiting fragmented forests or remnant forest patches. As indicated in our proposed rule, these species could be exposed to pesticides via pesticide drift into forests that are adjacent to crop-growing areas, by traveling over pesticide treated land when dispersing between forest patches, or by consuming prey that have been exposed to pesticides (see *Pesticides*). Also, the most commonly used insecticides in Sri Lanka—carbofuran, chlorpyrifos, and diazinon—can remain active in the environment for days after application (Kamrin 1997, in Christensen *et al.* 2009, unpaginated; Karmin 1997, in Harper *et al.* 2009, unpaginated; U.S. National Library of Medicine 1995, in EXTOXNET 1996, unpaginated). Therefore, these five species could be directly and negatively affected by these pesticides after spraying occurs. They could also be indirectly affected by pesticides through consumption of contaminated prey, or reduction or depletion of prey populations. Taken together, and considering the extent of pesticide use and misuse in the country, it is likely that the five species addressed in this rule are directly or indirectly negatively affected by pesticides to some extent and that these effects likely exacerbate the effects of other threats acting on these species.

Public Comments

We received 115 public comments on the proposed listing of these species, most from people involved in the tarantula hobby as owners, breeders, or sellers. We reviewed all comments received from the public for substantive issues and new information regarding the listing of the five species addressed in this rule. Public comments are addressed in the following summary and incorporated into the final rule as appropriate. A few commenters provided new information on *Poecilotheria* biology or trade, and we have incorporated this information into the corresponding sections of this rule.

(1) Comment: Several commenters questioned certain information in our proposed rule. Several claimed that we inaccurately characterized the degree or effects (or both) of inbreeding or maladaptation in captive specimens of these species. Another questioned our assessment of the ability of these species to adapt to changing climate in Sri Lanka. Many of these commenters cited their own anecdotal observations of captive specimens to support their claims while the remaining commenters provided no new information. A few other commenters claimed, more generally, that we used outdated references or erroneous information, or misrepresented the findings of cited authors. However, these commenters also provided no new references or information supporting their claims.

Our Response: The Act requires that we use the best available scientific and commercial data to determine if a species meets the definition of a ''threatened species'' or an ''endangered species'' because of any one or a combination of the five factors found in section 4(a)(1) of the Act. This analysis includes an analysis of the extent to which captive-held members of a species create or contribute to threats to the species (for example, by fueling trade) or the extent to which captive-held members of a species remove or reduce threats to the species by contributing to the conservation of the species (for example, by providing specimens for population augmentation or reintroduction). In conducting our analysis, we reviewed all relevant information available to us on these species, including information submitted to us following the initiation of the 12-month status reviews for these species. We based our proposed rule, including the discussion and conclusions regarding captive *Poecilotheria,* on the best scientific and commercial data available to us at the time of our proposed rule. In addition, we reviewed all comments and information submitted by the public and peer reviewers during the public comment period for our proposed rule and base this final rule on the best available information.

Although some commenters provided anecdotal observations of captive specimens to support their assertions regarding the effects of inbreeding and maladaptation in captive specimens, or the ability of captive specimens to adapt to climate conditions, observations of health or survivability in captive conditions are not informative to predicting health or survivability in wild conditions because selection pressures in the wild differ greatly from those in captivity. Therefore, in this final rule we did not change any of our conclusions on these topics. However, we revised the section on Captive *Poecilotheria* to clarify the bases of our conclusions.

(2) Comment: A few commenters suggested that we did not consider the knowledge or efforts of hobbyists in our proposal.

Our Response: As required by the Act, we based our determinations on the best scientific and commercial information available. In doing so, we reviewed all information available to us on these species, including information submitted to us by the public following initiation of our 12-month status reviews for these species. This included information and dozens of articles from hobbyist publications. Further, we cited several of these sources in our proposal and retained these citations in this final rule.

(3) Comment: Some commenters believe that we inaccurately suggested in our proposed rule that *all* captive-bred specimens of these species have limited value to the conservation of these species—that all are inbred, maladapted to conditions in the wild, or hybridized—and that we did not acknowledge the knowledge and good practices of reputable breeders. A few suggest that genetic tests could determine which captives could potentially be useful for a conservation breeding program.

Our Response: We appreciate the level of knowledge and care taken by reputable hobbyists when breeding these species. However, we acknowledged the uncertainties pertaining to the levels of inbreeding and hybridization in pet trade specimens in our proposed rule by indicating that captive individuals of these species ''*may* be inbred or maladapted to conditions in the wild'' and ''likely include an *unknown number* of hybrids'' (see Captive *Poecilotheria*). Further, as indicated above, we have revised the section on captive *Poecilotheria* to clarify the bases of our conclusions. With respect to determining the genetic appropriateness of captive specimens for conservation via genetic testing, the Act requires us to make our decision based on the best available information at the time we make our decision, and we are not aware of any genetic studies on any individuals of these species, captive or wild. Even if such information existed, we have no information indicating that pet trade specimens are contributing to the conservation of these species in the wild, for instance, as part of a reintroduction program. Therefore, we have not changed our conclusions regarding captive specimens of these species.

(4) Comment: A few commenters assert that the extent of hybridization of these species in the pet trade is likely low because tarantula hobbyists are strongly opposed to hybridization of species, and because breeders can distinguish between species of adult specimens and take care not to cross-breed them.

Our Response: Again, we appreciate the level of knowledge and care taken by reputable hobbyists when breeding these species. However, because (1) genetic studies have not been conducted on any of these species, (2) evidence indicates that hybrids do occur in the hobby, (3) hybridization may not be visually apparent in captive individuals, and (4) the lineages of pet trade specimens of these species are not documented, the extent of hybridization in any particular captive specimen—be it high, low, or nonexistent—is unknown.

(5) Comment: Several commenters believe that captive-bred specimens in the pet trade are beneficial or necessary to the conservation of these species. They believe captive-bred specimens provide a safety net for these species to prevent extinction, increase public awareness, provide for education and research, supply zoos, and take the collection pressure off wild populations by fulling the demand for these species as pets. Two commenters assert that these species are not in danger of extinction because many exist in captivity.

Our Response: The goal of the Act is survival and recovery of endangered and threatened species and the ecosystems on which they depend. Therefore, when analyzing threats to a species, we focus our analysis on threats acting upon its survival in the wild, generally within the native range of the species. In our assessment of the status of a species, the extent to which captive-held members of a species create or contribute to threats to the species (for example, by fueling trade) or the extent to which captive-held members of a species remove or reduce threats to the species by contributing to the conservation of the species in the wild (for example, by providing specimens for population augmentation or reintroduction) is part of the analysis we conduct under section 4(a)(1) of the Act to determine if the species meets the definition of an endangered species or a threatened species. Further, the Act requires that we make our decision based on the best scientific and commercial data available at the time our decision is made. As indicated in our proposed rule, we are not aware of any existing conservation programs for these species or information indicating that pet trade specimens contribute to the viability of these species within their native ranges in the wild, and have clarified this in revisions to the Captive *Poecilotheria* section of this rule. We also determined that pet trade specimens likely hold limited value to the conservation of these species in the wild. However, we acknowledge that some pet trade specimens could potentially contribute to the conservation of these species in the wild if, for example, they became part of a genetically managed conservation breeding program. Persons seeking to engage in otherwise prohibited activities with endangered wildlife for scientific purposes or to enhance the propagation or survival of these species may seek authorization from the Service (see *Available Conservation Measures*).

We also have no information indicating that current or future education or research efforts are being conducted or planned with captive-bred pet trade specimens of these species for conservation purposes, or any evidence that populations in the wild are benefiting from current education or research efforts using captive-bred pet trade specimens. The best scientific and commercial data available indicate that as of September 2017 there were only 19 specimens in captivity in zoos worldwide (11 *P. fasciata,* 1 *P. ornata,* 2 *P. vitatta,* 5 *P. subfusca*) (Species360 2017, unpaginated).

With respect to trade, certain prohibitions, certain exceptions, and other conservation measures established through the Act are available for endangered species upon listing (see *Available Conservation Measures*). Therefore, they are provided by law to fulfill the purposes and policy of the Act. The effects of legal trade of a species on wild populations and market demand for that species is a complex phenomenon influenced by a variety of factors (Bulte and Damania 2005, entire; Fischer 2004, entire), and we are not aware of any evidence indicating that the pet trade of captive-bred specimens of these species are benefitting wild populations.

(6) Comment: One commenter expressed concern that listing these species as endangered would likely result in their extinction due to forcing breeders to stop breeding unless they apply for a permit. The commenter also indicated that specimens possessed by hobbyists that are unable to be used in repopulation efforts would not fall under the protections of the Act because they are ''unpure specimens''.

Our Response: As explained in response to comments below, captive breeding and many activities related to captive breeding are not prohibited under the Act. Persons seeking to engage in activities that are not prohibited under the Act do not need a permit under the Act. While we are not certain how this commenter defines ''unpure'', the protections of the Act apply to all members of these five species as explained in response to comments below. We recommend that breeding records be maintained to show parentage.

(7) Comment: Several commenters requested we exempt captive-bred specimens and their offspring from possession and interstate sales regulations, allowing ownership and interstate trade of these species to occur without obtaining a permit under the Act.

Our Response: Because we determined that all five of these species meet the definition of an ''endangered species'' under the Act, section 9(a)(1) of the Act and our implementing regulations at 50 CFR 17.21 set forth a series of general prohibitions that apply to all members of each of these species, whether captive or wild. The prohibitions cannot be revised through a regulation under section 4(d) of the Act, because such regulations apply to threatened species. The Act also does not allow for captive-bred specimens of these listed species to be assigned separate legal status from their wild counterparts. However, no permit is required for activities that do not constitute prohibited acts. As noted in response to comments below, the Act does not prohibit captive breeding of listed species and also does not prohibit a number of activities related to captive breeding, such as ownership. Furthermore, we may authorize otherwise prohibited activities for scientific purposes or to enhance the propagation or survival of these species, in accordance with the Act and our regulations (see *Available Conservation Measures*).

(8) Comment: Several commenters suggested that, rather than list these species as endangered species under the Act, we instead take another action such as: List them in a CITES Appendix, list them as threatened species with a section 4(d) rule that allows interstate trade, do not list them at all, or focus on ameliorating threats within these species' native ranges rather than on regulating domestic trade.

Our Response: When we receive a petition to list a species under the Act, we are required to make a determination as to whether that species meets the Act's definition of a threatened species or an endangered species. We are required to do this based solely on the best scientific and commercial data available, as it relates to the five listing factors in section 4(a)(1) of the Act. When we determine that a species meets the Act's definition of a threatened species or endangered species, we must list that species accordingly under the Act. We determined that these species

meet the definition of endangered species, and as such we must list them as endangered species. The Act and our regulations provide prohibitions and other conservation measures that apply to all endangered species as described above (see *Available Conservation Measures*). Because we found that listing these species as endangered is warranted, not listing them is not an option. We also cannot list them as threatened species with a section 4(d) rule because we found that they are endangered, not threatened species. Furthermore, because we found them warranted for listing, not listing them is not feasible. Finally, CITES has a different process and set of criteria for listing species in the CITES Appendices that is independent of listing under the Act. The portion of the comment suggesting a CITES listing is outside the scope of this agency action to consider whether these species should be listed as endangered species under the Act.

(9) Comment: One commenter asked how to acquire a permit for exemption from the prohibitions of the Act and how often permits need to be renewed.

Our Response: Information regarding permits for activities related to these five species can be obtained at our International Affairs program website at *https://www.fws.gov/international/.*

(10) Comment: Several commenters believe that trade in these species has little or no effect on wild populations and provided various reasons, including: They had never seen, or heard of others seeing, a wild-caught specimen; the captive stock is self-sustaining; wild-caught specimens are frowned upon in the hobby; and there is no financial incentive for the trade of wild-caught specimens. Others contend that listing and/or regulating trade in the United States is not necessary or useful because U.S. trade does not affect wild populations and because the primary threats to these species occur outside U.S. jurisdiction, in Sri Lanka.

Our Response: Evidence shows that wild-caught specimens of some of these species occur in trade (see *Trade*). Although the amount of trade in wild-caught specimens in the United States appears to be small, this does not mean trade, or U.S. trade, has no, or even little, effect on wild populations. As indicated in our proposed rule, collection of small numbers of individuals of these species could potentially have significant negative effects on wild populations of these species. With respect to U.S. jurisdiction and the regulation of trade, the Act requires the Service to determine if species qualify as endangered or threatened species regardless of whether a species is native to the United States. The protections of the Act include prohibitions on certain activities including import, export, take, and certain commercial activity in interstate or foreign commerce (see *Available Conservation Measures*). By regulating these activities, the Act helps to ensure that people under the jurisdiction of the United States do not contribute to the further decline of listed species.

(11) Comment: Several commenters raise concerns that listing would provide a disincentive to captive-breeding these species.

Our Response: It is not our intention to cause difficulties for breeders of these species or a decline in the pool of captive-held specimens. The Act does not prohibit or ''ban'' captive breeding of listed species. The Act also does not prohibit a number of activities related to captive breeding. For example, ownership, possession, or keeping of a listed species that was legally acquired and not taken in violation of the Act is not prohibited by the Act—nor is interstate transport of animals that are not for sale, not offered for sale, or not transported in the course of a commercial activity. Further, while the Act prohibits harassment of listed species (via the definition of ''take''), our regulations specify that, when captive animals are involved, harassment does not include generally accepted animal husbandry practices that meet or exceed AWA standards, breeding procedures, or provisions of veterinary care for confining, tranquilizing, or anesthetizing, when such practices, procedures, or provisions are not likely to result in injury (see the definition of harass at 50 CFR 17.3). In addition, activities that do not adversely affect these species, such as observations in behavioral research, are not considered take. Activities that are not prohibited by the Act do not require a permit under the Act.

The protections of the Act for endangered species include prohibitions on certain activities with any member of the listed species including import, export, take, and certain commercial activity in interstate or foreign commerce (see *Available Conservation Measures*). Permits may be issued to carry out otherwise prohibited activities, for scientific purposes or to enhance the propagation or survival of the species. For example, a permit could potentially be issued for import or export of captive-bred specimens if the activity were determined to enhance the propagation or survival of the species. Section 10(g) of the Act provides that any person claiming the benefit of any exemption or permit under the Act shall have the burden of proving that the exemption or permit is applicable, has been granted, and was valid and in force at the time of an alleged violation. While the Service may have information available to it that may assist in making required determinations prior to authorizing otherwise prohibited activities with listed species, the burden is on the applicant to provide necessary information for the Service to issue a permit.

Required Determinations

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

We have determined that environmental assessments and environmental impact statements, as defined under the authority of the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*), need not be prepared in connection with listing a species as an endangered or threatened species under the Endangered Species Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244).

References Cited

A complete list of references cited in this rulemaking is available on the internet at *http://www.regulations.gov* in Docket No. FWS–HQ–ES–2016–0076 and upon request from the Branch of Foreign Species, Ecological Services (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this final rule are the staff members of the Branch of Foreign Species, Ecological Services, Falls Church, VA.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Regulation Promulgation

Accordingly, we amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

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

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245; unless otherwise noted.

■ 2. In § 17.11(h), add the following entries to the List of Endangered and

Threatened Wildlife in alphabetical order under Arachnids:

■ a. Spider, ivory ornamental tiger;

■ b. Spider, ornate tiger;

■ c. Spider, Pedersen's tiger;

■ d. Spider, Smith's tiger; and

■ e. Spider, Sri Lanka ornamental tiger.

The additions read as follows:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Common name	Scientific name	Where listed	Status	Listing citations and applicable rules
* * *	* *	*	*	* *
ARACHNIDS				
* * *	* *	*	*	* *
Spider, ivory ornamental tiger	*Poecilotheria subfusca*	Wherever found	E	83 FR [*Insert* ***Federal Register*** *page where the document begins*], 7/31/2018.
* * *	* *	*	*	* *
Spider, ornate tiger	*Poecilotheria ornata*	Wherever found	E	83 FR [*Insert* ***Federal Register*** *page where the document begins*], 7/31/2018.
Spider, Pedersen's tiger	*Poecilotheria vittata*	Wherever found	E	83 FR [*Insert* ***Federal Register*** *page where the document begins*], 7/31/2018.
Spider, Smith's tiger	*Poecilotheria smithi*	Wherever found	E	83 FR [*Insert* ***Federal Register*** *page where the document begins*], 7/31/2018.
* * *	* *	*	*	* *
Spider, Sri Lanka ornamental tiger	*Poecilotheria fasciata*	Wherever found	E	83 FR [*Insert* ***Federal Register*** *page where the document begins*], 7/31/2018.
* * *	* *	*	*	* *

* * * * *

Dated: May 29, 2018.

James W. Kurth,

Deputy Director, U.S. Fish and Wildlife Service, Exercising the Authority of the Director, U.S. Fish and Wildlife Service.

[FR Doc. 2018–16359 Filed 7–30–18; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 217

[Docket No. 170908887–8622–02]

RIN 0648–BH24

Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to U.S. Navy Pier Construction Activities at Naval Submarine Base New London

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

ACTION: Final rule.

SUMMARY: Upon application from the U.S. Navy (Navy), NMFS is issuing regulations under the Marine Mammal Protection Act for the taking of marine mammals incidental to the pier construction activities conducted at the Naval Submarine Base New London in Groton, Connecticut, over the course of five years (2020–2025). These regulations allow NMFS to issue a Letter of Authorization (LOA) for the incidental take of marine mammals during the specified construction activities carried out during the rule's period of effectiveness, set forth the permissible methods of taking, set forth other means of effecting the least practicable adverse impact on marine mammal species or stocks and their habitat, and set forth requirements pertaining to the monitoring and reporting of the incidental take.

DATES: Effective March 1, 2020 through February 28, 2025.

ADDRESSES: To obtain an electronic copy of the Navy's LOA application or other referenced documents, visit the internet at: *www.nmfs.noaa.gov/pr/permits/incidental/construction.htm.* In case of problems accessing these documents, please call the contact listed below (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Shane Guan, Office of Protected Resources, NMFS; phone: (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Purpose and Need for Regulatory Action

This final rule establishes a framework under the authority of the MMPA (16 U.S.C. 1361 *et seq.*) to allow for the authorization of take of marine mammals incidental to the Navy's construction activities related to marine structure maintenance and pile replacement at a facility in Groton, Connecticut.

We received an application from the Navy requesting five-year regulations and authorization to take multiple species of marine mammals. Take would occur by Level A and Level B harassment incidental to impact and vibratory pile driving. Please see ''Background'' below for definitions of harassment.

Legal Authority for the Proposed Action

Section 101(a)(5)(A) of the MMPA (16 U.S.C. 1371(a)(5)(A)) directs the Secretary of Commerce 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 for up to five years if, after notice and public comment, the agency makes certain findings and issues regulations that set forth permissible methods of taking pursuant

to that activity and other means of effecting the ''least practicable adverse impact'' on the affected species or stocks and their habitat (see the discussion below in the ''Proposed Mitigation'' section), as well as monitoring and reporting requirements. Section 101(a)(5)(A) of the MMPA and the implementing regulations at 50 CFR part 216, subpart I, provide the legal basis for issuing this proposed rule containing five-year regulations, and for any subsequent letters of authorization (LOAs). As directed by this legal authority, this final rule contains mitigation, monitoring, and reporting requirements.

Summary of Major Provisions Within the Final Rule

Following is a summary of the major provisions of this final rule regarding Navy construction activities. These measures include:

- Required monitoring of the construction areas to detect the presence of marine mammals before beginning construction activities.
- Shutdown of construction activities under certain circumstances to avoid injury of marine mammals.
- Soft start for impact pile driving to allow marine mammals the opportunity to leave the area prior to beginning impact pile driving at full power.

Background

Sections 101(a)(5)(A) and (D) of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (Secretary) to allow, upon request, the incidental, but not intentional taking of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) if certain findings are made and regulations are issued or, if the taking is limited to harassment, notice of a proposed authorization is provided to the public for review.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such taking are set forth.

NMFS has defined ''negligible impact'' in 50 CFR 216.103 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.

The MMPA states that the term ''take'' means to harass, hunt, capture, kill or attempt to harass, hunt, capture, or kill any marine mammal. Except with respect to certain activities not pertinent here, 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).

Summary of Request

On March 22, 2017, NMFS received an application from the Navy requesting authorization to incidentally take harbor and gray seals, by Level A and Level B harassment, incidental to noise exposure resulting from conducting pier construction activities at the Navy Submarine Base New London in Groton, Connecticut, from October 2018 to March 2022. These regulations would be valid for a period of five years. On August 31, 2017, NMFS deemed the application adequate and complete. On May 23, 2018, the Navy requested that the rule be valid between March 1, 2020, and February 28, 2025, due to construction schedule changes.

The use of sound sources such as those described in the application (*e.g.,* piledriving) may result in the take of marine mammals through disruption of behavioral patterns or may cause auditory injury of marine mammals. Therefore, incidental take authorization under the MMPA is warranted.

Description of the Specified Activity

Overview

The Navy is planning to demolish Pier 32 and Pier 10 and construct a new Pier 32 at Naval Submarine Base New London (SUBASE), Groton, Connecticut.

Recent Global Shore Infrastructure Plans and Regional Shore Infrastructure Plans identified a requirement for 11 adequate submarine berths at SUBASE. There are currently six adequate berths available via Piers 6, 17, and 31, leaving a shortfall of five adequate berths. The remaining submarine berthing piers (8, 10, 12, 32, and 33) are classified as inadequate because of their narrow width and short length compared to current SSN (hull classification) berthing design standards (Unified Facilities Criteria 4–152–01, Design Standards for Piers and Wharves).

The Proposed Action is to demolish Pier 32 and Pier 10, and replace them with a new Pier 32 that meets all current Navy SSN pier standards to accommodate Virginia Class submarines. The Proposed Action includes:

- Construction of a new, larger Pier 32 to be located approximately 150 feet (ft) north of the current location.
- Upgrade of the quaywall, north of Pier 32, may be required to accommodate a crane weight test area.
- Demolition of existing Pier 32 and Pier 10.
- Dredging of the sediment mounds beneath the existing Pier 32 (approximately 9,400 cubic yards [cy]) and the existing Pier 10 (approximately 10,000 cy) to a depth of 36 ft below mean lower low water (−36 ft MLLW) plus 2 ft of over dredge (additional dredge depth that allows for varying degrees of accuracy of different types of dredging equipment). Any remaining timber piles beneath the existing piers would be pulled with a strap.
- Dredging of the berthing areas alongside the proposed new Pier 32 (approximately 74,000 sq ft) to a depth of −38 feet MLLW plus 2 feet of over dredge.
- Dredging of two additional areas (approximately 10,200 cy and 31,100 cy) in the Thames River navigation channel to a depth of −36 ft MLLW plus 2 ft of over dredge.

Two species of marine mammals are expected to potentially be present in the Thames River near SUBASE: Harbor seal (*Phoca vitulina*) and gray seal (*Halichoeris grypus*). Harbor seals and gray seals are more likely to occur at SUBASE from September to May.

Dates and Duration

Pile installation for the new Pier 32 and pile removal associated with the demolition of the existing Piers 32 and 10 is expected to take a total of approximately 3.5 years. Construction and demolition activities are expected to begin no earlier than March 2020 and proceed to completion in February 2025.

In-water activities expected to result in incidental takes of marine mammals would occur during approximately 35 non-consecutive months of the project beginning in March 2020. The estimated duration of pile installation and removal, including duration of the vibratory and impact hammer activities, is provided in Table 1 below for each year of construction and demolition. Also included in the Table are the durations for wood piles and steel fender piles to be pulled by a crane using a sling or strap attached to the pile. The durations of proposed pile driving/removal activities are primarily

derived from information provided by Naval Facilities Engineering Command (NAVFAC) Mid-Atlantic Public Works Department, Facilities Engineering and Acquisition Department (FEAD) Design Manager and the record of pile driving activities documented during the construction of SUBASE Pier 31 (American Bridge 2010–2011). The proposed new Pier 32 would be comparable to Pier 31 in design and location and would have similar sub-surface geological conditions along this reach of the Thames River.

Specified Geographical Region

SUBASE is located in the towns of Groton and Ledyard in New London County, Connecticut. SUBASE occupies approximately 687 acres along the east bank of the Thames River, 6 mi north of the river's mouth at Long Island Sound (Figure 1–1 in LOA application). The Thames River is the easternmost of Connecticut's three major rivers and is formed by the confluence of the Shetucket and Yantic rivers in Norwich, from which it flows south for 12 mi to New London Harbor. The Thames River discharges freshwater and sediment from the interior of eastern Connecticut into Long Island Sound. It is the main drainage of the Thames River Major Drainage Basin, which encompasses approximately 3,900 square mi of eastern Connecticut and central Massachusetts (USACE 2015). The lower Thames River and New London Harbor sustains a variety of military, commercial, and recreational vessel usage. New London Harbor provides protection to a number of these.

Detailed Description of Specified Activity

1. Construction of New Pier 32

Pile driving would most likely be conducted using a barge and crane. However, the contractor may choose to use a temporary pile-supported work trestle that would be constructed by driving approximately 60 steel 14-inch diameter H-piles.

Structural support piles for Pier 32 would consist of approximately 120 concrete-filled steel pipe piles measuring 36 inches in diameter. The piles would be driven between 40 ft below the mudline near the shore and 150 ft below the mudline at the end of the pier. Fender piles would also be installed and would consist of approximately 194 fiberglass-reinforced plastic piles measuring 16 inches in diameter.

Special construction features would include drilling rock sockets into bedrock in an estimated 60 places to hold the piles. A rotary drill using a rock core barrel and rock muck bucket would be used inside of the steel pipe piles to drill a minimum of 2 ft down into bedrock to create the rock socket that would be filled with concrete. Sediment would be lifted out and re-deposited within 10 ft of the pipe pile during rock socket drilling. Underwater noise from the rock drill as it is operated inside a steel pipe would be much less than that produced by vibratory and impact pile driving of the steel pipes (Martin et al. 2012).

Impact and vibratory hammers would be used for installing piles where rock sockets are not required. Based on previous construction projects at SUBASE, it is estimated that an average of one 36-inch pile per week (with driving on multiple days) and two plastic piles per day would be installed. The per-pile drive time for each pile type and method will vary based on environmental conditions (including substrate) where each pile is driven. Impact or vibratory pile driving may result in harassment of marine mammals.

Construction of Pier 32 may also require upgrade of the quaywall north of Pier 32 to provide the reinforcement needed to support a crane weight test area. Because there is potential that a work trestle would be used and the requirement for the upgrade will not be determined until final design, the pile driving is included in the analyzed activities. The quaywall upgrade would include up to approximately eighteen 30-inch diameter concrete-filled steel pipe piles that would be installed into rock sockets driven into bedrock adjacent and parallel to the existing steel sheet pile wall. Pile caps and a concrete deck would be installed above the piles. A fender system composed of approximately nine 16-inch diameter plastic piles would also be installed into rock sockets approximately 2 ft in front of the new deck.

2. Demolition and Removal of Pier 32 and Pier 10

When the new Pier 32 is operational, the existing Pier 32 would be demolished using a floating crane and a series of barges. Pier 10 would be demolished after the demolition of existing Pier 32. The concrete decks of the piers would be cut into pieces and placed on the barges. Demolition debris would be sorted and removed by barge and recycled to the maximum extent practicable. Any residual waste would be disposed of offsite in accordance with applicable federal, state, and local regulations. Once the decks are removed, the steel H piles and pipe piles that support the existing pier would be pulled using a vibratory extraction method (hammer). The vibratory hammer would be attached to the pile head with a clamp. Once attached, vibration would be applied to the pile that would liquefy the adjacent sediment allowing the pile to be removed.

Demolition of existing Pier 32 would include the removal by vibratory driver-extractor (hammer) of approximately 60 steel piles from the temporary work trestle, 120 concrete-encased steel H-piles, and 70 steel H-piles. Fifty-six wood piles would be pulled with a sling. Demolition of Pier 10 would include the removal by vibratory hammer of 24 concrete-encased, steel H-piles and 166 cast-in-place, reinforced concrete piles. Eighty-four steel fender piles and 41 wood piles would be pulled with a sling. A total of 440 piles would be removed by vibratory hammer for both piers and the work trestle.

3. Dredging of Pier Areas and Navigation Channel

The Proposed Action would also include dredging of approximately 60,000 cy of sediment in two areas of the Thames River navigation channel near Pier 32, the berthing areas alongside the new Pier 32, and underneath existing Pier 32 and Pier 10 after demolition. All dredging for the Proposed Action would support safe maneuvering for entry and departure of submarines at the proposed new Pier 32 and existing Piers 8, 12, 17, and 31. The proposed design dredge depth in all areas to be dredged is −36 ft relative to MLLW plus 2 ft of over dredge.

Dredging would be conducted in two phases. Dredging of the new Pier 32 area and the northern portion of the channel dredge areas would be conducted in the first construction year. The footprints of the demolished Pier 32 and Pier 10 and the southern portions of the channel dredge areas would be dredged after demolition of the existing piers in the fourth year of construction. Dredging would occur only during the period between October 1 and January 31 to avoid potential impacts on shellfish and fisheries resources in the area. Each dredging and disposal phase would take approximately 2 weeks to complete.

After the demolition of Pier 32, any remnant timber piles present underneath existing Pier 32 would be pulled with a strap. The sediment mound that has formed beneath the pier would be dredged (approximately 9,400 cy) to the design depth. Dredging would also be required immediately west of Piers 31 and 32 (approximately 10,200 cy) and along the eastern edge

(approximately 31,100 cy) of the navigation channel to achieve the required minimum depths to maneuver the submarines. Once the existing Pier 10 and any remnant timber piles are removed, the sediment mound beneath the old pier would be dredged (approximately 10,000 cy).

Since dredging and disposal activities would be slow moving and conspicuous to marine mammals, they pose negligible risks of physical injury. An environmental bucket would be used for dredging to minimize turbidity compared with the turbidity generated by hydraulic dredging. Noise emitted by dredging equipment is broadband, with most energy below 1 kilohertz (kHz), and would be similar to that generated by vessels and maritime industrial activities that regularly operate within the action area (Clarke et al. 2002; Todd et al. 2015). Due to the low noise output and slow and steady transiting nature of the dredging activity, NMFS does not consider it would result to the level of harassment under the MMPA. Therefore, dredging is not considered further in this document.

TABLE 1—SUMMARY OF CONSTRUCTION ACTIVITIES FOR THE NAVY SUBMARINE BASE NEW LONDON

Activity	Pile No.	Pile type	Method	Piles/day	Total driving days	Strike number (impact) or duration(s) per pile	Duration
Year 1							
Pier 32 construction	60	14″ steel H-pile temp. work trestle.	Impact	4	15	1,000 strikes	3 weeks.
	60	36″ x 100′ concrete-filled steel pipe piles.	Vibratory hammer & rock socket drilling.	0.5	120	1,200 seconds	6 months.
	20	36″ x 180′ concrete-filled steel piles.	Vibratory hammer	0.2	100	1,800 seconds	5 months.
	20	36″ x 180′ concrete-filled steel piles.	Impact hammer to last 20–40 ft.	2.5	8	1,000 strikes	2 weeks.
Quaywall upgrade	18	30″ x 100′ concrete-filled steel pipe piles.	Rock socket drilling	0.5	36	15,000 seconds	Concurrent with Pier 32.
	9	16″ fiberglass reinforced plastic piles.	Rock socket drilling	0.5	18	7,500 seconds..	
Year 2							
Pier 32 construction	40	36″ x 180′ concrete-filled steel piles.	Vibratory hammer	0.2	200	1,800 seconds	10 months.
	40	36″ x 180′ concrete-filled steel piles.	Impact hammer to drive last 20–40 ft.	2.5	16	1,000 strikes	3.5 weeks.
Year 3							
Pier 32 construction	194	16″ fiberglass reinforced plastic piles.	Vibratory hammer	2	97	1,200 seconds	5 months.
	64	16″ fiberglass reinforced plastic piles.	Impact hammer to drive last 20–40 ft.	2.5	26	1,000 strikes	1.5 months.
Year 4							
Pier 32 demolition	60	14″ steel H-piles temp. work trestle.	Vibratory hammer (removal) ..	5	14	1,200 seconds	3 weeks.
	24	33″ concrete-encased steel H piles.	Vibratory hammer (removal) ..	2	12	1,200 seconds	3.5 months.
	96	24″ concrete-encased steel H piles.	Vibratory hammer (removal) ..	2	48	1,200 seconds..	
	70	14″ steel H piles	Vibratory hammer (removal) ..	5	14	1,200 seconds..	
Pier 10 demolition	24	24″ concrete-encased steel H piles.	Vibratory hammer (removal) ..	9.5	2.5	1,200 seconds	0.5 month.
	166	24″ cast-in-place reinforced concrete piles.	Vibratory hammer (removal) ..	9.5	17.5	1,200 seconds	0.5 month.

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

Comments and Responses

NMFS published a proposed rule in the **Federal Register** on April 13, 2018 (83 FR 16027). During the 30-day public comment period on the proposed rule, NMFS received comments from the Marine Mammal Commission (Commission). We did not receive other comments.

Comment 1: The Commission recommends that NMFS require the Navy to conduct sound source verification (SSV) and the size of Level B harassment zone measurements for certain piles that data are lacking and where the zones are not based on modeling. These acoustic measurements include:

- Vibratory and impact installation of at least five 16-in fiberglass-reinforced plastic piles—measurements for source levels;
- Rock socket drilling of at least three 30-in and three 16-in piles—measurements for source levels and the extent of the Level B harassment zones;
- Vibratory installation of at least three 36-in steel piles—measurements for the extent of the Level B harassment zone; and
- Vibratory removal of at least three 24-in concrete and three 33-in concrete piles—measurements for source levels and the extent of the Level B harassment zones.

Response: NMFS discussed these recommendation with the Navy and the Navy agreed to conduct SSVs on the piles for which source level data are not already available. SSV measurements to be conducted are:

- Vibratory and impact installation of at least 5 16-in fiberglass reinforced plastic piles, and

• Rock socket drilling of at least 3 30-in and 3 16-in piles.

However, the Navy did not agree to conduct acoustic measurements to the extent of the Level B harassment zones. The Navy indicated that conducting hydroacoustic monitoring to the extent of the Level B harassment zones is not a common requirement based on the five most recent active IHAs, including U.S. Army Corps of Engineers' (USACE) Tampa Harbor Big Bend Channel expansion project, the City of Astoria's waterfront bridge replacement project, the Navy's Bravo wharf recapitalization project, and U.S. Coast Guard's (USCG) Monterey waterfront repair project. Instead, the Navy offered to conduct hydroacoustic measurements at several points between 10 and 500 m from the source and extrapolate the distance of the Level B harassment zone.

While being able to determine the extent of Level B harassment zones is critical to accurately assess the potential impacts to marine mammals, these zones can be determined by means other than direct measurements recommended by the Commission. Therefore, NMFS considers the Navy's proposal of extrapolating the Level B harassment zone using near- and far-field measurement data a valid approach.

Therefore, in the final rule, NMFS requires the Navy to conduct SSVs on the piles listed above and to conduct measurements on several locations between 10 and 500 m from the source to determine the Level B harassment zones for those zones that were not based on modeling.

These requirements are included in the final rule.

Comment 2: The Commission recommends that NMFS require the Navy to include certain metrics in the hydroacoustic monitoring report for measurements being conducted. These metrics include:

• Root-mean-square sound pressure levels (SPL_{rms}), 1-sec sound exposure levels (SELs), duration of recordings used to derive SELs, cumulative SEL (SEL_{cum}) based on the number of piles and driving duration for each scenario, and SEL source spectra for vibratory pile driving/removal source level measurements;

• Peak SPLs (SPL_{peak}), SPL_{rms}, integration time/pulse duration for SPL_{rms}, single-strike SPLs (SPL_{s-s}), SEL_{cum} based on the number of piles and driving duration for each scenario, and SEL_{s-s} spectra for impact pile driving source level measurements;

• The measured (or extrapolated, if not reached) distances at which the SPL_{rms} decays to 120 dB re 1 µPa or to ambient, whichever is higher, and integration time/pulse duration for SPL_{rms} for verification of the extent to the Level B harassment zones;

• All sound levels via medians, means, minimums, and maximums and linear average (*i.e.,* averaging the sound intensity/pressure before converting to dB); and

• Sediment type, water depth, hydrophone depth, etc.

Response: NMFS discussed this with the Navy and the Navy agreed to report these metrics in the acoustic monitoring report. These requirements are included in the final rule.

Comment 3: The Commission recommends that NMFS revise its draft rounding criteria and share it with the Commission.

Response: NMFS appreciates the Commission's ongoing concern in this matter. Calculating predicted takes is not an exact science and there are arguments for taking different mathematical approaches in different situations, and for making qualitative adjustments in other situations. We believe, however, that the methodology used for take calculation in this LOA remains appropriate and is not at odds with the 24-hour reset policy the Commission references. We look forward to continued discussion with the Commission on this matter and will share the rounding guidance as soon as is appropriate.

Description of Marine Mammals in the Area of the 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 (SAR; *www.nmfs.noaa.gov/pr/sars/*) and more general information about these species (*e.g.,* physical and behavioral descriptions) may be found on NMFS's website (*https://www.fisheries.noaa.gov/seals-sea-lions*).

Table 2 lists all species with expected potential for occurrence in location 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 (2017). 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. Atlantic SARs (Waring et al., 2017). All values presented in Table 2 are the most recent available at the time of publication and are available in the draft 2017 SARs (Hayes et al., 2017).

TABLE 2—MARINE MAMMALS THAT MAY OCCUR WITHIN NAVY SUBMARINE BASE NEW LONDON AREA

Common name	Scientific name	Stock	ESA/MMPA status	Stock abundance best/minimum population	Occurrence in study area
Order Carnivora					
Suborder Pinnipedia					
Family Phocidae (true seals):					
Gray seal	*Halichoerus grypus*	Western North Atlantic		505,000 *	Thames River.
Harbor seal	*Phoca vitulina*	Western North Atlantic		75,834 (0.15)/66,884	Thames River.

*There are an estimated 27,131 seals in U.S. waters; however, gray seals form one population not distinguished on the basis of the U.S./Canada boundary (Waring et al., 2017).

All species that could potentially occur in the proposed survey areas are included in table 2. As described below, all two species (with two managed stocks) temporally and spatially co-occur with the activity to the degree that take is reasonably likely to occur, and we have proposed authorizing it.

Marine Mammal Hearing

Hearing is the most important sensory modality for marine mammals underwater, and exposure to anthropogenic sound can have deleterious effects. To appropriately assess the potential effects of exposure to sound, it is necessary to understand the frequency ranges marine mammals are able to hear. Current data indicate that not all marine mammal species have equal hearing capabilities (*e.g.,* Richardson et al., 1995; Wartzok and Ketten, 1999; Au and Hastings, 2008). To reflect this, Southall et al. (2007) recommended that marine mammals be divided into functional hearing groups based on directly measured or estimated hearing ranges on the basis of available behavioral response data, audiograms derived using auditory evoked potential techniques, anatomical modeling, and other data. Note that no direct measurements of hearing ability have been successfully completed for mysticetes (*i.e.,* low-frequency cetaceans). Subsequently, NMFS (2016) described generalized hearing ranges for these marine mammal hearing groups. Generalized hearing ranges were chosen based on the approximately 65 dB threshold from the normalized composite audiograms, with the exception for lower limits for low-frequency cetaceans where the lower bound was deemed to be biologically implausible and the lower bound from Southall et al. (2007) retained. The functional groups and the associated frequencies are indicated below (note that these frequency ranges correspond to the range for the composite group, with the entire range not necessarily reflecting the capabilities of every species within that group):

- Low-frequency cetaceans (mysticetes): Generalized hearing is estimated to occur between approximately 7 Hz and 35 kHz;
- Mid-frequency cetaceans (larger toothed whales, beaked whales, and most delphinids): Generalized hearing is estimated to occur between approximately 150 Hz and 160 kHz;
- High-frequency cetaceans (porpoises, river dolphins, and members of the genera Kogia and Cephalorhynchus; including two members of the genus Lagenorhynchus, on the basis of recent echolocation data and genetic data): Generalized hearing is estimated to occur between approximately 275 Hz and 160 kHz.
- Pinnipeds in water; Phocidae (true seals): Generalized hearing is estimated to occur between approximately 50 Hz to 86 kHz;
- Pinnipeds in water; Otariidae (eared seals): Generalized hearing is estimated to occur between 60 Hz and 39 kHz.

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

For more detail concerning these groups and associated frequency ranges, please see NMFS (2016) for a review of available information. Two marine mammal species (both phocid species) have the reasonable potential to co-occur with the proposed survey activities. Please refer to Table 2.

Potential Impacts to Marine Mammals

The Navy's Submarine Base New London pier construction using in-water pile driving and pile removal could adversely affect marine mammal species and stocks by exposing them to elevated noise levels in the vicinity of the activity area.

Exposure to high intensity sound for a sufficient duration may result in auditory effects such as a noise-induced threshold shift (TS)—an increase in the auditory threshold after exposure to noise (Finneran *et al.,* 2005). Factors that influence the amount of threshold shift include the amplitude, duration, frequency content, temporal pattern, and energy distribution of noise exposure. The magnitude of hearing threshold shift normally decreases over time following cessation of the noise exposure. The amount of TS just after exposure is the initial TS. If the TS eventually returns to zero (*i.e.,* the threshold returns to the pre-exposure value), it is a temporary threshold shift (TTS) (Southall *et al.,* 2007).

Threshold Shift (noise-induced loss of hearing)—When animals exhibit reduced hearing sensitivity (*i.e.,* sounds must be louder for an animal to detect them) following exposure to an intense sound or sound for long duration, it is referred to as a noise-induced TS. An animal can experience TTS or permanent threshold shift (PTS). TTS can last from minutes or hours to days (*i.e.,* there is complete recovery), can occur in specific frequency ranges (*i.e.,* an animal might only have a temporary loss of hearing sensitivity between the frequencies of 1 and 10 kHz), and can be of varying amounts (for example, an animal's hearing sensitivity might be reduced initially by only 6 dB or reduced by 30 dB). PTS is permanent, but some recovery is possible. PTS can also occur in a specific frequency range and amount as mentioned above for TTS.

For marine mammals, published data are limited to the captive bottlenose dolphin, beluga, harbor porpoise, and Yangtze finless porpoise (Finneran, 2015). For pinnipeds in water, data are limited to measurements of TTS in harbor seals, an elephant seal, and California sea lions (Kastak *et al.,* 1999, 2005; Kastelein *et al.,* 2012b).

Lucke *et al.* (2009) found a TS of a harbor porpoise after exposing it to airgun noise with a received sound pressure level (SPL) at 200.2 dB (peak-to-peak) re: 1 micropascal (μPa), which corresponds to a sound exposure level of 164.5 dB re: 1 μPa^2 s after integrating exposure. Because the airgun noise is a broadband impulse, one cannot directly determine the equivalent of root mean square (rms) SPL from the reported peak-to-peak SPLs. However, applying a conservative conversion factor of 16 dB for broadband signals from seismic surveys (McCauley, *et al.,* 2000) to correct for the difference between peak-to-peak levels reported in Lucke *et al.* (2009) and rms SPLs, the rms SPL for TTS would be approximately 184 dB re: 1 μPa, and the received levels associated with PTS (Level A harassment) would be higher. Therefore, based on these studies, NMFS recognizes that TTS of harbor porpoises is lower than other cetacean species empirically tested (Finneran & Schlundt, 2010; Finneran *et al.,* 2002; Kastelein and Jennings, 2012).

Marine mammal hearing plays a critical role in communication with conspecifics, and interpretation of environmental cues for purposes such as predator avoidance and prey capture. Depending on the degree (elevation of threshold in dB), duration (*i.e.,* recovery time), and frequency range of TTS, and the context in which it is experienced, TTS can have effects on marine mammals ranging from discountable to serious (similar to those discussed in auditory masking, below). For example, a marine mammal may be able to readily compensate for a brief, relatively small amount of TTS in a non-critical frequency range that occurs during a time where ambient noise is lower and there are not as many competing sounds present. Alternatively, a larger amount and longer duration of TTS sustained during time when communication is critical for successful mother/calf interactions could have more serious

impacts. Also, depending on the degree and frequency range, the effects of PTS on an animal could range in severity, although it is considered generally more serious because it is a permanent condition. Of note, reduced hearing sensitivity as a simple function of aging has been observed in marine mammals, as well as humans and other taxa (Southall *et al.,* 2007), so one can infer that strategies exist for coping with this condition to some degree, though likely not without cost.

In addition, chronic exposure to excessive, though not high-intensity, noise could cause masking at particular frequencies for marine mammals, which utilize sound for vital biological functions (Clark *et al.,* 2009). Acoustic masking is when other noises such as from human sources interfere with animal detection of acoustic signals such as communication calls, echolocation sounds, and environmental sounds important to marine mammals. Therefore, under certain circumstances, marine mammals whose acoustical sensors or environment are being severely masked could also be impaired from maximizing their performance fitness in survival and reproduction.

Masking occurs at the frequency band that the animals utilize. Therefore, since noise generated from vibratory pile driving is mostly concentrated at low frequency ranges, it may have less effect on high frequency echolocation sounds by odontocetes (toothed whales). However, lower frequency man-made noises are more likely to affect detection of communication calls and other potentially important natural sounds such as surf and prey noise. It may also affect communication signals when they occur near the noise band and thus reduce the communication space of animals (*e.g.,* Clark *et al.,* 2009) and cause increased stress levels (*e.g.,* Foote *et al.,* 2004; Holt *et al.,* 2009).

Unlike TS, masking, which can occur over large temporal and spatial scales, can potentially affect the species at population, community, or even ecosystem levels, as well as individual levels. Masking affects both senders and receivers of the signals and could have long-term chronic effects on marine mammal species and populations. Recent science suggests that low frequency ambient sound levels have increased by as much as 20 dB (more than three times in terms of sound pressure level) in the world's ocean from pre-industrial periods, and most of these increases are from distant shipping (Hildebrand, 2009). For the Navy's Submarine Base New London pier construction, noises from vibratory pile driving and pile removal contribute to the elevated ambient noise levels in the project area, thus increasing potential for or severity of masking. Baseline ambient noise levels in the vicinity of project area are high due to ongoing shipping, construction and other activities in the Thames River.

Finally, marine mammals' exposure to certain sounds could lead to behavioral disturbance (Richardson *et al.,* 1995), such as: Changing durations of surfacing and dives, number of blows per surfacing, or moving direction and/or speed; reduced/increased vocal activities; changing/cessation of certain behavioral activities (such as socializing or feeding); visible startle response or aggressive behavior (such as tail/fluke slapping or jaw clapping); avoidance of areas where noise sources are located; and/or flight responses (*e.g.,* pinnipeds flushing into water from haulouts or rookeries).

The onset of behavioral disturbance from anthropogenic noise depends on both external factors (characteristics of noise sources and their paths) and the receiving animals (hearing, motivation, experience, demography) and is also difficult to predict (Southall *et al.,* 2007). Currently NMFS uses a received level of 160 dB re 1 µPa (rms) to predict the onset of behavioral harassment from impulse noises (such as impact pile driving), and 120 dB re 1 µPa (rms) for continuous noises (such as vibratory pile driving). For the Navy's Submarine Base New London pier construction, both 160- and 120-dB levels are considered for effects analysis because the Navy plans to use both impact pile driving and vibratory pile driving and pile removal.

The biological significance of many of these behavioral disturbances is difficult to predict, especially if the detected disturbances appear minor. However, the consequences of behavioral modification could be biologically significant if the change affects growth, survival, and/or reproduction, which depends on the severity, duration, and context of the effects.

Potential Effects on Marine Mammal Habitat

The primary potential impacts to marine mammal habitat are associated with elevated sound levels produced by vibratory pile removal and pile driving in the area. However, other potential impacts to the surrounding habitat from physical disturbance are also possible.

With regard to fish as a prey source for cetaceans and pinnipeds, fish are known to hear and react to sounds and to use sound to communicate (Tavolga *et al.,* 1981) and possibly avoid predators (Wilson and Dill, 2002). Experiments have shown that fish can sense both the strength and direction of sound (Hawkins, 1981). Primary factors determining whether a fish can sense a sound signal, and potentially react to it, are the frequency of the signal and the strength of the signal in relation to the natural background noise level.

The level of sound at which a fish will react or alter its behavior is usually well above the detection level. Fish have been found to react to sounds when the sound level increased to about 20 dB above the detection level of 120 dB (Ona, 1988); however, the response threshold can depend on the time of year and the fish's physiological condition (Engas *et al.,* 1993). In general, fish react more strongly to pulses of sound (such as noise from impact pile driving) rather than continuous signals (such as noise from vibratory pile driving) (Blaxter *et al.,* 1981), and a quicker alarm response is elicited when the sound signal intensity rises rapidly compared to sound rising more slowly to the same level.

During in-water pile driving only a small fraction of the available habitat would be ensonified at any given time. Disturbance to fish species would be short-term and fish would return to their pre-disturbance behavior once the pile driving activity ceases. Thus, the proposed construction would have little, if any, impact on marine mammals' prey availability in the area where construction work is planned.

Disposal of dredged material in the confined aquatic disposal (CAD) cell would have a direct impact to the benthos as a result of burial and suffocation. Most, if not all, sessile marine invertebrates are not expected to survive burial. Some motile marine organisms would be buried and unable to survive, while others such as burrowing specialists, may survive. Survival rates would depend primarily on burial depth. From 2010 through 2012, biannual benthic sampling of the CAD cell area was conducted to assess the timeframe for recovery of benthic populations of the CAD cells, in accordance with Water Quality Certificate conditions for the 2010 waterfront maintenance dredging project at the submarine base. The sampling results of the CAD cell were compared to sampling results of an undisturbed reference site located upriver. The degree of similarity of population and community structures was assessed. The results of the three year survey program indicated that a progressive recovery to a stable benthic population was occurring at the CAD cell. As demonstrated by the biannual

benthic survey, benthic assemblages are anticipated to recover within three to five years after the completion of the project, and disposal impacts would not be significant (CardnoTEC 2015).

Project activities would temporarily disturb benthic and water column habitats and change bottom topography to a minor degree, but effects on prey availability and foraging conditions for marine mammals would be temporary and limited to the immediate area of pier demolition/construction, dredging, and disposal. The new surfaces of piles and exposed concrete on the new pier would likely result in establishment of fouling communities on the new structures, and may attract fish and benthic organisms, resulting in small scale shifts in prey distribution.

There are no known haul outs within the vicinity of the Proposed Action.

The project activities would not permanently modify existing marine mammal habitat. The activities may kill some fish and cause other fish to leave the area temporarily, thus impacting marine mammals' foraging opportunities in a limited portion of the foraging range; but, because of the short duration of the activities and the relatively small area of the habitat that may be affected, the impacts to marine mammal habitat are not expected to cause significant or long-term negative consequences. Therefore, given the consideration of potential impacts to marine mammal prey species and their physical environment, the Navy's proposed construction activity at the submarine base would not adversely affect marine mammal habitat.

Estimated Take

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). Harassment is the only type of take expected to result from these activities.

Authorized takes would be by Level A and Level B harassments, in the form of mild permanent hearing threshold shift (Level A) and disruption of behavioral patterns (Level B) for individual marine mammals resulting from exposure to noise generated from impact pile driving and vibratory pile driving and removal. Based on the nature of the activity and the anticipated effectiveness of the mitigation measures (*e.g.,* shutdown measures—discussed in detail below in Mitigation section), serious injury or mortality is neither anticipated nor authorized.

As described previously, no mortality is anticipated or authorized for this activity. Below we describe how the take is estimated.

Described in the most basic way, 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. Below, we describe these components 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.,* 2011). 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.

Applicant's proposed activity includes the use of continuous (vibratory pile driving and removal) and impulsive (impact pile driving) sources, and therefore the 120 and 160 dB re 1 µPa (rms) levels are applicable.

Level A harassment for non-explosive sources—NMFS' Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing (Technical Guidance, 2016) 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). Applicant's proposed activity includes the use of non-impulsive (vibratory pile driving and pile removal) sources.

These thresholds were developed by compiling and synthesizing the best available science and soliciting input multiple times from both the public and peer reviewers to inform the final product, and are provided in the table below. The references, analysis, and methodology used in the development of the thresholds are described in NMFS' 2016 Technical Guidance, which may be accessed at: *http://www.nmfs.noaa.gov/pr/acoustics/guidelines.htm.*

TABLE 3—CURRENT ACOUSTIC EXPOSURE CRITERIA FOR NON-EXPLOSIVE SOUND UNDERWATER

Hearing group	PTS onset thresholds		Behavioral thresholds	
	Impulsive	Non-impulsive	Impulsive	Non-impulsive
Low-Frequency (LF) Cetaceans	$L_{pk,flat}$: 219 dB ..... $L_{E,LF,24h}$: 183 dB	$L_{E,LF,24h}$: 199 dB	$L_{rms,flat}$: 160 dB	$L_{rms,flat}$: 120 dB
Mid-Frequency (MF) Cetaceans	$L_{pk,flat}$: 230 dB ..... $L_{E,MF,24h}$: 185 dB	$L_{E,MF,24h}$: 198 dB.		
High-Frequency (HF) Cetaceans	$L_{pk,flat}$: 202 dB ..... $L_{E,HF,24h}$: 155 dB	$L_{E,HF,24h}$: 173 dB.		

TABLE 3—CURRENT ACOUSTIC EXPOSURE CRITERIA FOR NON-EXPLOSIVE SOUND UNDERWATER—Continued

Hearing group	PTS onset thresholds		Behavioral thresholds	
	Impulsive	Non-impulsive	Impulsive	Non-impulsive
Phocid Pinnipeds (PW) (Underwater)	$L_{pk,flat}$: 218 dB $L_{E,PW,24h}$: 185 dB	$L_{E,PW,24h}$: 201 dB.		
Otariid Pinnipeds (OW) (Underwater)	$L_{pk,flat}$: 232 dB $L_{E,OW,24h}$: 203 dB	$L_{E,OW,24h}$: 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 (Lpk) has a reference value of 1 µPa, and cumulative sound exposure level (LE) 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.

Source Levels

The project includes impact pile driving and vibratory pile driving and removal of various piles. Source levels of pile driving and removal activities are based on reviews of measurements of the same or similar types and dimensions of piles available in the literature (Caltrans, 2015; Martin et al., 2012; Dazey et al., 2012; WSDOT, 2007, 2012; NAVFAC Southwest, 2014). Based on this review, the following source levels are assumed for the underwater noise produced by construction activities:

- Impact driving of 14-inch steel H-piles for the temporary trestle is assumed to generate a peak SPL of 208 dB re 1µPa, and a root-mean-squared (rms) SPL of 187 dB re 1 µPa, based on adding 10 dB to a single-strike SEL of 177 dB re 1 µPa²-sec at 10 m (33 ft) reported by Caltrans (2015). This assumption is based on differences between SEL and rms values of other piles reported by Caltrans (2015).
- Impact driving of 36-inch steel piles would be assumed to generate an instantaneous peak SPL of 209 dB, an rms SPL of 198 dB, and a SEL of 183 dB at the 10 m (33 ft) distance, based on the weighted average of similar pile driving at the Bangor Naval Base, Naval Base Point Loma, Washington State Department of Transportation (WSDOT) Anacortes Ferry Terminal, and WSDOT Mukilteo Ferry Terminal.
- Vibratory driving of 36-inch steel piles would be assumed to generate a 168 dB SPLrms and a 168 dB SEL at 10 m (33 ft), based on the weighted average of similar pile driving measured at Bangor Naval Base, Naval Base Point Loma, and WSDOT Anacortes Ferry Terminal.
- Impact driving of the 16-inch plastic piles, for which no data specific to that size and composition are available, are assumed to be similar to available data on 13-inch plastic piles: 166 dB peak SPL and 153 dB rms SPL. No SEL measurements were made, but the SEL at 10 m (33 ft) can be assumed to be 9 dB less than the rms value (based on differences of rms and SEL values of in-water impact pile-driving data of other piles summarized by Caltrans 2015), which would put the SEL value for the plastic piles at 144 dB. For vibratory pile driving of the same plastic piles, the SPL rms of impact driving is used as a proxy due to lack of measurement.
- Vibratory removal of 14-inch steel H-piles is conservatively assumed to have rms and SEL values of 158 dB based on a relatively large set of measurements from the vibratory installation of 14-inch H-piles.
- Drilling the rock sockets is assumed to be an intermittent, non-impulsive, broadband noise source, similar to vibratory pile driving, but using a rotary drill inside a pipe or casing, which is expected to reduce sound levels below those of typical pile driving (Martin et al. 2012). Measurements made during a pile drilling project in 1–5 m (3–16 ft) depths at Santa Rosa Island, CA, by Dazey et al. (2012) appear to provide reasonable proxy source levels for the proposed activities. Dazey et al. (2012) reported average rms source levels ranging from 151 to 157 dB re 1µPa, normalized to a distance of 1 m (3 ft) from the pile, during activities that included casing removal and installation as well as drilling, with an average of 154 dB re 1µPa during 62 days that spanned all related drilling activities during a single season.
- Since no source level data are available for vibratory extraction of concrete or concrete encased 24-inch and 33-inch steel H-piles, conservative proxy source levels were based on the summary values reported for vibratory driving of 24-inch steel sheet piles by Caltrans (2015). There are two reasons for using 24-in steel sheet pile driving source level as a proxy: (1) In general, pile extraction generates less noise in comparison to pile driving, and (2) piling of concrete or concrete encased piles generated less noise in comparison to steel piles. Since there are no source levels available for extraction of the 24-in concrete or concrete encased piles and 33-in steel H-piles, we defer to the pile driving source level of 24-in steel sheet pile reported by Caltrans (2015). The Caltrans (2015) typical source level of 160 dB rms and SEL was used for vibratory removal of 24-inch concrete piles and 24-inch concrete encased steel H-piles, whereas the loudest source level of 165 dB rms and SEL was used for vibratory removal of 33-inch concrete encased steel piles.

A summary of source levels from different pile driving and pile removal activities is provided in Table 4.

TABLE 4—SUMMARY OF IN-WATER PILE DRIVING SOURCE LEVELS

[At 10 m from source]

Method	Pile type/size	SPL_{pk} (dB re 1 μ Pa)	SPL_{rms} (dB re 1 μ Pa)	SEL (dB re 1 μ Pa^2-s)
Impact driving	14-in steel H pile	208	187	177
Impact driving	36-in concrete-filled steel pile	209	198	183
Vibratory driving	30- and 36-in concrete-filled steel pipe pile; 16-in fiberglass plastic pile.	NA	168	168
Impact driving	16-in fiberglass plastic pile	166	153	144
Vibratory driving	16-in fiberglass plastic pile	NA	153	153
Rock socket drilling	30-in steel pile & 16-in plastic pile	NA	154	154
Vibratory removal	14-in steel H pile	NA	158	158
Vibratory removal	24-in concrete-encased steel H pile	NA	160	160
Vibratory removal	33-in concrete-encased steel H pile	NA	165	165

These source levels are used to compute the Level A injury zones and to estimate the Level B harassment zones. For Level A harassment zones, since the peak source levels for both pile driving methods are below the injury thresholds, cumulative SEL were used to do the calculations using the NMFS acoustic guidance (NMFS 2016).

Estimating Injury Zones

When 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 will result in some degree of overestimate of Level A 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 cumulative SEL (L_E), distances to marine mammal injury thresholds were estimated using NMFS' Optional User Spreadsheet based on the noise exposure guidance. For impact pile driving, the single strike SEL/pulse equivalent was used, and for vibratory pile driving, the rms SPL source level was used. Per the NMFS Spreadsheet, default Weighting Factor Adjustments (WFA) were used for calculating PTS from both vibratory and impact pile driving, using 2.5 kHz and 2.0 KHz, respectively. These WFAs are acknowledged by NMFS as conservative. A transmission loss coefficient of 15 is used with reported source levels measured at 10 m.

Estimating Behavioral Harassment Zones

Isopleths to Level B behavioral zones are based on rms SPL (SPL_{rms}) that are specific for non-impulse (vibratory pile driving) sources. Distances to marine mammal behavior thresholds were calculated using practical spreading.

In addition, based on the number of piers and high density of pilings along the shoreline, the Navy concluded that underwater sound transmission through these structures would be impeded similar to the interruption of sound transmission by natural projections of the shoreline. Using this assumption, the resulting Level B behavioral harassment zone for marine mammal disturbance for most project activities would be limited to the middle reaches of the Thames River, extending no farther south than the Amtrak Bridge, 3 miles (4,642 m) upstream from the mouth of the river.

A summary of the measured and modeled harassment zones is provided in Table 5. In modeling transmission loss from the project area, the conventional assumption would be made that acoustic propagation from the source is impeded by natural and manmade features that extend into the water, resulting in acoustic shadows behind such features. While not solid structures, given the density of structural pilings under the many pile-supported piers located south of Piers 32 and 10, coupled with the docking of submarines at these piers, the piers are presumed to disrupt sound propagation southward in the river.

TABLE 5—CALCULATED AREAS OF ZONE OF INFLUENCE AND MAXIMUM DISTANCES

Year	Activity description	Source level @ 10m, dB (rms/SEL)	Level A distance (m)/area (km^2)	Level B distance (m)/area (km^2)
1	Impact driving 14″ steel H-pile 1,000 strikes per pile, 4 piles/day	187/177	536/0.4468	631/0.5468.
	Vibratory & rock socket drilling installation of 36″ concrete-filled steel piles; average 10 minutes/day.	168	<4/<0.0001	4,642/2.2002.
	Impact driving 36″ concrete-filled steel piles; 1,000 strikes per pile; average 2.5 piles per day.	198/183	984/0.886	3,415/2.037.
	Rocket socket drilling of 30″ concrete-filled steel piles and 16″ fiberglass reinforced plastic piles; average 1.04 hours/day.	154	Activity will occur concurrently with above activities that have much bigger zones	
2	Vibratory installation of 36″ concrete-filled steel piles; average 6 minutes/day.	168	<4/<0.0001	4,642/2.2002.

TABLE 5—CALCULATED AREAS OF ZONE OF INFLUENCE AND MAXIMUM DISTANCES—Continued

Year	Activity description	Source level @ 10m, dB (rms/SEL)	Level A distance (m)/area (km^2)	Level B distance (m)/area (km^2)
	Impact pile driving 36″ concrete-filled steel piles; 1,000 strikes per pile; average 2.5 piles per day.	198/183	984/0.886	3,415/2.037.
3	Vibratory installation of 16″ fiberglass plastic piles; 40 minutes/day.	153	0.9/<0.0001	1,584/1.1584.
	Impact installation of 16″ fiberglass plastic piles; 1,000 strikes per pile; average 2.5 piles per day.	153/144	2.5/<0.0001	1/<0.000.
4	Vibratory removal of 14″ steel H-piles; average 100 minutes/day	158	<4/<0.0001	3,415/1.8372.
	Vibratory removal of 24″ concrete-filled steel piles (Pier 32); average 190 minutes/day.	160	2.7/<0.0001	4,642/2.2002.
	Vibratory removal of 30″ concrete-filled steel piles (Pier 32); average 40 minutes/day.	165	5.9/<0.0001	4,642/2.2002.
	Vibratory removal of 24″ concrete-filled steel piles (Pier 10); average 40 minutes/day.	160	7.7/<0.0001	4,642/2.2002.

Marine Mammal Occurrence

In this section we provide the information about the presence, density, or group dynamics of marine mammals that will inform the take calculations.

The Navy's Marine Species Density Database (NMSDD) has density estimates for harbor and gray seals that occur in Long Island Sound. The NMSDD density estimates for harbor seals and gray seals are the same, 0.0703/km^2 during fall, winter, and spring, and 0.0174/km^2 during summer months. These estimates, however, are based on broad-scale oceanic surveys, which have not extended up the Thames River.

Marine mammal surveys were conducted in fall 2014 and winter, spring, and summer of 2015 as part of a nearshore biological survey at Submarine Base New London. No marine mammals were observed (Tetra Tech 2016). Harbor seals have been sighted in the Thames River near the submarine base by Navy personnel. Both gray and harbor seals have rookeries in Long Island Sound. A two-year detailed, systematic survey of marine mammals in the Thames River began in January 2017. During the first nine months of the survey through September, one pinniped (gray seal) was observed approximately 2¾ miles downstream of SUBASE at a fishing dock near the ferry terminal, approximately 3,000 feet south of the Gold Star Memorial Bridge (I–95).

There are no survey-based estimates of the relative abundances of the two species in the Thames River. Up to two harbor seals have been observed near the submarine base by base personnel. No gray seals have been observed by the Navy close to the submarine base. However, the Navy states that during preparation of the LOA they have learned that since the population of gray seals is generally growing in the region that gray seals are likely to also occur in the area of effect by the first year of construction, 2020, but in smaller numbers. A ratio of 3 to 1 harbor seals to gray seals was identified as a reasonable approximation of their relative abundance. No evidence is available to suggest a different ratio. There are no areas (haul outs) where seals are known to be concentrated nor have there been contemporary sightings of larger numbers of seals along this stretch of the river, and the animals seen at the submarine base are likely to move up and down as well as across the river. Given that the Thames River is about 500 m (1,640 ft) wide at the Submarine Base New London, and similarly developed areas extend about 1 km (3,280 ft) up and down the river, the Navy believes it is reasonable to extrapolate the observations at the Submarine Base New London to an area of about 1 km^2 for the purpose of estimating density. This would result in an average density of 0.45 harbor and 0.15 gray seals per km^2 within the project ZOIs from September through May. Very few animals were sighted outside the September through May time frame. Therefore, the September through May data is used for density estimates to be conservative.

Take Calculation and Estimation

Here we describe how the information provided above is brought together to produce a quantitative take estimate. For both harbor and gray seals, estimated takes are calculated based on ensonified area for a specific pile driving activity multiplied by the marine mammal density in the action area, multiplied by the number of pile driving (or removal) days. Distances to and areas of different harassment zones are listed in Table 4.

For both Level A and Level B harassment, take calculations and assumptions are as follows:

- Number of takes per activity = density (average number of seals per km^2) * area of ZOI (km^2) * number of days, rounded to the nearest whole number.
- Seal density in the project area is estimated as 0.6/km^2 from September through May (zero from June through August), consisting of 75% harbor seals (0.45/km^2) and 25% gray seals (0.15/km^2).
- Assumes as a worst case that activities will occur up to a maximum of 180 workdays (5 days per week) when seals are present (September through May) during each full construction year.
- Assumes vibratory and impact hammer pile driving would not occur on the same days.
- Level A and Level B takes are calculated separately based on the respective ZOIs for each type of activity, providing a maximum estimate for each type of take which corresponds to the authorization requested under the MMPA.
- Assumes that the effective implementation of a 10 m shutdown zone will prevent non-acoustic injuries and will prevent animals from entering acoustic harassment ZOIs that extend less than 10 m from the source.

The maximum extent of the potential injury zone (for impact pile driving of steel piles) is 984 m (3,228 ft) from the source for 36-inch concrete-filled steel piles and 536 m (1,758 ft) for 14-inch steel H-piles; other potential acoustic injury ZOIs for vibratory pile extraction and installation are only 1 to 7.7 m (3 to 25 ft) from the source (Table 4). Seals within about 10 m (33 ft) of in-water construction or demolition may also be at risk of injury from interaction with construction equipment. These potential

injury zones and the 10 m (33 ft) shutdown distance would be monitored during all in-water construction/demolition activities, and the activities would be halted if a marine mammal were to approach within these distances.

The estimated numbers of instances of acoustic harassment (takes) by year, species and severity (Level A or Level B) are shown in Table 6. Total Level A takes are estimated as 12 harbor seals and 4 gray seals (total 16), and Level B takes are estimated as 504 harbor seals and 168 gray seals (total 672).

TABLE 6—ESTIMATED NUMBERS OF MARINE MAMMALS THAT MAY BE EXPOSED TO RECEIVED NOISE LEVELS THAT CAUSE LEVEL A AND LEVEL B HARASSMENT

Year	Species	Estimated Level A take	Estimated Level B take	Estimated total take	Abundance	Percentage
1	Harbor seal	6	166	172	75,834	0.23
	Gray seal	2	55	57	27,131	0.21
2	Harbor seal	6	177	183	75,834	0.24
	Gray seal	2	59	61	505,000	0.01
3	Harbor seal	0	51	51	75,834	0.07
	Gray seal	0	17	17	27,131	0.06
4	Harbor seal	0	110	110	75,834	0.13
	Gray seal	0	37	37	27,131	0.12

Mitigation

In order to issue an LOA under section 101(a)(5)(A) 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 and impact on operations.

Mitigation for Marine Mammals and Their Habitat

1. Time Restriction.

Work will occur only during daylight hours, when visual monitoring of marine mammals can be conducted.

2. Establishing and Monitoring Level A and Level B Harassment Zones, and Shutdown Zones. These zones may be adjusted as appropriate on the basis of the acoustic monitoring described below.

Before the commencement of in-water construction activities, which include impact pile driving and vibratory pile driving and pile removal, the Navy shall establish Level A harassment zones where received underwater SEL_{cum} could cause PTS (see Table 5 above).

The Navy shall also establish Level B harassment zones where received underwater SPLs are higher than 160 dB_{rms} re 1 µPa for impulsive noise sources (impact pile driving) and 120 dB_{rms} re 1 µPa for non-impulsive noise sources (vibratory pile driving and pile removal).

The Navy shall establish a 10-m (33-ft) shutdown zone for all in-water construction and demolition work.

If marine mammals are found within the shutdown zone, pile driving of the segment would be delayed until they move out of the area. If a marine mammal is seen above water and then dives below, the contractor would wait 15 minutes. If no marine mammals are seen by the observer in that time it can be assumed that the animal has moved beyond the shutdown zone.

If pile driving of a segment ceases for 30 minutes or more and a marine mammal is sighted within the designated shutdown zone prior to commencement of pile driving, the observer(s) must notify the pile driving operator (or other authorized individual) immediately and continue to monitor the shutdown zone. Operations may not resume until the marine mammal has exited the shutdown zone or 15 minutes have elapsed since the last sighting.

3. Shutdown Measures.

The Navy shall implement shutdown measures if a marine mammal is detected moving towards or entered the 10-m (33-ft) shutdown zone.

Further, the Navy shall implement shutdown measures if the number of authorized takes for any particular species reaches the limit under the LOA and such marine mammals are sighted within the vicinity of the project area and are approaching the Level B harassment zone during in-water construction activities.

In addition, the Navy shall implement shutdown measures if species not authorized to take are sighted within the vicinity of the project area and are approaching the Level B harassment zone during in-water construction activities.

4. Soft Start.

The Navy shall implement soft start techniques for impact pile driving. The Navy shall conduct an initial set of three strikes from the impact hammer at 40 percent energy, followed by a 1-minute waiting period, then two subsequent three strike sets. Soft start shall be required for any impact driving, including at the beginning of the day, and at any time following a cessation of impact pile driving of thirty minutes or longer.

Whenever there has been downtime of 30 minutes or more without impact driving, the contractor shall initiate

impact driving with soft-start procedures described above.

Based on our evaluation of the required measures, NMFS has determined that the prescribed mitigation measures provide the means 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.

Monitoring and Reporting

In order to issue an LOA for an activity, section 101(a)(5)(A) 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) state 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 proposed 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.

Monitoring Measures

The Navy shall employ trained protected species observers (PSOs) to conduct marine mammal monitoring for its Submarine Base New London pier construction project. The purposes of marine mammal monitoring are to implement mitigation measures and learn more about impacts to marine mammals from the Navy's construction activities. The PSOs will observe and collect data on marine mammals in and around the project area for 15 minutes before, during, and for 30 minutes after all pile removal and pile installation work.

Protected Species Observer Qualifications

NMFS-approved PSOs shall meet the following requirements:

1. Independent observers (*i.e.,* not construction personnel) are required;
2. At least one observer must have prior experience working as an observer;
3. Other observers may substitute education (undergraduate degree in biological science or related field) or training for experience;
4. Where a team of three or more observers are required, one observer should be designated as lead observer or monitoring coordinator. The lead observer must have prior experience working as an observer; and
5. NMFS will require submission and approval of observer CVs.

Marine Mammal Monitoring Protocols

The Navy shall conduct briefings between construction supervisors and crews and the PSO team prior to the start of all pile driving activities, and when new personnel join the work, in order to explain responsibilities, communication procedures, marine mammal monitoring protocol, and operational procedures. All personnel working in the project area shall watch the Navy's Marine Species Awareness Training video. An informal guide shall be included with the monitoring plan to aid in identifying species if they are observed in the vicinity of the project area.

The Navy will monitor the Level A and Level B harassment zones before, during, and after pile driving activities for all in-water constructions. The Marine Mammal Monitoring Plan would include the following procedures:

- PSOs will be primarily located on boats, docks, and piers at the best vantage point(s) in order to properly see the entire shutdown zone(s).
- PSOs will be located at the best vantage point(s) to observe the zone associated with behavioral impact thresholds.
- During all observation periods, PSOs will use high-magnification (25X), as well as standard handheld (7X) binoculars, and the naked eye to search continuously for marine mammals.
- Monitoring distances will be measured with range finders. Distances to animals will be based on the best estimate of the PSO, relative to known distances to objects in the vicinity of the PSO.
- Bearings to animals will be determined using a compass.
- Pile driving shall only take place when the shutdown and Level A zones are visible and can be adequately monitored. If conditions (*e.g.,* fog) prevent the visual detection of marine mammals, activities with the potential to result in Level A harassment shall not be initiated. If such conditions arise after the activity has begun, pile driving or pile removal activities shall be halted if the 10-m shutdown zone is not visible.
- Three (3) PSOs shall be posted to monitor marine mammals during in-water pile driving and pile removal. One PSO will be located on land and two will be located in a boat to monitor the farther locations.
- Pre-Activity Monitoring:

The shutdown zone will be monitored for 15 minutes prior to in-water construction/demolition activities. If a marine mammal is present within the 10-m shutdown zone, the activity will be delayed until the animal(s) leave the shutdown zone. Activity will resume only after the PSO has determined that, through sighting or by waiting 15 minutes, the animal(s) has moved outside the shutdown zone. If a marine mammal is observed approaching the shutdown zone, the PSO who sighted that animal will notify all other PSOs of its presence.

- During Activity Monitoring:

If a marine mammal is observed entering the Level A or Level B zones outside the 10-m shutdown zone, the pile segment being worked on will be completed without cessation, unless the animal enters or approaches the shutdown zone, at which point all pile driving activities will be halted. If an animal is observed within the shutdown zone during pile driving, then pile driving will be stopped as soon as it is safe to do so. Pile driving can only resume once the animal has left the shutdown zone of its own volition or

has not been re-sighted for a period of 15 minutes.

• Post-Activity Monitoring:

Monitoring of all zones will continue for 30 minutes following the completion of the activity.

Acoustic Monitoring

(1) Sound Source Verification

The Navy shall conduct pile driving sound source verification for the types and sizes of piles with no prior measurements. These piles include:

• Vibratory and impact installation of at least 5 16-in fiberglass reinforced plastic piles, and

• Rock socket drilling of at least 3 30-in and 3 16-in piles.

Sound source measurements of these piles sound be conducted at distances approximately 10 m from the source.

For vibratory pile driving/removal source level measurements, reports should include 1-s sound exposure level (SEL), source spectrum, duration of recordings used to derived the SEL, and 24-hour cumulative SEL extrapolated from measurements.

For impact pile driving source level measurements, report should include peak sound pressure level (SPL_{pk}), root-mean-square SPL (SPL_{rms}), single strike SEL (SEL_{ss}), integration time for SPL_{rms}, SEL_{ss} spectrum, and 24-hour cumulative SEL extrapolated from measurements.

(2) Level B Harassment Distance Verification

The Navy shall empirically determine the Level B harassment distance either by extrapolating from in situ measurements conducted at several points between 10 and 500 m from the source, or by direct measurements at far distance to locate the distance where the received levels reach 120 dB or below, or at the ambient noise level.

Level B behavioral harassment zones need to be empirically determined include:

• Rock socket drilling of at least 3 30-in and 3 16-in piles,

• Vibratory installation of at least 3 36-in steel piles, and

• Vibratory removal of at least 3 24-in concrete and 3 33-in concrete piles.

For extent of Level B distance verification, the Navy shall report the measured or extrapolated distances where the received levels SPL_{rms} decay to 120-dB or to the ambient noise level, whichever is higher, as well as integration time for such SPL_{rms}.

The sound levels reported should be in median and linear average (*i.e.,* taking averages of sound intensity before converting to dB).

The acoustic monitoring reports shall also include sediment type where measurements are made.

Reporting Measures

The Navy is required to submit an annual report within 90 days after each activity year, starting from the date when the LOA is issued (for the first annual report) or from the date when the previous annual report ended. These reports will detail the monitoring protocol, summarize the data recorded during monitoring, and estimate the number of marine mammals that may have been harassed during the period of the report. Results from acoustic monitoring should also be included within the monitoring report, as discussed above. NMFS will provide comments within 30 days after receiving these reports, and the Navy shall address the comments and submit revisions within 30 days after receiving NMFS comments. If no comment is received from NMFS within 30 days, the annual report is considered completed.

The Navy is also required to submit a draft monitoring report within 90 days after completion of the construction work or the expiration of the final LOA, whichever comes earlier. This report will synthesize all data recorded during marine mammal monitoring, and estimate the number of marine mammals that may have been harassed through the entire project. NMFS will provide comments within 30 days after receiving this report, and the Navy shall address the comments and submit revisions within 30 days after receiving NMFS comments. If no comment is received from NMFS within 30 days, the monitoring report is considered as final.

In addition, NMFS requires the Navy to notify NMFS' Office of Protected Resources and NMFS' Greater Atlantic Stranding Coordinator within 48 hours of sighting an injured or dead marine mammal in the construction site. The Navy shall provide NMFS and the Stranding Network with the species or description of the animal(s), the condition of the animal(s) (including carcass condition, if the animal is dead), location, time of first discovery, observed behaviors (if alive), and photo or video (if available).

In the event that the Navy finds an injured or dead marine mammal that is not in the construction area, the Navy will report the same information as listed above to NMFS as soon as operationally feasible.

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, this introductory discussion of our analyses applies to both of the species listed in Table 2, given that the anticipated effects of the Navy's Submarine Base New London pier construction project activities involving pile driving and pile removal on marine mammals are expected to be relatively similar in nature. There is no information about the nature or severity of the impacts, or the size, status, or structure of any species or stock that would lead to a different analysis by species for this activity, or else species-specific factors would be identified and analyzed.

Although a few individual seals (6 harbor seals and 2 gray seals each in year 1 and year 2) are estimated to experience Level A harassment in the form of PTS if they stay within the Level A harassment zone during the entire pile driving for the day, the degree of injury is expected to be mild and is not likely to affect the reproduction or survival of the individual animals. It is expected that, if hearing impairments occurs, most likely the affected animal would lose a few dB in its hearing sensitivity, which in most cases is not likely to affect its survival and

recruitment. Hearing impairment that might occur for these individual animals would be limited to the dominant frequency of the noise sources, *i.e.,* in the low-frequency region below 2 kHz. Nevertheless, as for all marine mammal species, it is known that in general these pinnipeds will avoid areas where sound levels could cause hearing impairment. Therefore it is not likely that an animal would stay in an area with intense noise that could cause severe levels of hearing damage.

Under the majority of the circumstances, anticipated takes are expected to be limited to short-term Level B harassment. Marine mammals present in the vicinity of the action area and taken by Level B harassment would most likely show overt brief disturbance (startle reaction) and avoidance of the area from elevated noise levels during pile driving and pile removal. Given the limited estimated number of incidents of Level A and Level B harassment and the limited, short-term nature of the responses by the individuals, the impacts of the estimated take cannot be reasonably expected to, and are not reasonably likely to, rise to the level that they would adversely affect either species at the population level, through effects on annual rates of recruitment or survival.

There are no known important habitats, such as rookeries or haul-outs, in the vicinity of the Navy's proposed Submarine Base New London pier construction project. The project also is not expected to have significant adverse effects on affected marine mammals' habitat, including prey, as analyzed in detail in the ''Anticipated Effects on Marine Mammal Habitat'' subsection.

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

Small Numbers

As noted above, only small numbers of incidental take may be authorized under section 101(a)(5)(A) of the MMPA for specified activities other than military readiness activities. The MMPA does not define small numbers and so, in practice, 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.

The estimated takes are below one percent of the population for all marine mammals (Table 6).

Based on the analysis contained herein of the proposed activity (including the prescribed 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 Subsistence 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.

Adaptive Management

The regulations governing the take of marine mammals incidental to Navy maintenance construction activities would contain an adaptive management component.

The reporting requirements associated with this proposed rule are designed to provide NMFS with monitoring data from the previous year to allow consideration of whether any changes are appropriate. The use of adaptive management allows NMFS to consider new information from different sources to determine (with input from the Navy regarding practicability) on an annual or biennial basis if mitigation or monitoring measures should be modified (including additions or deletions). Mitigation measures could be modified if new data suggests that such modifications would have a reasonable likelihood of reducing adverse effects to marine mammals and if the measures are practicable.

The following are some of the possible sources of applicable data to be considered through the adaptive management process: (1) Results from monitoring reports, as required by MMPA authorizations; (2) results from general marine mammal and sound research; and (3) any information which reveals that marine mammals may have been taken in a manner, extent, or number not authorized by these regulations or subsequent LOAs.

National Environmental Policy Act (NEPA)

Issuance of an MMPA authorization requires compliance with NEPA.

In accordance with NEPA (42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216–6A, we have determined that issuance of this rule and subsequent LOAs qualifies to be categorically excluded from further NEPA review. Issuance of the rule is consistent with categories of activities identified in CE B4 of the Companion Manual and we have not identified any extraordinary circumstances listed in Chapter 4 of the Companion Manual that would preclude use of this categorical exclusion.

Endangered Species Act (ESA)

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

Classification

Pursuant to the procedures established to implement Executive Order 12866, the Office of Management and Budget has determined that this proposed rule is not significant.

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA), the Chief Counsel for Regulation of the Department of Commerce has 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 U.S. Navy is the sole entity that would be subject to the requirements in these proposed regulations, and the Navy is not a small governmental jurisdiction, small organization, or small business, as defined by the RFA. Because of this certification, a regulatory flexibility analysis is not required and none has been prepared.

This proposed rule does not contain a collection-of-information requirement subject to the provisions of the Paperwork Reduction Act (PRA) because the applicant is a federal agency. Notwithstanding any other provision of law, no person is required to respond to nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the PRA unless that collection of information displays a currently valid OMB control number. These requirements have been approved by OMB under control number 0648–0151 and include applications for regulations, subsequent LOAs, and reports.

List of Subjects in 50 CFR Part 217

Exports, Fish, Imports, Incidental take, Indians, Labeling, Marine

mammals, Navy, Penalties, Reporting and recordkeeping requirements, Seafood, Sonar, Transportation.

Dated: July 20, 2018.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For reasons set forth in the preamble, 50 CFR part 217 is amended as follows:

PART 217—REGULATIONS GOVERNING THE TAKING AND IMPORTING OF MARINE MAMMALS

■ 1. The authority citation for part 217 continues to read as follows:

Authority: 16 U.S.C. 1361 *et seq.,* unless otherwise noted.

■ 2. Add subpart J to part 217 to read as follows:

Subpart J—Taking and Importing Marine Mammals; U.S. Navy's Submarine Base New London Pier Construction

Sec.

Subpart J—Taking and Importing Marine Mammals; U.S. Navy's Submarine Base New London Pier Construction

§ 217.90 Specified activity and specified geographical region.

(a) Regulations in this subpart apply only to the U.S. Navy (Navy) and those persons it authorizes or funds to conduct activities on its behalf for the taking of marine mammals that occurs in the area outlined in paragraph (b) of this section and that occurs incidental to the activities described in paragraph (c) of this section.

(b) The taking of marine mammals by the Navy may be authorized in Letters of Authorization (LOAs) only if it occurs within the Navy Submarine Base New London Study Area, which is located in the towns of Groton and Ledyard in New London County, Connecticut.

(c) The taking of marine mammals by the Navy is only authorized if it occurs incidental to the Navy's conducting in-water pier construction or demolition activities.

§ 217.91 Effective dates and definitions.

Regulations in this subpart are effective March 1, 2020 through February 28, 2025.

§ 217.92 Permissible methods of taking.

Under LOAs issued pursuant to § 216.106 of this chapter and § 217.96, the Holder of the LOAs (hereinafter ''Navy'') may incidentally, but not intentionally, take marine mammals within the area described in § 217.90(b) by Level A harassment and Level B harassment associated with in-water pile driving and pile removal activities, provided the activity is in compliance with all terms, conditions, and requirements of the regulations in this subpart and the applicable LOAs.

§ 217.93 Prohibitions.

Notwithstanding takings contemplated in § 217.92 and authorized by LOAs issued under § 216.106 of this chapter and § 217.96, no person in connection with the activities described in § 217.90 may:

(a) Violate, or fail to comply with, the terms, conditions, and requirements of this subpart or a LOA issued under § 216.106 of this chapter and § 217.96;

(b) Take any marine mammal not specified in such LOAs;

(c) Take any marine mammal specified in such LOAs in any manner other than as specified;

(d) Take a marine mammal specified in such LOAs if NMFS determines such taking results in more than a negligible impact on the species or stocks of such marine mammal; or

(e) Take a marine mammal specified in such LOAs if NMFS determines such taking results in an unmitigable adverse impact on the availability of such species or stock of marine mammal for taking for subsistence uses.

§ 217.94 Mitigation requirements.

When conducting the activities identified in § 217.90(c), the mitigation measures contained in any LOAs issued under § 216.106 of this chapter and § 217.96 must be implemented. These mitigation measures shall include but are not limited to:

(a) *Time restriction.* In-water construction and demolition work shall occur only during daylight hours.

(b) *Establishment of monitoring and shutdown zones.* (1) For all relevant in-water construction and demolition activity, the Navy shall designate Level A harassment zones with radial distances as identified in any LOA issued under § 216.106 of this chapter and § 217.96.

(2) For all relevant in-water construction and demolition activity, the Navy shall designate Level B harassment zones with radial distances as identified in any LOA issued under § 216.106 of this chapter and § 217.96.

(3) For all in-water construction and demolition activity, the Navy shall implement a minimum shutdown zone of a 10-m radius around the pile. If a marine mammal comes within or approaches the shutdown zone, such operations shall cease.

(c) *Monitoring visibility.* Pile driving shall only take place when the shutdown and Level A zones are visible and can be adequately monitored. If conditions (*e.g.,* fog) prevent the visual detection of marine mammals, activities with the potential to result in Level A harassment shall not be initiated. If such conditions arise after the activity has begun, pile driving or pile removal activities shall be halted if the 10-m shutdown zone is not visible.

(d) *Shutdown measures.* (1) The Navy shall deploy three protected species observers (PSOs) to monitor marine mammals during in-water pile driving and pile removal. One PSO shall be located on land and two shall be located in a boat to monitor the farther locations.

(2) Monitoring shall take place from 15 minutes prior to initiation of pile driving or removal activity through 30 minutes post-completion of pile driving or removal activity. Pre-activity monitoring shall be conducted for 15 minutes to ensure that the shutdown zone is clear of marine mammals, and pile driving or removal may commence when observers have declared the shutdown zone clear of marine mammals. In the event of a delay or shutdown of activity resulting from marine mammals in the shutdown zone, animals shall be allowed to remain in the shutdown zone (*i.e.,* must leave of their own volition) and their behavior shall be monitored and documented. Monitoring shall occur throughout the time required to drive or remove a pile. A determination that the shutdown zone is clear must be made during a period of good visibility (*i.e.,* the entire shutdown zone and surrounding waters must be visible to the naked eye).

(3) If a marine mammal approaches or enters the shutdown zone, or if a marine mammal not specified in the LOAs enters the Level B harassment zone, or if the take of a marine mammal species or stock has reached the take limits specified in any LOA issued under § 216.106 of this chapter and § 217.96 and enters the Level B harassment zone, all pile driving or removal activities at that location shall be halted. If pile driving or removal is halted or delayed due to the presence of a marine

mammal, the activity may not commence or resume until either the animal has voluntarily left and been visually confirmed beyond the shutdown zone or fifteen minutes have passed without re-detection of the animal.

(4) The Navy shall implement shutdown measures if the number of authorized takes for any particular species reaches the limit under the applicable LOA and if such marine mammals are sighted within the vicinity of the project area and are approaching the Level B harassment zone during in-water construction or demolition activities.

(e) *Soft start.* (1) The Navy shall implement soft start techniques for impact pile driving. The Navy shall conduct an initial set of three strikes from the impact hammer at 40 percent energy, followed by a 1-minute waiting period, then two subsequent three strike sets.

(2) Soft start shall be required for any impact driving, including at the beginning of the day, and at any time following a cessation of impact pile driving of 30 minutes or longer.

§ 217.95 Requirements for monitoring and reporting.

(a) *Marine mammal monitoring*—(1) *General requirements.* The Navy shall employ trained protected species observers (PSOs) to conduct marine mammal monitoring for its Submarine Base New London pier construction project. The PSOs shall observe and collect data on marine mammals in and around the project area for 15 minutes before, during, and for 30 minutes after all pile removal and pile installation work. PSOs shall have no other assigned tasks during monitoring periods, and shall be placed at the best vantage point(s) practicable to monitor for marine mammals and implement shutdown or delay procedures when applicable through communication with the equipment operator.

(2) *Protected species observer qualifications.* NMFS-approved PSOs shall meet the following requirements:

(i) Independent observers (*i.e.,* not construction personnel) are required;

(ii) At least one observer must have prior experience working as an observer;

(iii) Other observers may substitute education (undergraduate degree in biological science or related field) or training for experience;

(iv) Where a team of three or more observers are required, one observer should be designated as lead observer or monitoring coordinator. The lead observer must have prior experience working as an observer; and

(v) NMFS will require submission and approval of observer CVs.

(3) *Marine mammal monitoring protocols.* (i) The Navy shall conduct briefings between construction supervisors and crews and the PSO team prior to the start of all pile driving activities, and when new personnel join the work, in order to explain responsibilities, communication procedures, marine mammal monitoring protocol, and operational procedures. All personnel working in the project area shall watch the Navy's Marine Species Awareness Training video. An informal guide shall be included with the monitoring plan to aid in identifying species if they are observed in the vicinity of the project area.

(ii) The Navy shall monitor the Level A and Level B harassment zones before, during, and after pile driving activities for all in-water constructions. The Marine Mammal Monitoring Plan shall include the following procedures:

(A) *PSO location.* PSOs will be primarily located on boats, docks, and piers at the best vantage point(s) in order to properly see the entire shutdown zone(s).

(B) *PSO vantage point.* PSOs will be located at the best vantage point(s) to observe the zone associated with behavioral impact thresholds.

(C) *Observation equipment.* During all observation periods, PSOs will use high-magnification (25X), as well as standard handheld (7X) binoculars, and the naked eye to search continuously for marine mammals.

(D) *Ranging equipment.* Monitoring distances will be measured with range finders. Distances to animals will be based on the best estimate of the PSO, relative to known distances to objects in the vicinity of the PSO.

(E) *Bearing.* Bearings to animals will be determined using a compass.

(F) *Pre-activity monitoring.* The shutdown zone will be monitored for 15 minutes prior to in-water construction/demolition activities. If a marine mammal is present within the 10-m shutdown zone, the activity will be delayed until the animal(s) leaves the shutdown zone. Activity will resume only after the PSO has determined that, through sighting or by waiting 15 minutes, the animal(s) has moved outside the shutdown zone. If a marine mammal is observed approaching the shutdown zone, the PSO who sighted that animal will notify all other PSOs of its presence.

(G) *During activity monitoring.* If a marine mammal is observed entering the Level A or Level B harassment zones outside the 10-m shutdown zone, the pile segment being worked on will be completed without cessation, unless the animal enters or approaches the shutdown zone, at which point all pile driving activities will be halted. If an animal is observed within the shutdown zone during pile driving, then pile driving will be stopped as soon as it is safe to do so. Pile driving can only resume once the animal has left the shutdown zone of its own volition or has not been re-sighted for a period of 15 minutes.

(H) *Post-activity monitoring.* Monitoring of all zones will continue for 30 minutes following the completion of the activity.

(b) *Acoustic monitoring*—(1) *Sound source verification.* (i) The Navy shall conduct pile driving sound source verification for the following types and sizes of piles:

(A) Vibratory and impact installation of at least 5 16-in fiberglass reinforced plastic piles; and

(B) Rock socket drilling of at least 3 30-in and 3 16-in piles.

(ii) Sound source measurements of these piles sound shall be conducted at distances approximately 10 m from the source.

(iii) For vibratory pile driving/removal source level measurements, reports shall include 1-s sound exposure level (SEL), source spectrum, duration of recordings used to derived the SEL, and 24-hour cumulative SEL extrapolated from measurements.

(iv) For impact pile driving source level measurements, report should include peak sound pressure level (SPL_{pk}), root-mean-square SPL (SPL_{rms}), single strike SEL (SEL_{ss}), integration time for SPL_{rms}, SEL_{ss} spectrum, and 24-hour cumulative SEL extrapolated from measurements.

(2) *Level B harassment distance verification.* (i) The Navy shall empirically determine the Level B harassment distance either by extrapolating from in situ measurements conducted at several points between 10 and 500 m from the source, or by direct measurements to locate the distance where the received levels reach 120 dB or below, or at the ambient noise level.

(ii) Level B harassment zones to be empirically verified include:

(A) Rock socket drilling of at least 3 30-in and 3 16-in piles;

(B) Vibratory installation of at least 3 36-in steel piles; and

(C) Vibratory removal of at least 3 24-in concrete and 3 33-in concrete piles.

(iii) For extent of Level B harassment zone verification, the Navy shall report the measured or extrapolated distances where the received levels SPL_{rms} decay to 120-dB or to the ambient noise level,

whichever is higher, as well as integration time for such SPL_{rms}.

(3) *Source level calculation.* The sound levels reported should be in median and linear average (*i.e.,* taking averages of sound intensity before converting to dB).

(4) *Sediment type.* The passive acoustic monitoring reports shall also include sediment type where measurements are made.

(c) *Reporting measures*—(1) *Annual reports.* (i) The Navy shall submit an annual report within 90 days after each activity year, starting from the date when the LOA is issued (for the first annual report) or from the date when the previous annual report ended.

(ii) Annual reports shall detail the monitoring protocol, summarize the data recorded during monitoring, and estimate the number of marine mammals that may have been harassed during the period of the report.

(iii) Annual reports shall also include results from acoustic monitoring detailed in paragraph (b) of this section.

(iv) NMFS shall provide comments within 30 days after receiving annual reports, and the Navy shall address the comments and submit revisions within 30 days after receiving NMFS comments. If no comment is received from the NMFS within 30 days, the annual report is considered completed.

(2) *Final report.* (i) The Navy shall submit a comprehensive summary report to NMFS not later than 90 days following the conclusion of marine mammal monitoring efforts described in this subpart.

(ii) The final report shall synthesize all data recorded during marine mammal monitoring, and estimate the number of marine mammals that may have been harassed through the entire project.

(iii) NMFS would provide comments within 30 days after receiving this report, and the Navy shall address the comments and submit revisions within 30 days after receiving NMFS comments. If no comment is received from the NMFS within 30 days, the final report is considered as final.

(3) *Reporting of injured or dead marine mammals.* (i) In the unanticipated event that the construction or demolition activities clearly cause the take of a marine mammal in a prohibited manner, such as an injury, serious injury, or mortality, the Navy shall immediately cease all operations and immediately report the incident to the NMFS Office of Protected Resources, NMFS, and the Greater Atlantic Region Stranding Coordinators. The report must include the following information:

(A) Time, date, and location (latitude/longitude) of the incident;

(B) Description of the incident;

(C) Status of all sound source use in the 24 hours preceding the incident;

(D) Environmental conditions (*e.g.,* wind speed and direction, sea state, cloud cover, visibility, and water depth);

(E) Description of marine mammal observations in the 24 hours preceding the incident;

(F) Species identification or description of the animal(s) involved;

(G) The fate of the animal(s); and

(H) Photographs or video footage of the animal (if equipment is available).

(ii) Activities shall not resume until NMFS is able to review the circumstances of the prohibited take. NMFS shall work with the Navy to determine what is necessary to minimize the likelihood of further prohibited take and ensure MMPA compliance. The Navy may not resume their activities until notified by NMFS via letter, email, or telephone.

(iii) In the event that the Navy 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 (*i.e.,* in less than a moderate state of decomposition as described in the next paragraph), the Navy will immediately report the incident to the NMFS Office of Protected Resources, NMFS, and the Greater Atlantic Regional Stranding Coordinators. The report must include the same information identified in paragraph (c)(3)(i)(A) of this section. Activities may continue while NMFS reviews the circumstances of the incident. NMFS will work with the Navy to determine whether modifications in the activities are appropriate.

(iv) In the event that the Navy discovers an injured or dead marine mammal, and the lead protected species observer determines that the injury or death is not associated with or related to the activities authorized in the IHA (*e.g.,* previously wounded animal, carcass with moderate to advanced decomposition, or scavenger damage), the Navy shall report the incident to the NMFS Office of Protected Resources, NMFS, and the Greater Atlantic Regional Stranding Coordinators, within 24 hours of the discovery. The Navy shall provide photographs or video footage (if available) or other documentation of the stranded animal sighting to NMFS and the Marine Mammal Stranding Network. The Navy can continue its operations under such a case.

§ 217.96 Letters of Authorization.

(a) To incidentally take marine mammals pursuant to these regulations, the Navy must apply for and obtain LOAs in accordance with § 216.106 of this chapter for conducting the activity identified in § 217.90(c).

(b) LOAs, unless suspended or revoked, may be effective for a period of time not to extend beyond the expiration date of these regulations.

(c) If an LOAs expires prior to the expiration date of these regulations, the Navy may apply for and obtain a renewal of the LOAs.

(d) In the event of projected changes to the activity or to mitigation, monitoring, reporting (excluding changes made pursuant to the adaptive management provision of § 217.97(c)(1)) required by an LOA, the Navy must apply for and obtain a modification of LOAs as described in § 217.97.

(e) Each LOA shall set forth:

(1) Permissible methods of incidental taking;

(2) Means of effecting the least practicable adverse impact (*i.e.,* mitigation) on the species, their habitat, and the availability of the species for subsistence uses; and

(3) Requirements for monitoring and reporting.

(f) Issuance of the LOAs shall be based on a determination that the level of taking shall be consistent with the findings made for the total taking allowable under these regulations.

(g) Notice of issuance or denial of the LOAs shall be published in the **Federal Register** within 30 days of a determination.

§ 217.97 Renewals and modifications of Letters of Authorization.

(a) An LOA issued under § 216.106 of this chapter and § 217.96 for the activity identified in § 217.90(c) shall be renewed or modified upon request by the applicant, provided that:

(1) The proposed specified activity and mitigation, monitoring, and reporting measures, as well as the anticipated impacts, are the same as those described and analyzed for these regulations (excluding changes made pursuant to the adaptive management provision in paragraph (c)(1) of this section); and

(2) NMFS determines that the mitigation, monitoring, and reporting measures required by the previous LOAs under these regulations were implemented.

(b) For LOA modification or renewal requests by the applicant that include changes to the activity or the mitigation, monitoring, or reporting measures (excluding changes made pursuant to

the adaptive management provision in paragraph (c)(1) of this section) that do not change the findings made for the regulations or result in no more than a minor change in the total estimated number of takes (or distribution by species or years), NMFS may publish a notice of proposed LOA in the **Federal Register**, including the associated analysis of the change, and solicit public comment before issuing the LOA.

(c) An LOA issued under § 216.106 of this chapter and § 217.96 for the activity identified in § 217.90(c) may be modified by NMFS under the following circumstances:

(1) *Adaptive management.* After consulting with the Navy regarding the practicability of the modifications, NMFS may modify (including by adding or removing measures) the existing mitigation, monitoring, or reporting measures if doing so creates a reasonable likelihood of more effectively accomplishing the goals of the mitigation and monitoring set forth in the preamble for these regulations.

(i) Possible sources of data that could contribute to the decision to modify the mitigation, monitoring, or reporting measures in an LOA:

(A) Results from the Navy's monitoring from the previous year(s);

(B) Results from other marine mammal and/or sound research or studies; or

(C) Any information that reveals marine mammals may have been taken in a manner, extent or number not authorized by these regulations or subsequent LOAs.

(ii) If, through adaptive management, the modifications to the mitigation, monitoring, or reporting measures are substantial, NMFS shall publish a notice of proposed LOA in the **Federal Register** and solicit public comment.

(2) *Emergencies.* If NMFS determines that an emergency exists that poses a significant risk to the well-being of the species or stocks of marine mammals specified in LOAs issued pursuant to § 216.106 of this chapter and § 217.96, an LOA may be modified without prior notice or opportunity for public comment. Notice would be published in the **Federal Register** within thirty days of the action.

§ 217.98 [Reserved]

§ 217.99 [Reserved]

[FR Doc. 2018–15938 Filed 7–30–18; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 83, No. 147
Tuesday, July 31, 2018

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

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

6 CFR Part 5

[Docket No. DHS–2018–0002]

Privacy Act of 1974: Implementation of Exemptions; Department of Homeland Security/U.S. Citizenship and Immigration Services–018 Immigration Biometric and Background Check (IBBC) System of Records

AGENCY: Department of Homeland Security.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Homeland Security (DHS) is giving concurrent notice of a newly established system of records pursuant to the Privacy Act of 1974 for the ''Department of Homeland Security/U.S. Citizenship and Immigration Services–018 Immigration Biometric and Background Check System of Records'' and this proposed rulemaking. In this proposed rulemaking, the Department proposes to exempt portions of the system of records from one or more provisions of the Privacy Act because of criminal, civil, and administrative enforcement requirements.

DATES: Comments must be received on or before August 30, 2018.

ADDRESSES: You may submit comments, identified by docket number DHS–2018–0002 by one of the following methods:

- *Federal e-Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–343–4010.
- *Mail:* Philip S. Kaplan, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528–0655.

Instructions: All submissions received must include the agency name and docket number DHS–2018–0002 for this notice. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT:

For general questions please contact: Donald K. Hawkins, (202) 272–8030, *USCIS.PrivacyCompliance@uscis.dhs.gov*, Privacy Officer, U.S. Citizenship and Immigration Services, 20 Massachusetts Avenue NW, Washington, DC 20529.

For privacy questions please contact: Philip S. Kaplan, (202) 343–1717, *Privacy@hq.dhs.gov*, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528–0655.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the Privacy Act of 1974, 5 U.S.C. 552a, the DHS U.S. Citizenship and Immigration Services (USCIS) has relied on two preexisting DHS/USCIS Privacy Act system of records notices (SORN) for the maintenance of USCIS biometric and background check records: ''DHS/USCIS 002 Background Check Service,'' 72 FR 31082 (June 5, 2007), and ''DHS/USCIS–003 Biometric Storage System,'' 72 FR 17172 (April 6, 2007). DHS plans to rescind these SORNs. Records covered under these preexisting SORNs will now be covered by one new system of records named ''DHS/USCIS–018 Immigration Biometric and Background Check System of Records'' (IBBC). This SORN consolidates all USCIS records maintained on biometric and associated biographic information it collects pursuant to its mission to process and adjudicate immigration benefit requests and other immigration request forms (*e.g.,* applications and petitions). The purpose of this system is to verify identity and conduct criminal and national security background checks in order to establish an individual's eligibility for an immigration benefit or other request, and support domestic and international data sharing efforts. USCIS determines eligibility by capturing biometric and associated biographic data from benefit requestors, beneficiaries, and other categories of individuals to facilitate three key operational functions: (1) Verify an individual's identity; (2) conduct criminal and national security background checks; and (3) produce benefit cards/documents as a proof of benefit. Further, this system permits the sharing of information covered by this system between the United States and foreign partners to prevent terrorism, including terrorist travel; prevent serious crime and other threats to national security and public safety; and assist in the administration and enforcement of immigration laws.

A description of this consolidated system is further described in DHS/USCIS's notice of a new Privacy Act systems of records published elsewhere in this **Federal Register**.

II. Privacy Act

The Privacy Act embodies fair information practice principles in a statutory framework under which Federal Government agencies collect, maintain, use, and disseminate individuals' records. The Privacy Act applies to information that is maintained in a ''system of records.'' A ''system of records'' is a group of any records under the control of an agency from which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. In the Privacy Act, an individual is defined to encompass U.S. citizens and lawful permanent residents. Additionally, the Judicial Redress Act (JRA) provides a statutory right to covered persons to make requests for access and amendment to covered records, as defined by the JRA, along with judicial review for denials of such requests. In addition, the JRA prohibits disclosures of covered records, except as otherwise permitted by the Privacy Act.

The Privacy Act allows government agencies to exempt certain records from the access and amendment subsection 552a(d) provisions. If an agency claims an exemption, however, it must issue a Notice of Proposed Rulemaking and Final Rule to make clear to the public the reasons why a particular exemption is claimed.

DHS is claiming exemptions from certain requirements of the Privacy Act for DHS/USCIS–018 Immigration Biometric and Background Check System of Records. Information in DHS/USCIS–018 Immigration Biometric and Background Check System of Records relates to official DHS national security,

law enforcement, immigration, and intelligence activities. These exemptions are needed to protect ongoing investigations and law enforcement activities. Specifically, the exemptions are required to preclude subjects of these activities from frustrating these processes; to avoid disclosure of activity techniques; to protect the identities and physical safety of confidential informants and law enforcement personnel; to ensure DHS's ability to obtain information from third parties and other sources; and to safeguard classified information. Disclosure of information to the subject of the inquiry could also permit the subject to avoid detection or apprehension.

In appropriate circumstances, when compliance would not appear to interfere with or adversely affect the law enforcement purposes of this system and the overall law enforcement process, the applicable exemptions may be waived on a case by case basis.

List of Subjects in 6 CFR Part 5

Freedom of information, Privacy.

For the reasons stated in the preamble, DHS proposes to amend chapter I of title 6, Code of Federal Regulations, as follows:

PART 5—DISCLOSURE OF RECORDS AND INFORMATION

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

Authority: 6 U.S.C. 101 *et seq.;* Pub. L. 107–296, 116 Stat. 2135; 5 U.S.C. 301. Subpart A also issued under 5 U.S.C. 552. Subpart B also issued under 5 U.S.C. 552a.

■ 2. Add at the end of appendix C to part 5, the following new paragraph ''78'':

Appendix C to Part 5—DHS Systems of Records Exempt From the Privacy Act

* * * * *

78. The DHS/USCIS–018 Immigration Biometric and Background Check (IBBC) System of Records covers electronic and paper records and will be used by DHS and its components. The DHS/USCIS–018 IBBC System of Records covers information held by DHS/USCIS in connection with its several and varied missions and functions, including, but not limited to, the enforcement of civil and criminal laws; investigations, inquiries, and proceedings there under; and national security and intelligence activities. The DHS/USCIS–018 IBBC System of Records contains information that is collected by, on behalf of, in support of, or in cooperation with DHS and its components and may contain personally identifiable information collected by other Federal, state, local, tribal, foreign, or international government agencies.

The Secretary of Homeland Security, pursuant to Secretary's delegation 15002 to the Director of USCIS to conduct certain law enforcement activities when necessary to protect the national security and public safety, pursuant to 5 U.S.C. 552a(j)(2), has exempted this system from the following provisions of the Privacy Act: 5 U.S.C. 552a(c)(3), (c)(4); (d); (e)(1), (e)(2), (e)(3), (e)(4)(G), (e)(4)(H), (e)(4)(I), (e)(5), (e)(8); (f); and (g). Additionally, the Secretary of Homeland Security, pursuant to 5 U.S.C. 552a(k)(2), has exempted this system from the following provisions of the Privacy Act: 5 U.S.C. 552a(c)(3); (d); (e)(1), (e)(4)(G), (e)(4)(H), (e)(4)(I); and (f). Where a record received from another system has been exempted in that source system under 5 U.S.C. 552a(j)(2), DHS will claim the same exemptions for those records that are claimed for the original primary systems of records from which they originated and claims any additional exemptions set forth here.

Exemptions from these particular subsections are justified, on a case-by-case basis to be determined at the time a request is made, for the following reasons:

(a) From subsection (c)(3) and (4) (Accounting for Disclosures) because release of the accounting of disclosures could alert the subject of an investigation of an actual or potential criminal, civil, or regulatory violation to the existence of that investigation and reveal investigative interest on the part of DHS as well as the recipient agency. Disclosure of the accounting would therefore present a serious impediment to law enforcement efforts and/or efforts to preserve national security. Disclosure of the accounting would also permit the individual who is the subject of a record to impede the investigation, to tamper with witnesses or evidence, and to avoid detection or apprehension, which would undermine the entire investigative process.

(b) From subsection (d) (Access to Records) because access to the records contained in this system of records could inform the subject of an investigation of an actual or potential criminal, civil, or regulatory violation to the existence of that investigation and reveal investigative interest on the part of DHS or another agency. Access to the records could permit the individual who is the subject of a record to impede the investigation, to tamper with witnesses or evidence, and to avoid detection or apprehension. From subsection (d) (Amendment to Records) because permitting amendment of records could interfere with ongoing investigations and law enforcement activities and would impose an unreasonable administrative burden by requiring investigations to be continually reinvestigated. In addition, permitting access and amendment to such information could disclose security-sensitive information that could be detrimental to homeland security.

(c) From subsection (e)(1) (Relevancy and Necessity of Information) because in the course of investigations into potential violations of federal law, the accuracy of information obtained or introduced occasionally may be unclear, or the information may not be strictly relevant or necessary to a specific investigation. In the interests of effective law enforcement, it is appropriate to retain all information that may aid in establishing patterns of unlawful activity.

(d) From subsection (e)(2) (Collection of Information from Individuals) because requiring that information be collected from the subject of an investigation would alert the subject to the nature or existence of the investigation, thereby interfering with that investigation and related law enforcement activities.

(e) From subsection (e)(3) (Notice to Subjects) because providing such detailed information could impede law enforcement by compromising the existence of a confidential investigation or reveal the identity of witnesses or confidential informants.

(f) From subsections (e)(4)(G), (e)(4)(H), and (e)(4)(I) (Agency Requirements) and (f) (Agency Rules), because portions of this system are exempt from the individual access provisions of subsection (d) for the reasons noted above, and therefore DHS is not required to establish requirements, rules, or procedures with respect to such access. Providing notice to individuals with respect to existence of records pertaining to them in the system of records or otherwise setting up procedures pursuant to which individuals may access and view records pertaining to themselves in the system would undermine investigative efforts and reveal the identities of witnesses, and potential witnesses, and confidential informants.

(g) From subsection (e)(5) (Collection of Information) because with the collection of information for law enforcement purposes, it is impossible to determine in advance what information is accurate, relevant, timely, and complete. Compliance with subsection (e)(5) would preclude DHS agents from using their investigative training and exercise of good judgment to both conduct and report on investigations.

(h) From subsection (e)(8) (Notice on Individuals) because compliance would interfere with DHS's ability to obtain, serve, and issue subpoenas, warrants, and other law enforcement mechanisms that may be filed under seal and could result in disclosure of investigative techniques, procedures, and evidence.

(i) From subsection (g) (Civil Remedies) to the extent that the system is exempt from other specific subsections of the Privacy Act.

Philip S. Kaplan,

Chief Privacy Officer, Department of Homeland Security.

[FR Doc. 2018–16137 Filed 7–30–18; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 316

[Docket No. FSIS 2018–0019]

RIN 0583–AD69

Elimination of the Requirement That Livestock Carcasses Be Marked ''U.S. Inspected and Passed'' at the Time of Inspection Within a Slaughter Establishment for Carcasses to be Further Processed Within the Same Establishment

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: FSIS is proposing to amend the Federal meat inspection regulations to eliminate the requirement that livestock carcasses be marked with the official inspection legend at the time of inspection in a slaughter establishment, if the carcasses are to be further processed in the same establishment.

DATES: Comments must be received on or before October 1, 2018.

ADDRESSES: FSIS invites interested persons to submit comments on this proposed rule. Comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* This website provides the ability to type short comments directly into the comment field on this web page or attach a file for lengthier comments. Go to *http://www.regulations.gov.* Follow the on-line instructions at that site for submitting comments.
- *Mail, including CD–ROMs:* Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Room 6065, Washington, DC 20250–3700.
- *Hand- or courier-delivered submittals:* Deliver to 1400 Independence Avenue SW, Room 6065, Washington, DC 20250–3700.
- *Instructions:* All items submitted by mail or electronic mail must include the Agency name and docket number FSIS–2018–0005. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to *http://www.regulations.gov.*

Docket: For access to background documents or comments received, call (202) 720–5627 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Room 6065, Washington, DC 20250–3700.

FOR FURTHER INFORMATION CONTACT: Roberta Wagner, Assistant Administrator, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture; Telephone: (202) 205–0495.

SUPPLEMENTARY INFORMATION:

Background

In the past, slaughter establishments often would ship carcasses to other establishments for further processing into primal, subprimal, and other meat cuts and products. Today however, most establishments that slaughter swine, cattle, or sheep also fabricate the carcasses into various primal and subprimal parts, as well as other meat products. After a carcass has passed inspection, the slaughter establishment typically moves it, under control, to another department in the same establishment for further processing. The establishment then typically ships the resulting meat food products, rather than marked carcasses, in fully labeled containers either for further processing at other establishments or into commerce.

The Federal Meat Inspection Act (FMIA) requires the inspection of all livestock carcasses and parts of livestock carcasses prepared in slaughter establishments as articles of commerce capable of use as human food (21 U.S.C. 604). In this same provision, the FMIA requires that such carcasses and parts of carcasses found to be not adulterated be stamped as ''inspected and passed'' before they enter commerce. The FMIA also gives FSIS broad authority to promulgate rules and regulations necessary to carry out its provisions (21 U.S.C. 621).

The regulations at 9 CFR 316.9 set forth more prescriptive, and partially outdated, requirements for the marking of inspected carcasses. Specifically, the regulation at 9 CFR 316.9(a) requires each carcass at an official establishment to be marked at the time of inspection with the official inspection legend. This requirement is intended to prevent uninspected carcasses from being shipped in commerce from slaughter establishments to processing establishments or elsewhere. However, given contemporary practices at slaughter establishments, marking the carcass on the slaughter floor is often unnecessary, as the carcass will be moved elsewhere in the same establishment for further processing.

Requests To Move Carcasses and Parts of Carcasses To Processing Without Marking the Carcass

Numerous slaughter establishments have requested waivers from the requirement in 9 CFR 316.9(a), *i.e.,* that the carcasses they further process in-house not be required to be marked at the time of inspection. The information presented with these requests has described the steps that establishments would take to ensure that uninspected, unmarked, or adulterated product does not enter commerce. These steps typically include: (1) Ensuring that all carcasses inspected and passed by USDA, but not marked on the slaughter floor, are stored and processed in the establishment; (2) ensuring that all products shipped from the establishment bear the mark of inspection or are shipped in fully labeled containers that bear the mark of inspection; and (3) ensuring that FSIS still maintains control over any carcasses that do not pass inspection.

FSIS has granted many of these waivers, per the regulations at 9 CFR 303.1, thereby allowing inspected and passed carcasses to move, without the mark of inspection, from the slaughter floor to processing departments in the same establishment. At one point, because of the high number of waivers granted, FSIS issued an administrative notice to inspectors (FSIS Notice 17–16) with instructions for verification activities at establishments that had received a waiver from these requirements. FSIS has allowed this notice to expire, in anticipation of this rulemaking. Further, based on discussions with FSIS District Offices, while a significant number of establishments are currently operating under such waivers, there are no reports of unmarked carcasses being shipped into commerce.

FSIS has carefully considered the available information on allowing establishments to move carcasses and parts of carcasses to processing without marking the carcass with the inspection legend. From its experience with establishments to which it has provided waivers, the Agency has concluded that controls that establishments have put in place and Agency procedures to address inspection of unmarked carcasses have been successful in preventing unmarked carcasses from leaving the establishment for processing in an outside facility. FSIS is thus proposing that establishments not be required to mark carcasses with the inspection legend when the carcasses leave the slaughter floor to be further processed within the same establishment. However, all primals, subprimals, parts and other meat food products will have to be properly labeled and bear the mark of inspection before entering commerce.

Under the proposed rule, FSIS inspection personnel will continue to

verify that the establishment has in place in its Hazard Analysis and Critical Control Point (HACCP) plan, Sanitation Standard Operating Procedures (SOPs), or other prerequisite programs, controls to ensure that unmarked carcasses are further processed in the establishment and that carcasses that are not further processed in the establishment do not leave the establishment unmarked. Additionally, should this rule become final, inspectors would verify through records review or direct observation that the establishment's procedures ensure that: (1) The establishment properly identifies and handles carcasses or parts eligible for the mark of inspection through edible channels, so that only edible, inspected and passed product proceeds to fabrication; (2) the establishment can account for the number of carcasses it slaughters and moves through its establishment and that it correctly identifies the species slaughtered on the final label; (3) retained carcasses or parts remain under FSIS control until the establishment makes corrections that render the carcass or part eligible to bear the mark of inspection (*e.g.,* carcasses retained for residue sample or pending pathology disposition are held in FSIS controlled retained cages in the cooler); and (4) whole carcasses transported to another establishment bear the mark of inspection.

Executive Orders 12866 and 13563, and the Regulatory Flexibility Act

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 benefits, distributive impacts, and equity). Executive Order (E.O.) 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This proposed rule has been designated as a ''non-significant'' regulatory action under section 3(f) of E.O. 12866. Accordingly, the rule has not been reviewed by the Office of Management and Budget (OMB) under E.O. 12866.

Economic Impact Analysis

FSIS is proposing to remove the requirement for carcasses slaughtered in an establishment to bear the mark of inspection after being inspected and passed on the slaughter floor if the carcasses are to be further processed in the same establishment. Since this requirement is no longer necessary to prevent adulterated food product from entering commerce (see explanation in the Background section above), removing it will have no negative public health impact. Nor will it impose costs on the industry or the Agency.

In regard to benefits from the rulemaking, removing an unnecessary requirement will allow establishments the flexibility to be innovative and to operate in the most efficient manner. In addition, it will also allow FSIS to utilize its resources more appropriately by relieving inspectors of unnecessary tasks. The expected benefits from this proposed rule would accrue from time and resource savings. Inspected and passed carcasses meant for further processing would not have to wait for the mark of inspection but could move directly to further processing. Thus, establishments that slaughter livestock and process livestock carcasses in the same facility would benefit from fewer delays in their operations and greater flexibility to conduct processing operations on inspected and passed carcasses.

Agency data show that there are approximately 797 meat slaughtering establishments, and approximately 676 of them (~85 percent) do both slaughtering and processing.[1] FSIS estimates that approximately 644 of these 676 establishments (~95 percent) further process the carcasses they slaughter. Given that the annual production of meat by Federal inspected establishments is approximately 150 million heads,[2] roughly 120.9 million carcasses are subject to the requirements in 9 CFR 316.9 (150 million × 85 percent × 95 percent). Assuming that it takes establishment labor, on average, 3 seconds to stamp each carcass, and that approximately half of the establishments already have waivers from the requirement, approximately 50,417 additional hours would be saved. Most establishments use hired workers to do the stamping. If we assume the average hourly pay (salary plus benefits) is $20,[3] then the time saved is equivalent to approximately $1.01 million annually.

In addition, such establishments would no longer need to replace the broken or worn out stamps previously used for marking carcasses on the slaughter floor. Typically, a stamp (usually made of bronze) costs $225 and lasts 5 years.[4] The annualized cost of the stamp is $55 (if the interest rate is 7 percent) or $50 (if the interest rate is 3 percent). Assuming each establishment (that does not already have a waiver from the requirement) uses one stamp per year, the annual savings on these stamps would be between $16,700 and $18,600.

Additionally, establishments would no longer need to make written requests for waivers from the requirement to stamp carcasses further processed within the same establishment and would no longer need to wait to have such requests approved. Further, because FSIS inspectors would no longer need to ensure that inspected and passed carcasses bear the mark of inspection before they are sent for further processing, FSIS inspectors would have greater flexibility to focus on activities that are more important in ensuring food safety, such as verifying that establishments meet HACCP regulations and collecting product samples. However, the time needed for submitting a written waiver request and waiting for approval is minimal, and the saving of that time would be offset by the increase in time needed for establishments to amend their HACCP plans, Sanitation SOPs, or prerequisite programs to add controls for the movement of these unmarked carcasses under this proposed rule. Similarly, the time saved for FSIS inspectors to ensure that inspected carcasses bear the mark of inspection would be offset by the increase in time to verify that establishments meet HACCP regulations.

There are no expected costs associated with this proposed rule. Establishments already operating under a waiver will have procedures in their HACCP plans, Sanitation SOPs, or prerequisite programs that ensure that carcasses that are not further processed in the establishment do not leave the establishment unmarked. Other establishments will need to revise these procedures. However, FSIS expects that any costs associated with revising the procedures would be offset by increased flexibility allowed to those establishments as discussed in the foregoing section.

Regulatory Flexibility Act Assessment

The FSIS Administrator has made a preliminary determination that this

[1] Data source: Public Health Inspection System as of June 2017, provided by FSIS's Office of Data Integration and Food Protection.

[2] Livestock Slaughter 2016 Summary (April 2017). USDA, National Agricultural Statistics. *http://usda.mannlib.cornell.edu/usda/current/LiveSlauSu/LiveSlauSu-04-19-2017.pdf,* p.15. accessed 06/01/2017.

[3] Data source: Bureau of Labor Statistics (BLS) most recent report of average wage of meat slaughterers and packers. *https://www.bls.gov/oes/current/oes513023.htm/*, accessed 06/2017.

[4] Data from Ketchum Manufacturing Inc., a manufacturer of meat stamps, through telephone interview on 4/17/2017.

proposed rule will not have a significant economic impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act (5 U.S.C. 601). The proposed rule will not increase costs to the industry.

Executive Order 13771

Consistent with E.O. 13771 (82 FR 9339, February 3, 2017), FSIS has estimated that this proposed rule would yield cost savings. Therefore, if finalized as proposed, this rule is expected to be an E.O. 13771 deregulatory action.

Paperwork Reduction Act

There are no paperwork or recordkeeping requirements associated with this proposed rule under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

E-Government Act

FSIS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, *et seq.*) by, among other things, promoting the use of the internet and other information technologies and providing increased opportunities for citizen access to Government information and services, and for other purposes.

Executive Order 12988, Civil Justice Reform

This proposed rule has been reviewed under E.O. 12988, Civil Justice Reform. Under this rule: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) no administrative proceedings will be required before parties may file suit in court challenging this rule.

Executive Order 13175

This rule has been reviewed in accordance with the requirements of E.O. 13175, ''Consultation and Coordination with Indian Tribal Governments.'' E.O. 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.

FSIS has assessed the impact of this rule on Indian tribes and determined that this rule does not, to our knowledge, have tribal implications that require tribal consultation under E.O. 13175. If a Tribe requests consultation, FSIS will work with the Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions and modifications identified herein are not expressly mandated by Congress.

USDA Non-Discrimination Statement

No agency, officer, or employee of the USDA shall, on the grounds of race, color, national origin, religion, sex, gender identity, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, or political beliefs, exclude from participation in, deny the benefits of, or subject to discrimination any person in the United States under any program or activity conducted by the USDA.

How To File a Complaint of Discrimination

To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at *http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf,* or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email: *Mail:* U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW, Washington, DC 20250–9410; *Fax:* (202) 690–7442; *Email: program.intake@usda.gov*.

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.), should contact USDA's TARGET Center at (202) 720–2600 (voice and TDD).

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS web page located at: *http://www.fsis.usda.gov/federal-register.*

FSIS also will make copies of this publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. Constituent updates are available on the FSIS web page. Through the web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: *http://www.fsis.usda.gov/subscribe.* Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

List of Subjects in 9 CFR Part 316

Food labeling, Food packaging, Meat inspection.

For the reasons set forth in the preamble, FSIS is proposing to amend 9 CFR part 316 as follows:

PART 316—MARKING PRODUCTS AND THEIR CONTAINERS

■ 1. The authority citation for part 316 is revised to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.18, 2.55.

■ 2. In § 316.9, revise paragraph (a), redesignate paragraphs (b) through (d) as paragraphs (c) through (e), respectively, and add a new paragraph (b) to read as follows:

§ 316.9 Products to be marked with official marks.

(a) Each carcass that has been inspected and passed in an official establishment must be marked at the time of inspection with the official inspection legend containing the number of the official establishment, if the carcass is to be shipped into commerce from the establishment without further processing.

(b) A passed and inspected carcass that is to be further processed in the slaughtering establishment need not be marked with the official inspection legend at the time of inspection, provided the establishment develops and implements, as part of a HACCP plan, Sanitation SOPs, or other prerequisite program, procedures to ensure that:

(1) Unmarked carcasses are further processed only in the slaughtering establishment;

(2) Unmarked carcasses that, for any reason, are not further processed in the establishment do not leave the establishment unmarked; and

(3) Unmarked and retained carcasses or parts remain under FSIS control until the establishment makes any corrections that are necessary to render the carcass or part eligible to bear the mark of inspection.

* * * * *

Done in Washington, DC.

Paul Kiecker,

Acting Administrator.

[FR Doc. 2018–16345 Filed 7–30–18; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 318 and 381

[Docket No. FSIS 2016–0032]

RIN 0583–AD66

Preparation of Uninspected Products Outside of the Hours of Inspectional Supervision

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: FSIS is proposing to amend the Federal meat and poultry products inspection regulations to eliminate prescriptive requirements governing the manufacture of uninspected products, such as pet food, in edible product areas of official establishments and to allow official establishments to manufacture such products outside the hours of inspection.

DATES: To receive full consideration, comments should be received by August 30, 2018.

ADDRESSES: FSIS invites interested persons to submit comments on this proposed rule. Comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* This website provides the ability to type short comments directly into the comment field on this web page or attach a file for lengthier comments. Go to *http://www.regulations.gov.* Follow the on-line instructions at that site for submitting comments.
- *Mail, including CD–ROMs, etc.:* Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Room 6065, Washington, DC 20250–3700.
- *Hand- or courier-delivered submittals:* Deliver to 1400 Independence Avenue SW, Room 6065, Washington, DC 20250–3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS–2018–0005. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to *http://www.regulations.gov.*

Docket: For access to background documents or comments received, call (202) 720–5627 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Room 6065, Washington, DC 20250–3700.

FOR FURTHER INFORMATION CONTACT: Roberta Wagner, Assistant Administrator, Office of Policy and Program Development; Telephone: (202) 205–0495.

SUPPLEMENTARY INFORMATION:

Background

FSIS regulations at 9 CFR 318.12 and 381.152 govern the manufacture of pet food and other uninspected, inedible products in official meat and poultry establishments. These regulations set forth prescriptive requirements intended to prevent the creation of insanitary conditions in official establishments, the commingling of inedible and edible meat and poultry products, and the movement of inedible meat and poultry products into commerce as human food. They also require that pet food and other inedible products be manufactured in official establishments *only* when an FSIS inspector is on premises.

These prescriptive requirements for the production of pet food and other inedible products (*e.g.,* inedible rendered fats, lungs, lung lobes, and experimental products) are incompatible with the Hazard Analysis and Critical Control Point (HACCP) regulations at 9 CFR part 417 and the related sanitation regulations at 9 CFR part 416. Under the HACCP regulations, establishments are responsible for developing and implementing HACCP plans incorporating the controls determined by the establishment to be necessary and appropriate to produce safe, unadulterated products. Specifically under HACCP, official establishments must determine the food safety hazards reasonably likely to occur in the production process; institute controls necessary to prevent those hazards from occurring or keeping them within acceptable limits; monitor the performance of controls and verify the HACCP system is working as intended; and maintain required HACCP records. HACCP is a flexible system that appropriately places the responsibility for food safety on establishments and enables them to tailor their control systems to the needs of specific processes and operating conditions.

Similarly, the Sanitation Performance Standards (SPS) and requirements for Sanitation Standard Operating Procedures (SOPs) at 9 CFR part 416 set forth sanitation objectives to be achieved, while allowing establishments to develop and employ innovative and effective sanitation procedures customized to the nature of their operations. Under the Sanitation SOP regulations, FSIS requires that all inspected establishments develop and implement written Sanitation SOPs to prevent direct contamination or adulteration of product before and during operations. An establishment's Sanitation SOP typically covers the scheduled, daily pre-operational and operational cleaning and sanitation of equipment and surfaces that may contact product directly. Under the SPS regulations, establishments must address all of the other aspects of establishment sanitation that can affect food safety, *e.g.,* pest control, adequate ventilation, lighting, and plumbing systems.

Under the HACCP and sanitation requirements, an establishment that produces both edible and inedible meat and poultry products must develop and implement the controls and procedures necessary to prevent the adulteration of edible products by insanitary conditions and product commingling, as well as the movement of inedible products into commerce as human food. FSIS inspectors verify the implementation and effectiveness of these controls through inspection, records review and, as necessary, product sampling. Thus, FSIS inspectors do not need to be present in an official establishment when it manufactures inedible products in order to verify that edible products are not adulterated as a result.

Proposed Changes

FSIS is proposing to eliminate the prescriptive regulatory requirements at 9 CFR 318.12 and 381.152 governing the manufacture of uninspected, inedible products, such as pet food, and restricting the hours during which such products may be prepared in an official establishment. Specifically, these regulations set forth specific requirements regarding the sanitary handling of inedible products and their separation from edible products, as well as the placement, movement and cleaning of equipment in areas where inedible product is manufactured. They also require that the manufacture of uninspected, inedible products be conducted only during those hours in which the establishment operates under inspectional supervision. These regulations were issued before FSIS published its HACCP and Sanitation SOP regulations, when prescriptive regulatory requirements were deemed necessary to prevent the adulteration of meat and poultry products by the

preparation of inedible products in the same establishment.

FSIS is proposing to replace the prescriptive requirements in 9 CFR 318.12 and 381.152 with general standards governing the manufacture of uninspected, inedible products in official establishments. The proposed standards require that the manufacture of uninspected products in official establishments must not result in the adulteration of meat and poultry products, create insanitary conditions whereby meat and poultry products may be adulterated, or prevent or otherwise interfere with inspection or other program tasks performed by FSIS personnel. Establishments that manufacture pet food and other inedible products should be meeting these proposed standards already, through the implementation of their HACCP plans, Sanitation SOPs or other prerequisite programs.

Executive Order 12866 and the Regulatory Flexibility Act

This proposed rule has been designated as a ''non-significant'' regulatory action under section 3(f) of Executive Order (E.O.) 12866. Accordingly, the proposed rule has not been reviewed by the Office of Management and Budget under E.O. 12866.

Economic Impact Analysis

As stated above, the HACCP and the sanitation regulations provide a framework or food safety system for establishments to produce safe, unadulterated product. Compliance with these requirements makes the prescriptive requirements in 9 CFR 318.12 and 381.151 unnecessary. Because these prescriptive requirements are no longer necessary to ensure the production of safe, unadulterated food, removing them will have no negative public health impact. In addition, this rule will not impose costs on the industry or the Agency.

Further, removing the unnecessary, prescriptive requirements should allow establishments additional flexibility to be innovative and to operate in the most efficient manner. Similarly, the rule should also allow FSIS to use its resources more appropriately by relieving inspectors of unnecessary tasks.

Regulatory Flexibility Act (RFA)

FSIS has examined the economic implications of the proposed rule as required by the RFA (5 U.S.C 601–612). If a rule has a significant economic impact on a substantial number of small entities, the RFA requires that regulatory options that would lessen the economic effect of the rule on small entities be analyzed. FSIS has determined that, should it become final, the proposed rule would not have a significant impact on a substantial number of small entities.

Executive Order 13771

This proposed rule, if finalized as proposed, is expected to be a deregulatory action under E.O. 13771. Assessment of the costs and cost savings may be found in the preceding economic analysis.

Paperwork Reduction Act

There are no paperwork or recordkeeping requirements associated with this proposed rule under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

E-Government Act

FSIS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, *et seq.*) by, among other things, promoting the use of the internet and other information technologies and providing increased opportunities for citizen access to Government information and services, and for other purposes.

Executive Order 12988, Civil Justice Reform

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under this rule: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) no administrative proceedings will be required before parties may file suit in court challenging this rule.

Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, ''Consultation and Coordination with Indian Tribal Governments.'' E.O. 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.

FSIS has assessed the impact of this rule on Indian tribes and determined that this rule does not, to our knowledge, have tribal implications that require tribal consultation under E.O. 13175. If a Tribe requests consultation, the Food Safety and Inspection Service will work with the Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions and modifications identified herein are not expressly mandated by Congress.

USDA Non-Discrimination Statement

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How To File a Complaint of Discrimination

To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at *http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf,* or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email: *Mail:* U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW, Washington, DC 20250–9410; *Fax:* (202) 690–7442; Email: *program.intake@usda.gov.*

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addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: *http://www.fsis.usda.gov/subscribe.* Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

List of Subjects

9 CFR Part 318

Food additives, Food packaging, Laboratories, Meat inspection, Reporting and recordkeeping requirements, Signs and symbols.

9 CFR Part 381

Administrative practice and procedure, Animal diseases, Crime, Exports, Food grades and standards, Food labeling, Food packaging, Government employees, Grant programs-agriculture, Intergovernmental relations, Laboratories, Meat inspection, Nutrition, Polychlorinated biphenyls, Poultry and poultry products, Reporting and recordkeeping requirements, Seizures and forfeitures, Signs and symbols, Technical Assistance, Transportation.

For the reasons set forth in the preamble, FSIS is proposing to amend 9 CFR parts 318 and 381 as follows:

PART 318—ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND PREPARATION OF PRODUCTS

■ 1. The authority citation for part 318 continues to read as follows:

Authority: 7 U.S.C. 138f, 450, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

■ 2. Section 318.12 is revised to read as follows:

§ 318.12 Manufacture of uninspected, inedible products at official establishments.

(a) Official establishments may manufacture pet food or similar uninspected, inedible products in areas where edible products also are produced, provided that the manufacture of uninspected, inedible products does not:

(1) Adulterate edible products;

(2) Create insanitary conditions in the official establishment whereby edible products may be adulterated; or

(3) Prevent or interfere with inspection or other program tasks performed by FSIS personnel in the official establishment.

(b) Pet food and similar uninspected, inedible products must be distinguished from edible products so as to avoid their distribution as human food. Pet food or similar uninspected, inedible products must be labeled or otherwise identified in accordance with § 325.11(d) of this subchapter.

PART 381—POULTRY PRODUCTS INSPECTIONS REGULATIONS

■ 3. The authority citation for part 381 continues to read as follows:

Authority: 7 U.S.C. 138f; 7 U.S.C. 450; 21 U.S.C. 451–470; 7 CFR 2.18, 2.53.

■ 4. Section 381.152 is revised to read as follows:

§ 381.152 Manufacture of uninspected, inedible products at official establishments.

(a) Official establishments may manufacture pet food or similar uninspected, inedible products in areas where edible products also are produced, provided that the manufacture of uninspected, inedible products does not:

(1) Adulterate edible products;

(2) Create insanitary conditions in the official establishment whereby edible products may be adulterated; or

(3) Prevent or interfere with inspection or other program tasks performed by FSIS personnel in the official establishment.

(b) The immediate container of uninspected, inedible products manufactured in an official establishment shall be conspicuously labeled so as to distinguish them from human food.

Done in Washington, DC.

Paul Kiecker,

Acting Administrator.

[FR Doc. 2018–16339 Filed 7–30–18; 8:45 am]

BILLING CODE 3410–DM–P

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 41

RIN 3038–AE61

Position Limits and Position Accountability for Security Futures Products

AGENCY: Commodity Futures Trading Commission.

ACTION: Proposed rule.

SUMMARY: The Commodity Futures Trading Commission (''CFTC'' or ''Commission'') is proposing to amend its position limits rules for security futures products (''SFPs'') by: Increasing the default level of equity SFP position limits, and modifying the criteria for setting a higher level of position limits and position accountability levels. In addition, the proposed amended position limit regulation would provide discretion to a designated contract market (''DCM'') to apply limits to either a person's net position or a person's position on the same side of the market. The Commission also proposes criteria for setting position limits on an SFP on other than an equity security, generally based on an estimate of deliverable supply.

DATES: Comments must be received on or before October 1, 2018.

ADDRESSES: You may submit comments, identified by RIN 3038–AE61 and ''Position Limits and Position Accountability for Security Futures Products,'' by any of the following methods:

- *CFTC website: http://comments.cftc.gov.* Follow the instructions for submitting comments through the Comments Online process on the website.
- *Mail:* Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.
- *Hand delivery/courier:* Same as Mail above.

Please submit your comments using only one method.

All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *http://www.cftc.gov.* You should submit only information that you wish to make available publicly. If you wish the Commission to consider information that is exempt from disclosure under the Freedom of Information Act, a petition for confidential treatment of the exempt information may be submitted according to the procedures set forth in section 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 *http://www.cftc.gov* that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the rulemaking will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other

[1] All Commission regulations referred to herein are found in chapter I of title 17 of the Code of Federal Regulations. Commission regulations are accessible on the Commission's website, *http://www.cftc.gov.*

applicable laws, and may be accessible under the Freedom of Information Act.

FOR FURTHER INFORMATION CONTACT: Thomas M. Leahy, Jr., Associate Director, Product Review, Division of Market Oversight, 202–418–5278, *TLeahy@cftc.gov;* or Riva Spear Adriance, Senior Special Counsel, Chief Counsel's Office, Division of Market Oversight, 202–418–5494, *radriance@cftc.gov;* Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.

SUPPLEMENTARY INFORMATION:

I. Background

A. Overview

On December 21, 2000, the Commodity Futures Modernization Act (''CFMA'') became law and amended the Commodity Exchange Act (''CEA''). The CFMA removed a long-standing ban [2] on trading futures on single securities and narrow-based security indexes [3] in the United States. As amended by the CFMA, in order for a DCM to list SFPs,[4] the SFPs and the securities underlying the SFPs must meet a number of criteria.[5] One of the criteria requires that trading in the SFP is not readily susceptible to manipulation of the price of such SFP, nor to causing or being used in the manipulation of the price of any underlying security, option on such security, or option on a group or index including such securities.[6]

As the Commission noted when it proposed to adopt criteria for trading of SFPs:

> It is important that the listing standards and conditions in the CEA and the [Securities Exchange Act of 1934 (''Exchange Act'')] be easily understood and applied by [DCMs]. The rules proposed today address issues related to these standards and establish uniform requirements related to position limits, as well as provisions to minimize the potential for manipulation and disruption to the futures markets and underlying securities markets.[7]

Among those provisions is current Commission regulation 41.25(a)(3), which requires a DCM that lists SFPs to establish position limits or position accountability standards. The Commission's SFP position limits regulations were set at levels that are generally comparable but not identical to the limits that currently apply to options on individual securities.[8]

Under the existing regulations, a DCM is required to establish for each SFP a position limit, applicable to positions held during the last five trading days of an expiring contract month, of no greater than 13,500 (100-share) contracts, except under specific conditions.[9] If a security underlying an SFP has either (i) an average daily trading volume of at least 20 million shares; or (ii) an average daily trading volume of at least 15 million shares and at least 40 million shares outstanding, then the DCM may establish a position limit for the SFP of no more than 22,500 contracts.[10] A DCM may adopt position accountability for an SFP on a security that has: (i) An average daily trading volume of at least 20 million shares; and (ii) at least 40 million shares outstanding.[11] Under any position accountability regime, upon a request from a DCM, traders holding a position of greater than 22,500 contracts, or such lower threshold as specified by the DCM, must provide information to the exchange regarding the nature of the position.[12] Under position accountability, traders must also consent to halt increases in the size of their positions upon the direction of the DCM.[13] The position limits and position accountability trigger levels specified in the Commission's regulations are based on a contract size of 100 shares in the underlying security. DCMs may use part 150 of the Commission's regulations as guidance when approving exemptions from SFP position limit rules.[14]

B. Differences Between Initially Adopted SFP and Equity Option Position Limit Rules

In response to the 2001 Proposed SFP rules, three commenters noted several differences between the SFP position limit regulations and position limit rules for equity security options listed on national security exchanges or associations (''NSE'') approved by the Securities and Exchange Commission (''SEC''): (1) The specification that position limits for SFPs are on a net, rather than a gross,[15] basis; (2) the numerical limits on SFPs differ from those on security options; and (3) the position limits for SFPs are applicable only during the last five trading days prior to expiration, rather than at any time in the lifespan of a security option contract.[16] Commenters also requested that the Commission coordinate with the SEC so that the SFP position limit regulations are the same as those applicable to security and securities index options, or, alternatively, that such position limit regulations more closely resemble existing limits on security and securities index options.[17] The Commission noted that the provisions in Commission regulation 41.25(a)(3) as finalized were consistent with the Commission's customary approach for all other futures markets,[18] were necessary to effectively oversee the markets, and were consistent with the obligation of a DCM to prevent manipulation of the price of an SFP and its underlying security or securities.[19]

There was one other difference between the position limit rules for SFPs and security options, on which no one commented. Specifically, the volume test adopted by the Commission for position limits on SFPs was based on *average* trading volume over a six-month period while the volume test for security options was based on *total* trading volume over a six-month period. This difference typically results in position limits for SFPs that are more restrictive than those on analogous security options.[20]

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[2] *See* section 251(a) of the CFMA. This trading previously was prohibited by 7 U.S.C. 2(a)(1)(B)(v).

[3] *See* 7 U.S.C. 1a(35) for the definition of ''narrow-based security index.''

[4] The term ''security futures product'' is defined in section 1a(45) of the CEA and section 3(a)(56) of the Exchange Act to mean a security future or any put, call, straddle, option, or privilege on any security future. The term ''security future'' is defined in section 1a(44) of the CEA and section 3(a)(55)(A) of the Exchange Act to include futures contracts on individual securities and on narrow-based security indexes. The term ''narrow-based security index'' is defined in section 1a(35) of the CEA and section 3(a)(55)(B) of the Exchange Act.

[5] *See* 7 U.S.C. 2(a)(1)(D)(i).

[6] 7 U.S.C. 2(a)(1)(D)(i)(VII).

[7] *See* Listing Standards and Conditions for Trading Security Futures Products, proposed rules, 66 FR 37932, 37933 (July 20, 2001) (''2001 Proposed SFP Rules''). The Commission further noted, ''The speculative position limit level adopted by a [DCM] should be consistent with the obligation in section 2(a)(1)(D)(i)(VII) of the CEA that the [DCM] maintain procedures to prevent manipulation of the price of the [SFP] and the underlying security or securities.'' *Id.* at 37935.

[8] *See* Listing Standards and Conditions for Trading Security Futures Products, 66 FR 55078, 55082 (November 1, 2001) (''2001 Final SFP Rules'').

[9] 17 CFR 41.25(a)(3)(i). The 13,500 limit level is premised on an SFP contract size of 100 shares of an underlying equity security.

[10] 17 CFR 41.25(a)(3)(i)(A).

[11] 17 CFR 41.25(a)(3)(i)(B).

[12] *Id.*

[13] *Id.*

[14] Although part 150 previously provided requirements for exchange-set position limits, it was rendered ''mere guidance'' by the CFMA. *See, e.g.,* 81 FR 96704, 96742 (Dec. 30, 2016); *see also* 74 FR 12178, 12183 (March 23, 2009) (noting ''the part 150 rules essentially constitute guidance for DCMs administering position limits regimes'').

[15] The Commission understands that ''gross'' in this context means on the same side of the market, as discussed *infra.*

[16] 2001 Final SFP Rules at 55081.

[17] *Id.* at 55082.

[18] *See infra* discussion regarding part 150 of the Commission's regulations.

[19] 2001 Final SFP Rules at 55082.

[20] Although DCMs may adopt for certain SFPs position accountability provisions with an accountability level of 22,500 (100-share) SFP contracts, in lieu of position limits, the analogous security option is subject to a position limit likely

C. Subsequent Developments in SFP Position Limit Regulations

Since the 2001 Final SFP Rules, the Commission's SFP position limit regulations have not been substantively amended to account for SFPs on securities other than common stock, although the statute authorizes it. CEA section 2(a)(1)(D)(i) authorizes DCMs to list for trading SFPs based upon common stock and such other equity securities as the Commission and the Securities and Exchange Commission jointly determine appropriate.[21] The CFMA further authorized the Commission and the SEC (collectively ''Commissions'') to allow SFPs to be based on securities other than equity securities.[22] The Commissions used their authority to allow SFPs on Depositary Receipts; [23] Exchange Traded Funds, Trust Issued Receipts and Closed End Funds; [24] and debt securities.[25]

D. Subsequent Equity Security Option Position Limit Increases

Since the Commission's initial adoption of SFP position limits, the SEC has granted approval to increase position limits for equity security options listed on NSEs, but the Commission has not amended its SFP regulations to reflect those changes. For example, under current position limits for equity security options that are uniform across rules of NSEs,[26] position limits are at least 25,000 option contacts.[27] Also, as noted above, NSEs set higher levels based on six-month total trading volume or, alternatively, a combination of six-month total trading volume and shares outstanding, as shown in Table A.[28]

TABLE A—NSE EQUITY SECURITY OPTION POSITION LIMITS

[As of Dec. 6, 2017]

Option contract limit (100 shares/contract)	Six-month total trading volume is at least:	Or, if six-month total trading volume and shares currently outstanding are at least:	
	Trading volume (shares)	Trading volume (shares)	Shares outstanding
25,000	Default	Default	Default.
50,000	20 million	15 million	40 million.
75,000	40 million	30 million	120 million.
200,000	80 million	60 million	240 million.
250,000	100 million	75 million	300 million.

Each equity security option contract limit is applicable on a gross basis to option positions on both sides of the market.[29] The NSEs permit certain exemptions, including for qualified hedging transactions and positions and for facilitation of orders with customers. Generally, limits for options on registered investment companies, organized as open-end management companies, unit investment trusts or similar entities, are the same as the positions limits applicable to equity options.[30]

In addition to position limits under NSE rules, NSEs establish uniform exercise limits for the aggregate exercise of a long position in any option contract within any five consecutive business days, generally at the levels of the applicable position limits.[31] This exercise limit may serve to reduce the potential for manipulation (such as a squeeze on short option position holders) by restricting the number of shares demanded for delivery by a long call option position holder, in a similar manner to a DCM's position limit, under current Commission regulation 41.25(a)(3), thus restricting the number of shares that may be demanded during the last five days of trading.

E. Commission's Position Limit Approach in Other Commodity Futures

The Commission's customary approach for position limits in futures contracts other than SFPs is found in part 150 of the Commission's regulations, which establishes a position limits regime that generally includes three components: (1) The level of the limits, which sets a threshold that restricts the number of speculative positions that a person may hold in the spot-month, individual month, and all months combined; (2) exemptions for positions that constitute bona fide hedging transactions and certain other types of transactions; and (3) rules to determine which accounts and positions a person must aggregate for the purpose of determining compliance with the position limit levels. For exchange-set position limits, on physically-delivered contracts, the spot month limit level should be no greater than one-quarter of the estimated spot month deliverable supply, calculated separately for each month to be listed, and for cash settled contracts, the spot month limit level should be no greater than necessary to minimize the potential for manipulation

to be set at a level of 250,000 (100-share) option contracts, as shown below in Table A.

[21] 7 U.S.C. 2(a)(1)(D)(i)(III).

[22] 7 U.S.C. 2(a)(1)(D)(v)(I).

[23] *See* Joint Order Granting the Modification of Listing Standards Requirements under section 6(h) of the Securities Exchange Act of 1934 and the Criteria under section 2(a)(1) of the Commodity Exchange Act, August 20, 2001 *https://www.sec.gov/rules/other/34-44725.htm.*

[24] *See* 67 FR 42760 (June 25, 2002).

[25] *See* 17 CFR 41.21(a)(2)(iii) (providing that the underlying security of an SFP may include a note, bond, debenture, or evidence of indebtedness); *see also* 71 FR 39534 (July 13, 2006) (describing debt securities to include notes, bonds, debentures, or evidences of indebtedness).

[26] *See, e.g.,* the Cboe Exchange, Inc. (''Cboe'') rule 4.11, Nasdaq ISE, LLC (''ISE'') rule 412, NYSE American LLC (''NYSE American'') rule 904, Nasdaq PHLX LLC (''Phlx'') rule 1001.

[27] *See, e.g.,* 73 FR 10076 (February 25, 2008) (granting permanent approval of an increase in position and exercise limits for equity security options).

[28] *Id.* at 10076–77.

[29] For example, Cboe applies limits to an aggregate position in an option contract ''of the put type and call type on the same side of the market.'' Cboe rule 4.11. For this purpose, under the rule, long positions in put options are combined with short positions in call options; and short positions in put options are combined with long position in call options.

[30] NSEs have established position limits higher than shown in Table A for certain security options on products with broad-based holdings of underlying securities; for example, the Cboe position limit in the DIAMONDS Trust option is 300,000 contracts, iShares Russell 2000 Index Fund option is 500,000 contracts, PowerShares QQQ Trust option is 900,000 contracts, and iShares MSCI Emerging Markets Index Fund option is 500,000 contracts. Similarly, BOX Options Exchange, Inc., Cboe, Nasdaq ISE, LLC, Nasdaq PHLX, LLC, NYSE American, LLC, and NYSE Arca, Inc. all recently adopted position limits for security options on the Standard and Poor's Depositary Receipts Trust that are 1,800,000 contracts. *See, e.g.,* 83 FR 28274 (June 18, 2018) (allowing the SPY Pilot Program to terminate and making immediately effective the new limit).

[31] *See, e.g.,* Cboe rule 4.12, ISE rule 414, NYSE American rule 905, and Phlx rule 1001.

or distortion of the contract's or the underlying commodity's price.[32]

II. The Proposal

A. Overview

The Commission notes that SFPs and security options may serve economically equivalent or similar functions.[33] As noted above, when adopted, the Commission's SFP position limits regulations were set at levels that are generally comparable but not identical to the limits that currently apply to options on individual securities. However, over time, while the default level for position limits for SFPs did not change, those of security options on the same security have in some cases changed, allowing the position limit for the security option, as observed above, to be set at a much higher default level. This may place SFPs at a competitive disadvantage. One goal of this proposal, therefore, is to provide a level regulatory playing field.[34]

When determining appropriate limit levels, the Commission took note of the experience of NSEs over several years with higher position limit levels on security options, with no apparent significant issues, suggesting, therefore, that it may be reasonable for SFP position limits to closely resemble existing contract limits for equity options at NSEs. To allow DCMs to adapt as NSE position limits change, the current draft would be flexible, providing a formula for a DCM to set a higher level, rather than the specific levels in a current rule of an NSE.

However, as has been noted, some aspects of the position limits regime under current Commission regulation 41.25 differ from those on security options as the Commission determined certain approaches were necessary to effectively oversee the markets, and consistent with the obligation of a DCM to prevent manipulation of the price of an SFP and its underlying security or securities.[35] In light of its experience since the first adoption of a position limits regime for SFPs in 2001, the Commission believes in the merit of updating Commission regulation 41.25 under an incremental approach, for example, by providing DCMs with discretion to increase limits, generally consistent with those currently permitted for equity options listed by an NSE, while allowing the Commission to assess the impact on SFP markets.

The Commission proposes to maintain the requirement in current Commission regulation 41.25(a)(3) that DCMs establish position limits or, in certain cases, accountability standards for SFPs. The proposal would increase the default level for speculative position limits in SFPs in equity securities to 25,000 100-share contracts (or the equivalent if the contract size is different than 100 shares per contract) from 13,500 100-share contracts. The proposal would change the criterion that DCMs use to set higher levels of speculative position limits to no more than 12.5 percent of the estimated deliverable supply [36] of the relevant underlying security, from no greater than 22,500 100-share contracts if certain criteria are met in current Commission regulation 41.25(a)(3)(i).[37] The proposed 12.5 percent criterion is discussed further below. In this regard, the Commission believes that exchange-set position limits for SFPs based on estimated deliverable supply would provide flexibility to DCMs while ensuring that position limits appropriately reflect current market conditions for the specific securities that underlie their SFPs.

The Commission also proposes to amend the position accountability provisions so that a DCM could substitute position accountability for position limits when six-month total trading volume in the underlying security exceeds 2.5 billion shares and there are more than 40 million shares of estimated deliverable supply, rather than the current criteria of six-month average daily trading volume in the underlying security exceeds 20 million shares and there are more than 40 million outstanding shares. In addition, the maximum accountability level under the position accountability regime would be increased to 25,000 contracts, from the current level of 22,500 contracts.

This proposal also addresses SFPs based on products other than a single equity security. As discussed below, these products are a physically-delivered basket equity SFP, a cash-settled equity index SFP, and an SFP on one or more debt securities.[38]

The Commission proposes to maintain the provision that requires position limits to be applied during a period of time of no shorter than the last five trading days in an expiring contract month. However, the proposed regulation would require a longer period than five trading days in the event the terms of an SFP provide for delivery prior to the last five trading days.

The Commission proposes that a DCM should have discretion to apply position limits or position accountability levels either on a net basis, as under current regulations, or on the same side of the market.[39] If a DCM imposes limits on the same side of the market, then the DCM could not net positions in SFPs in the same security on opposite sides of the market.

This proposal permits DCMs to approve exemptions to limits, provided such exemptions are consistent with the guidance in current Commission regulation 150.5, which addresses exchange-set position limits, rather than consistent with current Commission regulation 150.3, which addresses exemptions to Commission-set position limits. In addition, the proposal permits DCMs to approve exemptions consistent with those of an NSE.

Under this proposal, DCMs would be required to calculate estimated deliverable supply and six-month total trading volume no less frequently than semi-annually, rather than the monthly requirement under the current regulations. The proposal requires that a DCM lower the position limit levels if the estimated deliverable supply

[32] *See* 17 CFR 150.5(b)(1); *see also supra* note 14.

[33] For example, the price of a long call option with a strike price well below the prevailing market price of the underlying security is expected to move almost in lock step with the price of a long SFP on the same underlying security. Similarly, the price of a long put option with a strike price well above the prevailing market price of the underlying security is expected to move almost in lock step with the price of a short SFP on the same underlying security.

[34] As the Commission notes above, commenters also requested that the SFP position limit regulations be the same as those applicable to security and securities index options, or, alternatively, that such position limit regulations more closely resemble existing limits on security and securities index options. *See supra* note 17 and accompanying text.

[35] *See* 2001 Final SFP Rules at 55082. The approach NSEs may use to set an equity option's position limit is not consistent with existing Commission policy and may, in the Commission's opinion, as noted previously, render position limits ineffective.

[36] *See infra* regarding proposed guidance on estimated deliverable supply.

[37] The current criteria for a level higher than 13,500 100-share contracts are six-month average daily trading volume in the underlying security exceeds 20 million shares, or exceeds 15 million shares and there are more than 40 million shares of the underlying security outstanding.

[38] The SFP definition permits the listing of SFPs on debt securities (other than exempted securities). *See supra* note 22 and accompanying text. While an SFP may not be listed on a debt security that is an exempted security, futures contracts may be listed on an exempted security. *See infra* note 69 and accompanying text.

[39] The Commission notes that, although it has not proposed an aggregation rule that would define ''person'' for purposes of SFP position limits, current 17 CFR 150.5(g) provides guidance to DCMs in setting aggregation standards for exchange-set position limits. The Commission believes a DCM should have reasonable discretion to set aggregate standards based on a person's control or ownership of SFP positions, including in the same manner as that of an NSE for equity security options.

justifies lower position limits. Similarly, the proposal requires that a DCM adopt position limits if the estimated deliverable supply or six-month total trading volume no longer supports position accountability provisions.

Finally, as discussed further below, these proposed regulations provide the definitions for ''estimated deliverable supply and ''same side of the market'', terms used in Commission regulation 41.25, by adding those definitions into a new paragraph (a).[40]

B. Section-by-Section Discussion

1. Commission Regulation 41.25(a), Definitions

The proposal includes two definitions used in Commission regulation 41.25: Estimated deliverable supply; and same side of the market. These definitions are included in new paragraph (a).

Estimated deliverable supply is defined under the proposal as the quantity of the security underlying a security futures product that reasonably can be expected to be readily available to short traders and salable by long traders at its market value in normal cash marketing channels during the specified delivery period. The proposal provides guidance for estimating deliverable supply in proposed appendix A to subpart C of part 41, as discussed below.

The proposal defines same side of the market to mean long positions in physically-delivered security futures contracts and cash settled security futures contracts, in the same security, and, separately, short positions in physically-delivered security futures contracts and cash settled security futures contracts, in the same security. The Commission invites comment on whether it should also include options on security futures contracts in this definition, although options on SFPs are not currently permitted to be listed.[41] Generally, a long call and a short put, on a futures equivalent basis, would be aggregated with a long futures contract; and a short call and a long put, on a futures equivalent basis, would be aggregated with a short futures contract.

2. Commission Regulation 41.25(b)(3), Position Limits or Accountability Rules Required

As with current Commission regulation 41.25(a)(3), under this proposal, the paragraph, as re-designated regulation 41.25(b)(3), would continue to require a DCM to establish position limits or position accountability rules in each SFP for the expiring futures contract month.

3. Commission Regulation 41.25(b)(3)(i), Limits for Equity SFPs

Proposed changes to regulation 41.25(a)(3)(i), re-designated as regulation 41.25(b)(3)(i), would increase the default level of position limits in an equity SPF to no greater than 25,000 100-share contracts (or the equivalent if the contract size is different than 100 shares per contract), either net or on the same side of the market, from the existing regulation's default level of no greater than 13,500 100-share contracts on a net basis. The default level of 25,000 100-share contracts is equal to 2,500,000 shares. The Commission notes that 12.5 percent of 20 million shares equals 2,500,000 shares. Thus, for an equity security with less than 20 million shares of estimated deliverable supply, the default position limit level for the equity SFP would be larger than 12.5 percent of estimated deliverable supply. While a DCM could adopt the default position limit for SFPs in equity securities with fewer than 20 million shares, consistent with a position limit applicable to an option on that security, the Commission would expect a DCM to assess the liquidity of trading in the underlying security to determine whether the DCM should set a lower position limit level, as appropriate to ensure compliance with DCM Core Principles 3 and 5. In this regard, the Commission seeks comment on whether it should provide greater specificity with respect to this liquidity assessment and whether there are circumstances where the position limit level should be set lower than 25,000 100-share contracts (for example, no greater than 12.5 percent of estimated deliverable supply).[42]

The Commission notes that minimum position limits for equity security option positions on NSEs are 25,000 100-share option contracts on the same side of the market. Thus, the proposal would allow a DCM to coordinate the default position limit level for SFPs to that of an equity option traded on a NSE. Accordingly, as previously requested by commenters in the context of the CFTC's adoption of its current SFP position limit requirements, this proposed default level for SFP limits would closely resemble existing minimum limit levels on security options.

As noted above, SFPs and security options may serve economically equivalent or similar functions.[43] However, under current Commission regulation 41.25(a)(3), as previously detailed, the default level for position limits for SFPs must be set no greater than 13,500 (100-share) contracts, while security options on the same security may be, and currently are, set at a much higher default level of 25,000 contracts,[44] which may place SFPs at a competitive disadvantage. Closer coordination of limit levels is intended to provide a level regulatory playing field.

However, because limit levels would not apply to a market participant's combined position between SFPs and security options, the Commission is not proposing a default limit level for an SFP higher than 12.5 percent of estimated deliverable supply. That is, under the proposal, a market participant with positions at the limits in each of an SFP and a security option on the same underlying security might be equivalent to about 25 percent of estimated deliverable supply, which is at the outer bound of where the Commission has historically permitted spot month limit levels. The Commission invites comment on whether this proposed default level is appropriate.

The proposal would include, in the requirements for limits for equity SFPs, securities such as exchange trading funds (''ETFs'') and other securities that represent ownership in a group of underlying securities. The Commission requests comment on whether this is appropriate and invites further comment, below, in the discussion of estimated deliverable supply.

This proposal would provide discretion to a DCM to apply position limits on a gross basis (''on the same side of the market'') or net basis, rather than the current regulation's net basis.

[40] In connection with adding the definitions into a new paragraph (a), paragraphs (a) through (d) would be re-designated as paragraphs (b) through (e).

[41] Under CEA section 2(a)(1)(D)(iii)(II), the CFTC and SEC may, by Order, jointly determine to permit the listing of options on SFPs; that authority has not been exercised.

[42] Core Principle 3, 7 U.S.C. 7(d)(3), provides that DCMs shall list only contracts that are not readily susceptible to manipulation, while Core Principle 5, 7 U.S.C. 7(d)(5), provides for the adoption of position limits and position accountability, as is necessary and appropriate, to deter the threat of manipulation. Moreover, 7 U.S.C. 2(a)(1)(D)(i)(VII) and 17 CFR 41.22(f) require that trading in an SFP: (i) Be not readily susceptible to manipulation of the SFP; or (ii) cause the manipulation of any underlying security, an option on such security, or an option on a group or index including such security or securities.

[43] For example, the price of a long call option with a strike price well below the prevailing market price of the underlying security is expected to move almost in lock step with the price of a long SFP on the same underlying security. Similarly, the price of a long put option with a strike price well above the prevailing market price of the underlying security is expected to move almost in lock step with the price of a short SFP on the same underlying security.

[44] *See* current Cboe rule 4.11.

For example, if there were a physically-delivered SFP on equity XYZ, a dividend-adjusted SFP on equity XYZ, and a cash-settled SFP on equity XYZ, then a DCM's rules could provide that long positions held by the same person across each of these classes of SFP based on equity XYZ would be aggregated for the purpose of determining compliance with the position limit. A gross position in a futures contract is larger than a net position in the event a person holds positions on opposite sides of the market. That is, a net basis is computed by subtracting a person's short futures position from that person's long futures positions, and, under current regulations, a single position limit applies on a net basis to that net long or net short position. Under the proposal, at the discretion of a DCM, a person's long futures position would be subject to the position limit and, separately, a person's short futures position also would be subject to the position limit. As previously requested by commenters, adding this proposed gross basis approach (in addition to net basis) to SFP limits would more closely resemble existing limits on security options that apply on the same side of the market per the rules of the NSEs. A DCM that elects to implement limits on a gross basis would be providing its market participants with the same metric for position limit compliance as is currently the case on NSEs, which may reduce compliance costs and encourage cross-market participation. However, limits on a gross basis may be more restrictive than limits on a net basis, which could reduce the position sizes that may be held, without an applicable exemption.

In addition, the Commission would continue to permit DCMs to apply limits on a net basis at the DCM's discretion. In this regard, the Commission believes it is possible for a DCM's application of limits to further the goals of the CEA whether applied on a net or a gross basis.[45] This would be true, for example, if a DCM applied limits on a net basis and did not permit netting of physically-delivered contracts with cash settled contracts. But if, instead, the DCM permitted netting of physically-delivered contracts and cash settled contracts in the same security, it would render position limits ineffective.[46] For example, a person should not be permitted to avoid limits by obtaining a large long position in a physically-delivered contract (which could be used to corner or squeeze) and a similarly large short position in a cash settled contract that would net to zero.

4. Commission Regulation 41.25(b)(3)(i)(A), Higher Position Limits in Equity SFPs[47]

For an SFP based on an underlying security with an estimated deliverable supply of more than 20 million shares, the proposal would permit a DCM to set a higher limit level based on 12.5 percent of the estimated deliverable supply of the underlying security, if appropriate in light of the liquidity of trading in the underlying security. By way of example, if the estimated deliverable supply were 40 million shares, then the proposed regulation would permit a DCM to set a limit level of no greater than 50,000 100-share contracts; computed as 40 million shares times 12.5 percent divided by 100 shares per contract.

This level of 50,000 100-share contracts is the same as permitted under current rules of NSEs for an underlying security with 40 million shares outstanding, although an NSE would also require the most recent six-month trading volume of the underlying security to have totaled at least 15 million shares. While this proposed provision for SFP position limits would more closely resemble existing limits on security options, the Commission is proposing to permit a DCM to use its discretion in assessing the liquidity of trading in the underlying security, rather than imposing a prescriptive trading volume requirement.[48] The Commission preliminarily does not believe that trading volume alone is an appropriate indicator of liquidity.[49] In this regard, the proposed regulation would permit a DCM to set a position limit at a level lower than 12.5 percent of estimated deliverable supply. The Commission invites comment on whether it is appropriate to provide a DCM with discretion in its assessment of liquidity in the underlying security, rather than the Commission imposing a liquidity requirement. Core Principle 5 requires DCMs to adopt, as is necessary and appropriate, position limits to deter the adverse market impact of manipulation. The Commission invites comment on whether estimated deliverable supply alone serves as an adequate proxy for market impact.

Although the Commission is proposing a criterion of 12.5 percent of estimated deliverable supply, the Commission expects a DCM to conduct a reasoned analysis as to whether setting a level for a limit based on such criterion is appropriate. In this regard, for example, assume security QRS and security XYZ have equal free float of shares. Assume, however, that trading in QRS is not as liquid as trading in XYZ. Under these assumptions, it may be appropriate for a DCM to adopt a position limit for XYZ equivalent to 12.5 percent of deliverable supply, but to adopt a lower limit for QRS because a lesser number of shares would be readily available for shorts to make delivery.

The Commission notes that the proposed criterion of 12.5 percent of estimated deliverable supply is half the level for DCM-set spot month speculative position limits in current Commission regulation 150.5(c),[50] which, as previously noted, has been rendered ''mere guidance'' since the CFMA.[51] That regulation provides that, for physically-delivered contracts, the spot month limit level should be no greater than one-quarter of the estimated spot month deliverable supply.[52] The Commission is proposing a lower percent of estimated deliverable supply in light of current limits on equity security options listed at NSEs. In this regard, the proposal would result in SFP position limits that closely resemble the existing 25,000 and 50,000 contract

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[45] CEA section 2(a)(1)(D)(i)(VII) requires that trading in SFPs is not readily susceptible to manipulation of the price of the SFP, the SFP's underlying security, or an option on the SFP's underlying security.

[46] Although no DCM currently lists both physically-delivered SFPs contracts and cash-settled SFP contracts for the same underlying security, and this concern may be theoretical, the Commission believes that providing clarity reduces uncertainty regarding netting in such circumstances, which may facilitate listing of such contracts in the future. Therefore, the Commission proposes to provide in 17 CFR 41.25(b)(3)(vii) that, for a DCM applying limits on a net basis, netting of physically-delivered contracts and cash settled-contracts in the same security is not permitted as it would render position limits ineffective. This concern is not applicable to a DCM applying limits on the same side of the market, as limits are applied separately to long positions and to short positions.

[47] As noted above, the proposal would re-designate 17 CFR 41.25(a)(3)(i)(A) as 17 CFR 41.25(b)(3)(i)(A).

[48] Generally, under CEA section 5(d)(1)(B), unless otherwise restricted by a Commission regulation, a DCM has reasonable discretion in establishing the manner in which it complies with core principles, including Core Principle 5 regarding position limits or position accountability. *See* 7 U.S.C. 7(d)(1) and (5).

[49] Under current 17 CFR 41.25(a)(3)(i)(A), for example, a DCM may adopt a net position limit no greater than 22,500 shares, provided the six-month average daily trading volume exceeds 15 million shares and there are more than 40 million shares of the security outstanding. The Commission notes that almost all stocks with at least 40 million shares outstanding also had a six-month average trading volume of at least 15 million shares. Thus, the current trading volume criterion generally is not a meaningful restriction.

[50] 17 CFR 150.5(c).

[51] *See supra* discussion of the impact of the CFMA on part 150; *see also* 74 FR 12177 at 12183 (March 23, 2009).

[52] 17 CFR 150.5(c)(1).

limits for equity options at NSEs, set when certain trading volume has been reached or a combination of trading volume and shares currently outstanding, as shown in Table A above. For example, a position at a 50,000 (100-share) option contract limit is equivalent to 5 million shares. 12.5 percent of 40 million shares equals 5 million shares; that is, the proposed criterion for a DCM to set a limit would be similar to that of the criteria for an NSE to set such a limit. Under this proposal, a similar 50,000 contract position limit on an SFP on such a security would be an increase from the 22,500 contract limit currently permitted for such an SFP. The Commission believes the proposed incremental approach to increasing SFP limits is a measured response to changes in the SFP markets, while retaining consistency with the existing requirements for equity security options listed by NSEs.

However, as noted above, SFPs and equity security options in the same underlying security are not subject to a combined position limit across DCMs and NSEs. Accordingly, the Commission is proposing a maximum SFP limit level that is half the guidance level for DCM-set spot month futures contract limits of 25 percent of estimated deliverable supply.

Further, as shown in Table A above, the Commission notes that limits for equity security options at NSEs do not increase in a linear manner for all increases in shares outstanding; for example, upon a doubling of shares outstanding, the 100-share equity security option contract limit increases only to 75,000 contracts from 50,000 contracts, while, under similar circumstances of a doubling of estimated deliverable supply, the Commission proposes to permit a linear increase for a SFP limit to 100,000 contracts from 50,000 contracts. The Commission invites comments as to whether the proposed linear approach based on estimated deliverable supply is appropriate.

Alternative Criteria for Setting Levels of Limits. As an alternative to the proposed criteria for setting position limit levels based on estimated deliverable supply, the Commission invites comments on whether the Commission should permit a DCM to mirror the position limit level set by an NSE in a security option with the same underlying security or securities as that of the DCM's SFP. This alternative has the advantage of consistency in position limits across exchange-traded derivatives based on the same security.

However, the Commission notes that NSEs may set an equity option's position limit by the use of trading volume as a sole criterion. That approach is not consistent with existing Commission policy regarding use of estimated deliverable supply to support position limits in an expiring contract month, as stated in part 150 of the Commission's regulations.[53] The Commission notes that use of trading volume as a sole criterion for setting the level of a position limit could result in a position limit that exceeds the number of outstanding shares when the underlying security exhibits a very high degree of turnover. Such a resulting high limit level would render position limits ineffective.

5. Commission Regulation 41.25(b)(3)(i)(B), Position Accountability in Lieu of Limits [54]

This proposal would continue to permit a DCM to substitute position accountability for a position limit in an equity SFP that meets two criteria. The proposal would require six-month total trading volume of at least 2.5 billion shares, which generally is equivalent to the current first criterion that six-month average daily trading volume in the underlying security must exceed 20 million shares.[55] The proposal would tighten the second criterion. Rather than require that the underlying security have more than 40 million shares outstanding, under the proposal the second criterion would require the underlying security to have more than 40 million shares of estimated deliverable supply, which generally would be smaller than shares outstanding. This change conforms to the proposed use of estimated deliverable supply in setting a position limit. The Commission believes an appropriate refinement to its criterion for position accountability is to quantify those equity shares that are readily available in the market, rather than all shares outstanding. Generally, a short position holder may expect to obtain at or close to fair value shares that are readily available in the market and a long position holder may expect to sell such shares at or close to fair value. However, in contrast, shares that are issued and outstanding by a corporation may not be readily available in a timely manner, such as shares held by the corporation as treasury stock.[56] Therefore, to ensure that position holders will generally be able to obtain equity shares at or close to fair value, the DCM should consider whether the shares are readily available in the market when estimating deliverable supply.

In addition, the proposal would amend the accountability level to no greater than 25,000 contracts, either net or on the same side of the market, from 22,500 contracts net, conforming to the proposed default position limit level. The Commission notes a DCM would be able to set a lower accountability level, should it desire. The Commission preliminarily believes it is appropriate to set a position accountability level no higher than 25,000 contracts because the Commission believes a DCM should have the authority, but not the obligation, to inquire with very large position holders and to order such position holders not to increase positions.[57] The Commission preliminarily believes a maximum position accountability level of 25,000 contracts is at the outer bounds for purposes of providing a DCM with authority to obtain information from position holders; for example, a position of 25,000 100-share contracts has a notional size of $125 million when the price of the underlying stock is $50 per share.

6. Commission Regulation 41.25(b)(3)(ii), Limits for Physically-Delivered Basket Equity SFPs

This proposal would amend the existing position limits and position accountability provisions for a physically-delivered SFP comprised of more than one equity security [58] by

[53] For example, Cboe rules also permit a 50,000 contract position limit based on the total most recent six-month trading volume of 20 million shares, without regard to shares outstanding.

[54] As noted above, the proposal would re-designate 17 CFR 41.25(a)(3)(i)(B) as 17 CFR 41.25(b)(3)(i)(B).

[55] 20 million shares times 125 trading days in a typical six-month period equals 2.5 billion shares. In regards to total trading volume rather than average daily trading volume, the Commission notes that use of total trading volume is consistent with the rules of NSEs, which use six-month total trading volume in their criteria for setting position limits, as shown in Table A above.

[56] Treasury stock means any shares that a company holds itself. Such treasury stock may be authorized by the corporate charter but not yet issued to the public or, in contrast, may have been previously issued to the public but was the subject of a stock repurchase program to buy back the shares from the public.

[57] By way of comparison, under 17 CFR 15.03, the Commission's reporting level for large traders (''reportable position'') is 1,000 contracts for individual equity SFPs and 200 contracts for narrow-based SFPs. Under 17 CFR 18.05, the Commission may request any pertinent information concerning such a reportable position.

[58] The Commission notes that there is not a limit *per se* on the maximum number of securities in a narrow-based security index. Rather, under CEA section 1a(35), a narrow-based security index generally means, among other criteria, an index that

Continued

basing the criteria on the underlying equity security with the lowest estimated deliverable supply, rather than the lowest average daily trading volume.[59] Specifically, under the proposal, for an SFP on more than one security, the criteria in proposed regulations 41.25(b)(3)(i)(A) and (B)[60] would apply to the underlying security with the lowest estimated deliverable supply in the basket, with an appropriate adjustment to the level of the position limit or accountability level for a contract size different than 100 shares per underlying security.

The proposal is based on the premise that the limit on a physically-delivered basket equity SFP should be consistent with the most restrictive of each limit that would be applicable to SFPs based on each component of such basket of deliverable securities. This would restrict a person from obtaining a larger exposure to a particular security through a physically-delivered basket equity SFP, than could be obtained directly in a single equity SFP. However, this proposal would not aggregate positions in single equity SFPs with positions in basket deliverable SFPs.

7. Commission Regulation 41.25(b)(3)(iii), Limits for Cash-Settled Equity Index SFPs

For setting levels of limits on an SFP comprised of more than one security, current Commission regulation 41.25(a)(3)(ii) specifies certain criteria for trading volume and shares outstanding that must be applied to the security in the index with the lowest average daily trading volume. However, the Commission is not proposing to retain those criteria for setting levels of limits for cash-settled equity index SFPs for a number of reasons. For an equity index that is price weighted, it appears that use of shares outstanding or trading volume may result in an inappropriately restrictive level for a position limit.[61] For an equity index that is value weighted, it also appears that such use may result in an inappropriately restrictive level for a position limit.[62] The Commission observes that while trading volume, as an indicator of liquidity, may be an appropriate factor for a DCM to consider in setting position limits, trading volume is not generally used in construction of equity indexes.

Proposed appendix A to subpart C provides guidance and acceptable practices for setting the limit level for a cash-settled equity index SFP, discussed below. However, as noted above, the proposal would continue to require a DCM, for cash-settled equity index SFPs, to establish position limits or position accountability rules in each SFP for the expiring futures contract month in the last five trading days of an expiring contract month. As also discussed above, the proposal provides discretion to a DCM to set such a limit either net or on the same side of the market.

8. Commission Regulation 41.25(b)(3)(iv), Limits for Debt SFPs[63]

As previously detailed, for setting levels of limits on an SFP comprised of more than one security, current Commission regulation 41.25(a)(3)(ii) specifies certain criteria for trading volume and shares outstanding that must be applied to the security in the index with the lowest average daily trading volume. However, the Commission is not proposing to retain those criteria for setting levels of limits for debt SFPs because debt securities generally are neither issued in terms of shares nor trading volume measured in terms of shares.

Proposed appendix A to subpart C provides guidance and acceptable practices for setting the limit level for a debt SFP, discussed below. This proposal would require a DCM to set a position limit on a debt SFP, either net or on the same side of the market, applicable to positions held during the last five trading days of an expiring contract month, as is the case for equity SFPs under the proposal.

9. Commission Regulation 41.25(b)(3)(v), Required Minimum Position Limit Time Period

Although DCMs do not currently list SFPs where the product permits delivery before the close of trading, the Commission proposes that, for such a product, the DCM would be required to apply position limits beginning no later than the first day that long position holders may be assigned delivery notices, if such period is longer than the last five trading days of an expiring contract month. The Commission notes that the current DCM practice for other commodity futures contracts is to apply spot month position limits at the close of business before delivery notices are assigned to holders of long positions in futures contracts that provide for physical delivery prior to the close of trading. Further, this provision is analogous to provisions of NSEs that apply exercise limits for any five consecutive business days, applicable to American exercise style equity options.[64]

10. Commission Regulation 41.25(b)(3)(vi), Requirements for Re-Setting Levels of Position Limits[65]

This proposal would require a DCM to consider, on at least a semi-annual basis, whether position limits were set at appropriate levels, through consideration of estimated deliverable supply. In the event that estimated deliverable supply has decreased, then a DCM would be required to lower the level of a position limit in light of that decreased deliverable supply. In the event that estimated deliverable supply has increased, then a DCM would have discretion to increase the level of a position limit. In addition, a DCM that has substituted a position accountability rule for a position limit would be required to consider whether estimated deliverable supply and total six-month

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has 9 or fewer component securities; in which a component security comprises more than 30 percent of the index's weighting; in which the five highest weighted component securities in the aggregate comprise more than 60 percent of the index's weight; or in which the lowest weighted component securities, comprising the lowest 25 percent of the index's weight, have an aggregate dollar value of average daily trading volume of less than $50 million.

[59] This means that, under proposed 17 CFR 41.25(b)(3)(i), the default level position limit would be no greater than 25,000 100-share contracts, unless the underlying equity security with the lowest estimated deliverable supply supports a higher level.

[60] As noted above, as proposed, 17 CFR 41.25(a)(3)(i)(A) and (B) would be re-designated as 17 CFR 41.25(b)(3)(i)(A) and (B).

[61] For example, assume the level of a simple price-weighted index is computed by adding the price of each equity security in the index and dividing by the number of different equity securities. For such a simple index, a given percentage change in the price of a company with a higher share price would have a greater impact on the index than a given percentage change in the price of a company with a lower share price. In such a circumstance, the Commission preliminarily believes the DCM should have discretion, in setting the position limit, to give consideration to the equity (or equities) with the greater weight(s) in the index, rather than only with regard to the equity with the lowest number of shares outstanding.

[62] For example, the level of a value-weighted index will change in relation to the change in the market capitalization of each component equity security. In such a circumstance, a given percentage change in the market value of a higher capitalized company would have a greater impact on the index than a given percentage change in the market value of a lower capitalized company. In such a circumstance, the Commission preliminarily believes the DCM should have discretion, in setting the position limit, to give consideration to the equity (or equities) with the greater weight(s) in the index, rather than only with regard to the equity with the lowest number of shares outstanding.

[63] As noted above, as proposed, 17 CFR 41.25(a)(3) would be re-designated as 17 CFR 41.25(b)(3).

[64] American exercise style refers to the right of an option holder to exercise the option at any time prior to, and including, expiration. In contrast, a European exercise style option only can be exercised at expiration.

[65] The proposal would re-designate 17 CFR 41.25(a)(3)(iv) to 17 CFR 41.25(b)(3)(vi).

trading volume continue to justify that position accountability rule.

Current provisions require a DCM to calculate trading volume monthly. The Commission believes that review of position limit levels and position accountability rules on at least a semi-annual basis rather than a monthly basis generally should be adequate to ensure appropriate levels because deliverable supply generally does not change to a great degree from month to month. For example, the number of shares outstanding may increase through periodic issuance of additional shares, and may decrease through stock repurchase programs, but, as a general observation, such issuance or repurchases are not a large percentage of free float. Of course, there could be situations where deliverable supply changes to a great degree before the semi-annual period and the rule does not prevent a DCM from considering those changes before such period.

The Commission also proposes a technical change to the filing requirement whenever a DCM makes such changes to limit levels. While the proposal continues to provide that changes to limit levels be filed pursuant to the requirements of Commission regulation 41.24, it removes the superfluous provision in the current regulation that provides that the change be effective no earlier than the day after the DCM has provided notification to the Commission and to the public. Instead, the regulation simply cites to Commission regulation 41.24, which specifies that changes must be received by the Commission no later than the day prior to the implementation.

11. Appendix A to Subpart C of Part 41, Guidance and Acceptable Practices for Position Limits and Position Accountability for SFPs

Section (a), Guidance on Estimating Deliverable Supply. The proposal provides guidance for estimating deliverable supply. For an equity security, deliverable supply should be no greater than the free float of the security. For a debt security, deliverable supply should not include securities that are committed for long-term agreements (*e.g.,* closed-end investment companies, structured products, or similar securities).

Regarding the guidance for estimating deliverable supply for equity securities, free float of the security generally means issued and outstanding shares less restricted shares. Restricted shares include restricted and control securities, which are not registered with the SEC to sell in a public marketplace.[66] The Commission requests comment on whether there are any other adjustments that should be made in estimating deliverable supply for equities. For example, should the guidance exclude from deliverable supply any equity shares held by ETFs, mutual funds, or similar investment vehicles? If so, how would such counts of shares be determined or estimated?

Also regarding the guidance for estimating deliverable supply for equity securities, the Commission notes that authorized participants may increase the number of outstanding shares in an ETF.[67] In setting a position limit for an ETF, the Commission has not proposed that DCMs look through the ETF to the lowest deliverable supply in an underlying security, as is the case in the proposal for limits for physically-delivered basket equity SFPs. Rather, the Commission has proposed to restrict the estimate of deliverable supply in an ETF to existing shares of the ETF. As an alternative, the Commission requests comment on whether an estimate of deliverable supply for an ETF should include an allowance for the creation of ETF shares. If so, how would one estimate such an allowance?

Section (b), Guidance on Setting Limits on Cash-Settled Equity Index SFPs. As noted above, the Commission is proposing guidance for setting limits on cash-settled equity index SFPs. This proposed guidance would permit a DCM to set the limit level for a cash-settled SFP on a narrow-based security index of equity securities to that of a similar narrow-based security index equity option listed on an NSE. As an alternative for setting the level based on that of a similar equity option, the proposal provides guidance and acceptable practices that would allow a DCM, in setting a limit, to consider the deliverable supply of securities underlying the equity index, and the equity index weighting and SFP contract multiplier.

As an example of an acceptable practice, for a cash-settled equity index SFP on a security index weighted by the number of shares outstanding, a DCM could set a position limit as follows: First, compute the limit on an SFP on each underlying security under proposed regulation (b)(3)(i)(A) (currently designated as (a)(3)(i)(A)); second, multiply each such limit by the ratio of the 100-share contract size and the shares of the security in the index; and third, determine the minimum level from step two and set the limit to that level, given a contract size of one dollar times the index, or for a larger contract size, reduce the level proportionately. As the Commission is proposing for physically-delivered basket equity SFPs, the proposal is based on the premise that the limit on a cash-settled SFP on a narrow-based security index of equity securities should be as restrictive as the limit for an SFP based on the underlying security with the most restrictive limit.

Section (c), Guidance on Setting Limits on Debt SFPs. The proposal would provide guidance that an appropriate level for limits on debt SFPs generally would be no greater than the equivalent of 12.5 percent of the par value of the estimated deliverable supply of the underlying debt security. The Commission notes that this approach is guidance because there may be other reasonable bases for setting levels of debt SFPs position limits and the Commission does not want to foreclose those bases. For example, a coupon stripped from an interest bearing corporate bond does not have a par value in terms of such corporate bond, but instead such coupon is the amount of interest due at the time the corporate issuer is scheduled to pay such coupon under the corporate bond indenture.[68]

Although no DCM currently lists an SFP based on a debt security, the Commission believes a framework for position limits may reduce uncertainty regarding acceptable practices for listing such contracts on non-exempted securities and, thereby, may facilitate listing of such contracts. The Commission notes that futures contracts in exempted securities, such as U.S. Treasury notes, have been listed for many years.[69] The Commission is proposing 12.5 percent of the par value of the estimated deliverable supply of the underlying debt security as guidance

[66] For a general discussion of restricted and control securities, *see https://www.sec.gov/reportspubs/investor-publications/investorpubsrule144htm.html.*

[67] An authorized participant generally is an institutional investor, such as a broker dealer, who acts to create or redeem ETF shares. The authorized participant buys shares that underlie the ETF and exchanges those underlying shares with the ETF sponsor for shares in the ETF, thus creating new ETF shares that it may sell to the public. An authorized participant may also purchase ETF shares in the market place and redeem those shares with the ETF sponsor, thus reducing the number of ETF shares outstanding.

[68] An interest bearing bond may be structured in a conduit and divided into separate obligations, where the cash flow from the principal of the bond and the cash flow from each coupon may be sold as separate securities. Each such separate security is a zero-coupon security.

[69] In this regard, an exempted security refers to certain exempted securities under the Securities Act of 1933 or the Securities Exchange Act of 1934. *See* CEA section 2(a)(1)(C).

on an appropriate basis based on the existing levels of limits for equity option contracts on NSEs. The Commission invites comment on whether a level based on par value is appropriate, or whether some other metric would be appropriate.

Section (d), Guidance on Position Accountability. The Commission proposes, as guidance, that a DCM may adopt a position accountability rule for any SFP, including an SFP where a position limit is required or adopted. Under the proposal, a position accountability rule would provide, at a minimum, that the DCM have authority to obtain information from a market participant with a position at or above the accountability level and that the DCM have authority, in its discretion, to order such a market participant to halt increasing their position. The Commission notes that position accountability can work in tandem with a position limit rule, particularly where the accountability level is set at a low level, in comparison to the level of the position limit. Further, the Commission notes that a DCM may adopt a position accountability rule to provide authority to the DCM to order market participants to reduce position sizes, for example, to maintain orderly trading or to ensure an orderly delivery.

Section (e), Guidance for Exemptions.[70] The proposed regulation would continue to provide a DCM with discretion to grant exemptions to position limits. The proposal provides guidance that such exemptions may be consistent with current Commission regulation 150.5 regarding exchange-set position limits or consistent with rules of an NSE regarding securities option exemptions. This guidance differs from the provisions of the current regulation, which references Commission regulation 150.3 regarding federal position limits in certain physical commodity futures contracts. The Commission believes the guidance should reference exemption provisions applicable to exchange-set limits in Commission regulation 150.5, rather than federal limits, because the exemptions for federal limits are written largely in terms of the federal limits on physical commodity contracts in Commission regulation 150.2.

[70] In addition to re-designating 17 CFR 41.25(a)(3) as 17 CFR 41.25(b)(3), the proposal would re-designate current 17 CFR 41.25(a)(3)(iii) to appendix A to subpart C.

III. Related Matters

A. Regulatory Flexibility Act

The Regulatory Flexibility Act (''RFA'')[71] requires that federal agencies consider whether a proposed rule will have a significant economic impact on a substantial number of small entities and, if so, provide a regulatory flexibility analysis of the impact. The proposed amendments generally apply to exchange-set position limits. The proposed amendments would permit a DCM to increase the level of position limits for SFPs and may change the application of those limits from a trader's net position to a trader's gross position. The proposed amendments would affect DCMs. The Commission has previously established certain definitions of ''small entities'' to be used in evaluating the impact of its rules on small entities in accordance with the RFA, and has previously determined that DCMs are not small entities for purpose of the RFA.[72]

Therefore, the Commission believes that the amendments to the SFP position limits regulations would not have a significant economic impact on a substantial number of small entities. Accordingly, the Chairman, on behalf of the Commission, hereby certifies, pursuant to 5 U.S.C. 605(b), that the proposed amendments will not have a significant economic impact on a substantial number of small entities.

B. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (''PRA'')[73] provides that a federal agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number issued by the Office of Management and Budget (''OMB''). The collection of information related to this proposed rule is OMB control number 3038–0059—Security Futures Products.[74] As a general matter, the proposed amendments to the SFP position limits regulation (1) permit a DCM to increase the level of limits; and (2) may change the application of exchange-set limits from a net basis to a gross basis. The Commission believes that the proposed amendments will not impose any new information collection requirements that require approval of OMB under the PRA. As such, the proposed amendments do not impose any new burden or any new information collection requirements in addition to those that already exist in connection with filing to list SFPs under Commission regulation 41.23 or to amend exchange rules for SFPs under Commission regulation 41.24.[75]

[71] 5 U.S.C. 601 *et seq.*

[72] *See* Policy Statement and Establishment of Definitions of ''Small Entities'' for Purposes of the Regulatory Flexibility Act, 47 FR 18618, 18619 (Apr. 30, 1982).

[73] 44 U.S.C. 3501 *et seq.*

[74] Regarding Security Futures Products (OMB Control No. 3038–0059), the Commission recently published a notice of a request for extension of the currently approved information collection. *See* 82 FR 48496 (Oct. 18, 2017).

C. Cost-Benefit Considerations

1. Introduction

Section 15(a) of the CEA requires the CFTC to consider the costs and benefits of its actions before promulgating a regulation under the CEA or issuing certain orders.[76] CEA section 15(a) further specifies that the costs and benefits shall be evaluated in light of 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 CFTC considers the costs and benefits resulting from its discretionary determinations with respect to the section 15(a) factors below.

Where reasonably feasible, the CFTC has endeavored to estimate quantifiable costs and benefits. Where quantification is not feasible, the CFTC identifies and describes costs and benefits qualitatively.

The CFTC requests comment on the costs and benefits associated with the proposed rule amendments. In particular, the CFTC requests that commenters provide data and any other information or statistics that the commenters relied on to reach any conclusions regarding the CFTC's proposed considerations of costs and benefits.

2. Economic Baseline

The CFTC's economic baseline for this proposed rule amendment analysis is the SFP position limits rule requirement that exists today. In the 2001 Final SFP Rules, the Commission adopted an SFP position limits rule that is consistent with the statutory requirements of CEA section 2(a)(1)(D). In particular, CEA section 2(a)(1)(D)(i)(VII) requires generally that

[75] Similarly, the Commission previously determined that a rule expanding the listing standards for security futures did not require a new collection of information on the part of any entities. *See* 71 FR 39534 at 39539 (July 13, 2006) (adopting a rule to permit security futures to be based on individual debt securities or a narrow-based security index comprised of such securities).

[76] 7 U.S.C. 19(a).

trading in an SFP is not readily susceptible to manipulation of the price of that SFP or its underlying security. The CFTC regulation that is in effect currently states that, ''the [DCM] shall have rules in place establishing position limits or position accountability procedures for the expiring futures contract month.'' [77] The 2001 Final SFP Rules also provide criteria for a maximum level of position limits and criteria that permit a DCM to adopt an exchange rule for position accountability in lieu of position limits.[78] In addition, the 2001 Final SFP Rules permit a DCM to approve exemptions from position limits pursuant to exchange rules that are consistent with CFTC regulation 150.3.

The CFTC will analyze the costs and benefits of the rules in this proposal against the current default net position limit level of 13,500 (100-share) contracts; or a higher net position limit level of 22,500 (100-share) contracts for equity SFPs meeting either a criterion of at least 20 million shares of average daily trading volume, or criteria of at least 15 million shares of average daily trading volume and more than 40 million shares of the underlying security outstanding.

The current regulation permits (but does not require) a DCM to adopt an exchange rule for position accountability in lieu of position limits, provided that average daily trading volume in the underlying security exceeds 20 million shares and there are more than 40 million shares of the underlying security outstanding.

3. Summary of Proposed Requirements

For equity SFPs, the proposed amendment would increase the default position limit level from 13,500 (100-share) contracts to 25,000 (100-share) contracts. The proposed amendment also permits a DCM to establish a higher position limit level than 25,000 (100-share) contracts, equivalent to 12.5 percent of estimated deliverable supply of the underlying security (which, under proposed guidance, should not exceed the free float of the underlying security). In connection with this change, a DCM would be required to estimate deliverable supply at least semi-annually, rather than to calculate the average daily trading volume at least monthly.

Also for equity SFPs, the proposed amendment would change one of the criteria that permit a DCM to adopt an exchange rule for position accountability in lieu of position limits, from more than 40 million shares of the underlying security outstanding, to an estimated deliverable supply of more than 40 million shares. The proposal generally would retain the other criterion, namely six-month average daily trading volume in the underlying security exceeding 20 million shares, but convert that criterion to 2.5 billion shares of six-month total trading volume, based on 125 trading days in a typical six-month period.

For physically-delivered basket equity SFPs, the proposed amendment would change the criteria for the position limit to the underlying security with the lowest estimated deliverable supply, from the security in the index with the lowest average daily trading volume. The proposed amendment also would clarify that an appropriate adjustment would be made to the level of the limit for a contract size different than 100 shares per underlying security.

For SFPs that are cash settled to a narrow-based security index of equity securities, the proposed amendment provides guidance that a DCM may set the limit level to that of a similar narrow-based security index equity option. The proposal also provides guidance and an acceptable practice, which would provide a safe harbor for a DCM itself to set such a limit level.

For SFPs in debt securities, the proposal would establish a requirement that a DCM must adopt a position limit either net or on the same side of the market, and would provide guidance that the level of such limit generally should be set no greater than the equivalent of 12.5 percent of the par value of the estimated deliverable supply of the underlying debt security. There currently are no SFPs in debt securities listed for trading.

The proposal would establish a required minimum position limit time period beginning no later than the first day that a holder of a long position may be assigned a delivery notice, if such period is longer than the last five trading days, where the SFP permits delivery before the close of trading. There currently are no SFPs listed for trading that provide for delivery before the close of trading.

The proposed amendment would provide DCMs with the discretion to alter the basis for applying a position limit from a net position to a gross position on the same side of the market.[79]

The proposal would establish guidance that a DCM may adopt an exchange rule for position accountability in addition to an exchange rule for a position limit.

The proposal would amend the guidance for exemptions from position limits by changing the reference to CFTC regulation 150.3, regarding exemptions to federal position limits, to CFTC regulation 150.5, regarding guidance for exchange-set limits. The proposal also would add guidance for exemptions from position limits to permit a DCM to provide exemptions consistent with those of a NSE regarding securities options position limits or exercise limits.

The proposal would amend the requirements for re-setting levels of position limits by changing the required review period from monthly to semi-annually; and imposing a requirement that a DCM must lower the position limit for an SFP with data that no longer justifies a higher limit level, rather than guidance that a DCM may lower such position limit. The proposal also would make clear that a DCM must impose a position limit for an SFP with data that no longer justifies an exchange rule for position accountability in lieu of a position limit. The proposal would continue to permit a DCM to use discretion as to whether to increase the level of a position limit for an SFP with data that justifies a higher level.

The proposal would establish a general definition of estimated deliverable supply, consistent with the guidance on estimating deliverable supply in appendix C to part 38, and provide guidance on estimating delivery supply that is specific to an SFP.

Finally, the proposal would establish a definition of same side of the market, for clarity in the proposed limit levels on a gross basis. The definition would distinguish long positions for an SFP in the same security from short positions in an SFP in the same security.[80]

4. Costs

The proposal would as a general matter reduce costs relative to the existing Commission regulation 41.25(a)(3),[81] since it will reduce the frequency of hedge exemption requests (as discussed in the benefits section) and reduce the frequency of required DCM reviews of position limits from monthly to semi-annually. Under the

[77] 17 CFR 41.25(a)(3).

[78] 17 CFR 41.25(a)(3).

[79] In this regard, OneChicago, LLC (''OneChicago''), a DCM listing SFPs, permits concurrent long and short positions to be held. *See* OneChicago exchange rule 424, *available at https://www.onechicago.com/wp-content/uploads/content/OneChicago_Current_Rulebook.pdf.*

[80] These two definitions would be added into a new paragraph (a) of 17 CFR 41.25; in conjunction with the addition of the new paragraph (a), current paragraphs (a) through (d) would be re-designated as paragraphs (b) through (e).

[81] Re-designated under the proposal as 17 CFR 41.25(b)(3).

proposal, DCMs that list SFPs for trading would continue to be required to adopt position limits or position accountability, but the proposal would generally increase the levels of position limits. The Commission preliminarily believes that the proposal would impose certain costs on such DCMs, and that these costs are necessary to establish appropriate position limits or position accountability trigger levels based on deliverable supply and such additional criteria that the listing DCM determines to be appropriate. The Commission also believes that these costs are comparable to those incurred under current regulations (whereby DCMs must calculate average daily trading volume) and notes that these costs will be incurred only semi-annually under the proposal rather than monthly as under current regulations. The Commission believes that DCMs would be able to exercise control over the extent of these costs depending on the degree of standardization such DCMs use to determine position limits and accountability and the Commission anticipates that DCMs will choose from among the lower-cost options. For example, a DCM could, consistent with the proposal, adopt a simple rule for equity securities based on the number of free-float outstanding shares. For equity securities, free-float information is readily available on certain publicly-available market websites and on Bloomberg terminals and similar services (which DCMs are likely to have access to for other business reasons). Reducing the frequency with which DCMs are required to review position limits and accountability to semi-annually from monthly will reduce costs to DCMs. Thus, the Commission anticipates that estimating deliverable supply would not be more costly (and would likely be less costly) than estimating average daily trading volume as required under current regulations.

The Commission notes that under the proposed rule, DCMs have the discretion to implement the default position limit of 25,000 contracts regardless of deliverable supply and that this may result in position limit levels in some contracts greater than 12.5 percent of deliverable supply. However, this discretion is limited by Core Principle 5 (which requires DCMs to set position levels at necessary and appropriate levels to deter manipulation) and by Core Principle 3 (which requires that DCMs may only list contracts that are not readily susceptible to manipulation). To the extent that DCMs comply with these core principles, this DCM discretion should not impair the protection of market participants and the public or otherwise impose significant costs on the markets for SFPs market or related securities.

To the extent that a DCM lists equity SFPs on deliverable baskets, the costs of implementing the proposed position limit provisions for such SFPs would be similar to the costs of the analogous provisions for single stock SFPs, but there are no current costs associated with those proposed changes to the regulations since such SFPs are not currently listed for trading. There are also no listed SFPs at this time on debt securities. To the extent that there is less publicly-available information related to the deliverable supply of debt securities, estimating deliverable supply may be more costly for debt securities than for equity securities. However, these costs will only be incurred in the event that a DCM begins listing security futures on non-exempted debt securities. Moreover, these deliverable supply provisions are set out as guidance so that DCMs are free to implement less costly methods to comply with the rule, which provides only that futures on debt securities must have position limits. While DCMs have not listed debt security SFPs absent the proposed changes to the regulation, it is theoretically possible that the costs associated with estimating deliverable supply or otherwise determining position limit levels may affect future decisions regarding whether or not to list such SFPs. The costs of the proposed regulation for debt securities would be otherwise similar to the costs of the proposed regulation for equity securities.

The proposal to permit DCMs to implement position limits on a net basis or on positions on the same side of the market (*e.g.,* on physically-delivered and cash settled contracts on the same security, should a DCM ever list both types of contracts) would not require DCMs to change their current practice, and will thus not impose new costs on DCMs. Any change that imposes new costs on market participants would be made at the discretion of the DCM.

The proposal to establish a required minimum position limit time period beginning no later than the first day that a holder of a long position may be assigned a delivery notice, if such period is longer than the last five trading days, in instances where the SFP permits delivery before the close of trading currently imposes no costs since contracts of this nature are not currently listed for trading. If a DCM listed such contracts, the proposal would require market participants to incur the costs of complying with position limits or applying for hedge exemptions (and would require DCMs to incur the costs of reviewing such applications) earlier in the life of the contract than absent the proposal.

5. Benefits

The Commission reviews its regulations to help ensure they keep pace with technological developments and industry trends, and to reduce regulatory burden where needed. The proposal would allow DCMs to adopt position limits that they deem to be appropriate. The Commission preliminarily believes that DCMs will adopt position limits that are large enough not to significantly inhibit liquidity, but will appropriately mitigate against potential manipulations and other concerns that may be associated with overly large positions in SFPs. Moreover, to the extent that the proposal would lead to position limits that are higher than current position limits, the proposal could alleviate the costs to hedgers of filing hedge exemptions for positions that are larger than a current position limit, but lower than a new position limit under the proposal. In that regard, Commission staff reviewed the largest positions in SFPs that were held during the calendar year 2017 and found that there were 16 positions held during the last five trading days of expiring SFP contract months across all listed SFPs on OneChicago, currently the only DCM to list SFPs for trading. These positions generally appear to have been associated with securities lending agreements [82] and thus appear to have been eligible for hedge exemptions. These 16 positions exceeded the current applicable limit for their underlying securities of the default 13,500 contracts. If the proposed default position limit of 25,000 contracts had been in effect in 2017, fewer than four positions would have been above that default position limit and would have required hedge exemptions. While the Commission believes that the monetary cost of filing a hedge exemption form is very small for an entity large enough to maintain a position that exceeds a position limit (perhaps less than $100), it is possible that the burden of filing a hedge exemption may discourage hedging at sizes exceeding position limits and, thus, that raising position limits may encourage larger hedges. The Commission also notes that to the extent SFPs are now or in the future used for

[82] OneChicago describes itself on its website, *https://onechicago.com,* as ''the Securities Finance Exchange'' and states that ''single stock futures are ideally suited to replace 'agreements' in equity repo and securities lending transactions.''

speculation,[83] speculators could establish larger positions under the proposal without a need for concern about position limits and may thus increase their trading activity. Any potential increase in trading activity could improve liquidity in the SFP markets.

Requiring DCMs to set position limits and accountability based on semi-annual deliverable supply estimates should help ensure on an ongoing basis that position limits and accountability are set at levels that are necessary and appropriate to deter manipulation consistent with DCM Core Principles 3 and 5.

The Commission preliminarily believes that the proposed frameworks for position limits in SFPs on deliverable equity baskets and debt securities (all based on deliverable supply estimates) should help ensure that such products, if they are ever listed for trading, are reasonably protected from manipulation. Further, the Commission preliminarily believes that the proposal may help foster position limits consistent with those in analogous securities options (where applicable).

The proposal to permit DCMs to implement position limits on a net basis or on positions on the same side of the market (such as physically-delivered or cash settled contracts on the same security, should a DCM ever list both types of contracts) will give DCMs the discretion to implement position limits in a manner that they see fit.

The proposal to establish a required minimum position limit time period beginning no later than the first day that a holder of a long position may be assigned a delivery notice, if such period is longer than the last five trading days, where the SFP permits delivery before the close of trading currently provides no benefits since contracts of this nature are not listed for trading. If a DCM listed such contracts, the proposal would help ensure that such contracts are not readily susceptible to manipulation during the entire delivery period.

6. CEA Section 15(a) Factors

i. Protection of Market Participants and the Public

The Commission preliminarily believes that this proposal maintains the protection of market participants and the public provided by the current regulation. The proposal will continue to protect market participants and the public by maintaining the requirement that DCMs that list SFPs adopt and enforce appropriate position limits or position accountability consistent with DCM Core Principle 5 and implementing for SFPs the longstanding Commission policy that spot-month position limits should be set based on estimates of deliverable supply. Linking the levels of position limits and accountability to deliverable supply protects market participants and the public by helping prevent congestion, manipulation, or other problems that can be associated with speculative positions in expiring contracts that are overly large relative to deliverable supply.

ii. Efficiency, Competitiveness, and Financial Integrity of Markets

As discussed above, under the proposal, it is reasonable to anticipate that many or most SFPs would be subject to higher position limits compared to the current position limits. Therefore, hedgers may be able to take larger positions without the need to apply for hedge exemptions. This also could alleviate the DCM's need to review hedge exemptions improving resource allocation efficiency for exchanges and certain market participants. Moreover, with less restrictive position limits, it is theoretically possible that more traders could be enticed into the market and thus improve the liquidity and pricing efficiency of the SFP market.

The current position limit regulation (a default of 13,500 contracts) often leads to position limits that are tighter than analogous position limits for security options (a default of 25,000 contracts). The proposal would raise the default limit level in SFPs to match that in securities options. More closely aligning the position limits in SFPs to those in securities options may enhance the competitiveness of the SFP market relative to the securities option market.

iii. Price Discovery

The Commission believes that price discovery typically occurs in the liquid and generally transparent security markets underlying existing SFPs rather than the relatively low-volume SFPs themselves. Nevertheless, as noted above, to the extent that trading activity in SFP markets increases due to less restrictive position limits, the price discovery function of SFPs could be enhanced by reducing liquidity risk and thereby facilitating arbitrage between the underlying security and SFP markets.

iv. Sound Risk Management Practices

The current position limit regulation often leads to position limits that are tighter than analogous position limits for security options. It is conceivable that this could discourage potential hedgers or other risk managers from using SFPs rather than security options because of burdens associated with the hedge exemption process. Risk managers might also find that the liquidity risk in the current SFP market is too high, due to a lack of speculators in the SFP market (among other causes). In this regard, it is possible that the current position limits might be too tight for speculators to perform adequately their role of providing liquidity in a futures market. Because the proposal raises the default limit to 25,000 contracts to match the default in security options, and thus would likely lead to higher position limits for many SFPs, it is possible that both risk managers and speculators enter or increase trading in the SFP market under the proposal.

v. Other Public Interest Considerations

The Commission has not identified any additional public interest considerations associated with the proposal.

7. Consideration of Alternatives

The Commission considered regulations that would require DCMs to conform the position limits in SFPs to those in securities options to a greater degree than under the proposal (consistent with comments to the original SFP rule proposal), including applying position limits throughout the life of the contract (rather than only in the last five trading days) and no longer permitting position accountability for SFPs on securities with higher trading volume and deliverable supply. The Commission believes that permitting position accountability for certain SFPs and only requiring spot month limits is consistent with Core Principle 5 and that these requirements are sufficient to ensure that SFPs are not readily susceptible to manipulation as required by Core Principle 3. Thus, not permitting position accountability and requiring DCMs to apply position limits throughout the life of the contract would significantly increase costs on market participants while not significantly enhancing protection of market participants and the public or providing significant benefits beyond those of the proposed position limits framework.

The Commission also considered not setting default position limits for equity

[83] As noted above, SFPs may be used for securities finance transactions that are not speculative in nature.

SFPs and simply requiring that position limits and accountability be set based on deliverable supply, as is done in many other futures products. However, the Commission preliminarily determined not to make such a proposal because some exchanges and market participants (based on past comments)[84] appear to believe that there are benefits to conforming position limits in SFPs to those in securities options to the extent practicable.

8. Request for Comments

The Commission invites public comment on its cost-benefit considerations, including the CEA 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.

The Commission specifically seeks comment on the following:

1. Are there alternatives to the proposal (whether discussed in this release or not) that would be superior from a cost-benefit standpoint?

2. Would the proposal affect costs for those market participants that seek hedge exemptions?

3. Would DCMs that list for trading SFPs face additional costs in adopting and setting position limits and position accountability levels for SFPs under the proposal that are not discussed in this consideration of costs and benefits?

4. Do DCMs and market participants expect to see benefits under the proposal that are not discussed in this consideration of costs and benefits? Please quantify or describe such benefits.

5. Should the Commission eliminate default position limits for equity SFPs and instead simply require that position limits and accountability be set based on deliverable supply, as is done in many other futures products?

6. Is it feasible to estimate deliverable supply for debt securities at reasonable cost?

7. Are there benefits associated with the Commission implementing rules for types of SFPs that are not currently listed for trading? Does implementing such rules have the potential to impose costs associated with possibly deterring innovation?

D. Anti-Trust Considerations

CEA Section 15(b) 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, polices 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 CEA section 17.[85]

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 Act. The Commission requests comment on whether there are less anticompetitive means of achieving the relevant purposes of the Act that would further the objective of this proposal, such as leveling the regulatory playing field between SFPs and security options listed on NSEs.

List of Subjects in 17 CFR Part 41

Position accountability, Position limits, Security futures products.

For the reasons discussed in the preamble, the Commodity Futures Trading Commission proposes to amend 17 CFR part 41 as set forth below:

PART 41—SECURITY FUTURES PRODUCTS

■ 1. The authority citation for part 41 continues to read as follows:

Authority: Sections 206, 251 and 252, Pub. L. 106–554, 114 Stat. 2763, 7 U.S.C. 1a, 2, 6f, 6j, 7a–2, 12a; 15 U.S.C. 78g(c)(2).

■ 2. In § 41.25:

■ a. Redesignate paragraphs (a) through (d) as paragraphs (b) through (e);

■ b. Add new paragraph (a);

■ c. Revise newly redesignated paragraphs (b)(3), (c)(2) and (3), and (e).

The addition and revisions read as follows:

§ 41.25 Additional conditions for trading for security futures products.

(a) *Definitions.* For purposes of this section:

Estimated deliverable supply means the quantity of the security underlying a security futures product that reasonably can be expected to be readily available to short traders and salable by long traders at its market value in normal cash marketing channels during the specified delivery period. For guidance on estimating deliverable supply, designated contract markets may refer to appendix A of this subpart.

Same side of the market means the aggregate of long positions in physically-delivered security futures products and cash-settled security futures products, in the same security, and, separately, the aggregate of short positions in physically-delivered security futures products and cash-settled security futures products, in the same security.

(b) * * *

(3) *Speculative position limits.* A designated contract market shall have rules in place establishing position limits or position accountability procedures for the expiring futures contract month as specified in this paragraph (b)(3).

(i) *Limits for equity security futures products.* For a security futures product on a single equity security, including a security futures product on an underlying security that represents ownership in a group of securities, *e.g.,* an exchange traded fund, a designated contract market shall adopt a position limit no greater than 25,000 100-share contracts (or the equivalent if the contract size is different than 100 shares), either net or on the same side of the market, applicable to positions held during the last five trading days of an expiring contract month; except where:

(A) For a security futures product on a single equity security where the estimated deliverable supply of the underlying security exceeds 20 million shares, a designated contract market may adopt, if appropriate in light of the liquidity of trading in the underlying security, a position limit no greater than the equivalent of 12.5 percent of the estimated deliverable supply of the underlying security, either net or on the same side of the market, applicable to positions held during the last five trading days of an expiring contract month; or

(B) For a security futures product on a single equity security where the six-month total trading volume in the underlying security exceeds 2.5 billion shares and there are more than 40

[84] *See supra* discussion of the 2001 Final SFP Rules.

[85] 7 U.S.C. 19(b).

million shares of estimated deliverable supply, a designated contract market may adopt a position accountability rule, either net or on the same side of the market, applicable to positions held during the last five trading days of an expiring contract month. Upon request by a designated contract market, traders who hold positions greater than 25,000 100-share contracts (or the equivalent if the contract size is different than 100 shares), or such lower level specified pursuant to the rules of the designated contract market, must provide information to the designated contract market and consent to halt increasing their positions when so ordered by the designated contract market.

(ii) *Limits for physically-delivered basket equity security futures products.* For a physically-delivered security futures product on more than one equity security, *e.g.,* a basket of deliverable securities, a designated contract market shall adopt a position limit, either net or on the same side of the market, applicable to positions held during the last five trading days of an expiring contract month and the criteria in paragraph (b)(3)(i) of this section must apply to the underlying security with the lowest estimated deliverable supply. For a physically-delivered security futures product on more than one equity security with a contract size different than 100 shares per underlying security, an appropriate adjustment to the limit must be made. If each of the underlying equity securities in the basket of deliverable securities is eligible for a position accountability level under paragraph (b)(3)(i)(B) of this section, then the security futures product is eligible for a position accountability level in lieu of position limits.

(iii) *Limits for cash-settled equity index security futures products.* For a security futures product cash settled to a narrow-based security index of equity securities, a designated contract market shall adopt a position limit, either net or on the same side of the market, applicable to positions held during the last five trading days of an expiring contract month. For guidance on setting limits for a cash-settled equity index security futures product, designated contract markets may refer to section (b) of appendix A of this subpart.

(iv) *Limits for debt security futures products.* For a security futures product on one or more debt securities, a designated contract market shall adopt a position limit, either net or on the same side of the market, applicable to positions held during the last five trading days of an expiring contract month. For guidance on setting limits for a debt security futures product, designated contract markets may refer to section (c) of appendix A of this subpart.

(v) *Required minimum position limit time period.* For position limits required under this section where the security futures product permits delivery before the termination of trading, a designated contract market shall apply such position limits for a period beginning no later than the first day that long position holders may be assigned delivery notices, if such period is longer than the last five trading days of an expiring contract month.

(vi) *Requirements for re-setting levels of position limits.* A designated contract market shall calculate estimated deliverable supply and six-month total trading volume no less frequently than semi-annually.

(A) If the estimated deliverable supply data supports a lower speculative limit for a security futures product, then the designated contract market shall lower the position limit for that security futures product pursuant to the submission requirements of § 41.24. If the data require imposition of a reduced position limit for a security futures product, the designated contract market may permit any trader holding a position in compliance with the previous position limit, but in excess of the reduced limit, to maintain such position through the expiration of the security futures contract; provided, that the designated contract market does not find that the position poses a threat to the orderly expiration of such contract.

(B) If the estimated deliverable supply or six-month total trading volume data no longer supports a position accountability rule in lieu of a position limit for a security futures product, then the designated contract market shall establish a position limit for that security futures product pursuant to the submission requirements of § 41.24.

(C) If the estimated deliverable supply data supports a higher speculative limit for a security futures product, as provided under paragraph (b)(3)(i)(A) of this section, then the designated contract market may raise the position limit for that security futures product pursuant to the submission requirements of § 41.24.

(vii) *Restriction on netting of positions.* If the designated contract market lists both physically-delivered contracts and cash settled-contracts in the same security, it shall not permit netting of positions in the physically-delivered contract with that of the cash-settled contract for purposes of determining applicability of position limits.

(c) * * *

(2) Notwithstanding paragraph (c)(1) of this section, if an opening price for one or more securities underlying a security futures product is not readily available, the final settlement price of the security futures product shall fairly reflect:

(i) The price of the underlying security or securities during the most recent regular trading session for such security or securities; or

(ii) The next available opening price of the underlying security or securities.

(3) Notwithstanding paragraph (c)(1) or (2) of this section, if a derivatives clearing organization registered under Section 5b of the Act or a clearing agency exempt from registration pursuant to Section 5b(a)(2) of the Act, to which the final settlement price of a security futures product is or would be reported determines, pursuant to its rules, that such final settlement price is not consistent with the protection of customers and the public interest, taking into account such factors as fairness to buyers and sellers of the affected security futures product, the maintenance of a fair and orderly market in such security futures product, and consistency of interpretation and practice, the clearing organization shall have the authority to determine, under its rules, a final settlement price for such security futures product.

* * * * *

(e) *Exemptions.* The Commission may exempt a designated contract market from the provisions of paragraphs (b)(2) and (c) of this section, either unconditionally or on specified terms and conditions, if the Commission determines that such exemption is consistent with the public interest and the protection of customers. An exemption granted pursuant to this paragraph shall not operate as an exemption from any Securities and Exchange Commission rules. Any exemption that may be required from such rules must be obtained separately from the Securities and Exchange Commission.

■ 3. Add appendix A to subpart C to read as follows:

Appendix A to Subpart C of Part 41—Guidance on and Acceptable Practices for Position Limits and Position Accountability for Security Futures Products

(a) *Guidance for estimating deliverable supply.* (1) For an equity security, deliverable supply should be no greater than the free float of the security.

(2) For a debt security, deliverable supply should not include securities that are committed for long-term agreements (*e.g.,* closed-end investment companies, structured products, or similar securities).

(3) Further guidance on estimating deliverable supply, including consideration of whether the underlying security is readily available, is found in appendix C to part 38 of this chapter.

(b) *Guidance and acceptable practices for setting limits on cash-settled equity index security futures products*—(1) *Guidance for setting limits on cash-settled equity index security futures products.* For a security futures product cash settled to a narrow-based security index of equity securities, a designated contract market:

(i) May set the level of a position limit to that of a similar equity index option listed on a national security exchange or association; or

(ii) Should consider the deliverable supply of equity securities underlying the index, and should consider the index weighting and contract multiplier.

(2) *Acceptable practices for setting limits on cash-settled equity index security futures products.* For a security futures product cash settled to a narrow-based security index of equity securities weighted by the number of shares outstanding, a designated contract market may set a position limit as follows: First, determine the limit on a security futures product on each underlying equity security pursuant to § 41.25(b)(3)(i); second, multiply each such limit by the ratio of the 100-share contract size and the shares of the equity securities in the index; and third, determine the minimum level from step two and set the limit to that level, given a contract size of one U.S. dollar times the index, or for a larger contract size, reduce the level proportionately. If under these procedures each of the equity securities underlying the index is determined to be eligible for position accountability levels, the security futures product on the index itself is eligible for a position accountability level.

(c) *Guidance and acceptable practices for setting limits on debt security futures products*—(1) *Guidance for setting limits on debt security futures products.* A designated contract market should set the level of a position limit to no greater than the equivalent of 12.5 percent of the par value of the estimated deliverable supply of the underlying debt security. For a security futures product on more than one debt security, the limit should be based on the underlying debt security with the lowest estimated deliverable supply.

(2) *Acceptable practices for setting limits on debt security futures products.*

[Reserved.]

(d) *Guidance on position accountability.* A designated contract market may adopt a position accountability rule for any security futures product, in addition to a position limit rule required or adopted under this section. Upon request by the designated contract market, traders who hold positions, either net or on the same side of the market, greater than such level specified pursuant to the rules of the designated contract market must provide information to the designated contract market and consent to halt increasing their positions when so ordered by the designated contract market.

(e) *Guidance on exemptions from position limits.* A designated contract market may approve exemptions from these position limits pursuant to rules that are consistent with § 150.5 of this chapter, or to rules that are consistent with rules of a national securities exchange or association regarding exemptions to securities option position limits or exercise limits.

Issued in Washington, DC, on July 24, 2018, by the Commission.

Robert Sidman,

Deputy Secretary of the Commission.

Note: The following appendices will not appear in the Code of Federal Regulations.

Appendices to Position Limits and Position Accountability for Security Futures Products—Commission Voting Summary and Commissioner's Statement

Appendix 1—Commission Voting Summary

On this matter, Chairman Giancarlo and Commissioners Quintenz and Behnam voted in the affirmative. No Commissioner voted in the negative.

Appendix 2—Concurring Statement of Commissioner Rostin Behnam

I respectfully concur with the Commodity Futures Trading Commission's approval of its proposed rule regarding Position Limits and Position Accountability for Security Futures Products (the ''Proposal''). I commend staff on their hard work in producing this Proposal, and for their thoughtful responses to my questions. I look forward to hearing from market participants and other stakeholders regarding the amendments to the existing position limits rules for security futures products. In particular, I will be interested in comments regarding the appropriateness of increasing the default level of equity security futures products position limits from 13,500 contracts to 25,000 contracts. While today's Proposal only would amend the Commission's Part 41 rules regarding security futures products, I nonetheless encourage market participants and interested stakeholders to consider how the Proposal might impact or interplay with the Commission's position limits rules in Part 150 and any future amendments to them.

[FR Doc. 2018–16079 Filed 7–30–18; 8:45 am]

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DEPARTMENT OF EDUCATION

34 CFR Chapter VI

[Docket ID ED–2018–OPE–0076]

Negotiated Rulemaking Committee; Public Hearings

AGENCY: Office of Postsecondary Education, Department of Education.

ACTION: Intent to establish negotiated rulemaking committee.

SUMMARY: We announce our intention to establish a negotiated rulemaking committee to prepare proposed regulations for the Federal Student Aid programs authorized under title IV of the Higher Education Act of 1965, as amended (HEA) (title IV, HEA programs). We also announce our intention to create two subcommittees for this committee. In addition, we announce three public hearings at which interested parties may comment on the topics suggested by the Department and may suggest additional topics that should be considered for action by the negotiating committee. We will also accept written comments on the topics suggested by the Department and suggestions for additional topics that should be considered for action by the negotiating committee. The Department will present negotiators with proposed regulatory language at the first negotiating session.

DATES: The dates, times, and locations for the public hearings are listed under **SUPPLEMENTARY INFORMATION**. We must receive written comments on the topics suggested by the Department and additional topics that should be considered for action by the negotiating committee on or before September 14, 2018.

ADDRESSES: Submit your comments through the Federal eRulemaking Portal or via postal mail, commercial delivery, or hand delivery. We will not accept comments by fax or by email. To ensure that we do not receive duplicate copies, please submit your comments only once. In addition, please include the Docket ID at the top of your comments.

- *Federal eRulemaking Portal:* Go to *www.regulations.gov* to submit your comments electronically. Information on using *Regulations.gov*, including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under ''Help.''
- *Postal Mail, Commercial Delivery, or Hand Delivery:* The Department strongly encourages commenters to submit their comments electronically. However, if you mail or deliver your comments, address them to Aaron Washington, U.S. Department of Education, 400 Maryland Ave. SW, Room 294–12, Washington, DC 20202.

Privacy Note: The Department's policy is to make all comments received from members of the public available for public viewing in their entirety on the Federal eRulemaking Portal at *www.regulations.gov.* Therefore, commenters should be careful to include in their comments only information that they wish to make publicly available.

FOR FURTHER INFORMATION CONTACT:

For information about the public hearings, go to *www2.ed.gov/policy/highered/reg/hearulemaking/2018/index.html* or contact: Aaron Washington, U.S. Department of Education, 400 Maryland Ave. SW, Room 294–12, Washington, DC 20202. Telephone: (202) 453–7241. Email: *aaron.washington@ed.gov.*

For information about negotiated rulemaking in general, see *The Negotiated Rulemaking Process for Title IV Regulations, Frequently Asked Questions* at *www2.ed.gov/policy/highered/reg/hearulemaking/hea08/neg-reg-faq.html* or contact: Aaron Washington, U.S. Department of Education, 400 Maryland Ave. SW, Room 294–12, Washington, DC 20202. Telephone: (202) 453–7241. Email: *aaron.washington@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: Section 492 of the HEA requires that, before publishing any proposed regulations to implement programs authorized under title IV of the HEA, the Secretary obtain public involvement in the development of the proposed regulations. After obtaining advice and recommendations from the public, the Secretary conducts negotiated rulemaking to develop the proposed regulations. We announce our intent to develop proposed title IV regulations by following the negotiated rulemaking procedures in section 492 of the HEA.

We intend to select participants for the negotiated rulemaking committee from nominees of organizations and groups that represent the interests significantly affected by the proposed regulations. In accordance with section 492(b)(1) of the HEA, we will select from the nominees individual negotiators who reflect the diversity among program participants.

Regulatory Issues

We intend to convene a negotiated rulemaking committee to develop proposed regulations to revise the regulations related to the Secretary's recognition of accrediting agencies in 34 CFR part 602, and related parts as described below. The proposed topics for negotiation would include:

- Requirements for accrediting agencies in their oversight of member institutions;
- Requirements for accrediting agencies to honor institutional mission;
- Criteria used by the Secretary to recognize accrediting agencies, emphasizing criteria that focus on educational quality;
- Developing a single definition for purposes of measuring and reporting job placement rates; and
- Simplifying the Department's process for recognition and review of accrediting agencies.

In addition to developing proposed regulations on the core functions of accreditation, the committee would also develop proposed regulations in a number of areas to promote greater access for students to high-quality, innovative programs by revising the regulations related to:

(1) State authorization, to address the requirements related to programs offered through distance education or correspondence courses, including disclosures about such programs to enrolled and prospective students, and other State authorization issues (34 CFR 600.9 and 668.50);

(2) The definition of ''regular and substantive interaction,'' as that term is used in the definitions of ''correspondence course'' and ''distance education'' in 34 CFR 600.2, 600.7, and 668.10;

(3) The definition of the term ''credit hour'' as it is used in 34 CFR 600.2, 602.24, 603.24, and 668.8;

(4) The requirement that an institution demonstrate a reasonable relationship between the length of a program and entry-level requirements for the recognized occupation for which the program prepares the student (34 CFR 668.8(e)(1)(iii) and 668.14(b)(26));

(5) The arrangements between an institution and another institution or organization to provide a portion of an educational program (34 CFR 668.5);

(6) The roles and responsibilities of institutions and accrediting agencies in the teach-out process (34 CFR 600.32(d) and 602.24);

(7) The barriers to innovation and competition in postsecondary education or to student completion, graduation, or employment, including, but not limited to, those contained in the Department's institutional eligibility regulations (34 CFR part 600) and student assistance general provisions (34 CFR part 668);

(8) The simplification and clarification of program requirements to minimize inadvertent grant-to-loan conversions and to improve outcomes for Teacher Education Assistance for College and Higher Education (TEACH) Grant recipients (34 CFR part 686);

(9) Direct assessment programs and competency-based education (34 CFR 668.10), focusing on the ability of institutions to develop, and students to progress through, innovative programs responsive to student, employer, and societal needs, including consideration of regulations that are barriers to the implementation of such programs, such as certain requirements for term-based academic calendars and satisfactory academic progress; and

(10) In light of the recent United States Supreme Court decision in *Trinity Lutheran Church of Columbia, Inc.* v. *Comer,* 137 S. Ct. 2012 (2017), and the October 6, 2017, Memorandum for All Executive Departments and Agencies issued by the Attorney General of the United States pursuant to Executive Order No. 13798,[1] the committee would consider revisions to the various provisions of the regulations regarding the eligibility of faith-based entities to participate in the title IV, HEA programs, including the Gaining Early Awareness and Readiness for Undergraduate Programs program, and the eligibility of students to obtain certain benefits under those programs (34 CFR 600.11 and parts 628, 674, 675, 676, 682, 685, 690, 692, and 694).

Finally, we intend to convene two subcommittees for this committee. One subcommittee would address proposed regulations related to direct assessment programs/competency-based education (34 CFR 668.10) focusing on the ability of institutions to develop, and students to progress through, innovative programs responsive to student, employer, and societal needs. This subcommittee could consider revisions to regulations that are barriers to the implementation of such programs, including certain requirements for term-based academic calendars and satisfactory academic progress, among other topics. The second subcommittee would make recommendations to the committee regarding revisions to the regulations regarding the eligibility of faith-based entities to participate in the title IV, HEA programs. Proposed subcommittees are formed to address specified issues and to make recommendations to the committee regarding proposed regulatory language. Subcommittees do not make decisions for the committee. While committee meetings are open to the public to attend in person, subcommittee meetings will be made available through a Department-provided livestream.

We intend to provide draft proposed regulatory language for discussion by the negotiating committee and the subcommittees prior to the first meeting of the committee or subcommittees.

After reviewing the public comments presented at the hearings and in the written submissions, we will publish a

[1] *https://www.justice.gov/opa/press-release/file/1001891/download.*

document (or documents) in the **Federal Register** announcing the specific topics for which we intend to establish the negotiated rulemaking committee and a request for nominations for individual negotiators for the committee who represent the communities of interest that would be significantly affected by the proposed regulations. We will also announce the specific topics for which we intend to establish subcommittees and request nominations for individuals with pertinent expertise to participate on the subcommittees. This document will also be posted on the Department's website at: *www2.ed.gov/policy/highered/reg/hearulemaking/2018/index.html.*

Public Hearings

We will hold three public hearings for interested parties to discuss the rulemaking agenda. The public hearings will be held:

- September 6, 2018, at the U.S. Department of Education, 400 Maryland Ave. SW, Barnard Auditorium, Washington, DC 20202.
- September 11, 2018, at Xavier University, Convocation Center Annex, Room 111, Building 62, 7800 Washington Ave., New Orleans, LA 70125.
- September 13, 2018, at Gateway Technical College, SC Johnson iMET Center, 2320 Renaissance Blvd., Sturtevant, WI 53177.

The Washington, DC public hearing will be held from 9:00 a.m. to 4:00 p.m., Eastern Daylight Time. The New Orleans, LA and Sturtevant, WI public hearings will be held from 9:00 a.m. to 1:00 p.m., Central Daylight Time. Further information on the public hearing sites is available at *www2.ed.gov/policy/highered/reg/hearulemaking/2018/index.html.*

Individuals who would like to present comments at the public hearings must register by sending an email to *negreghearing@ed.gov.* The email should include the name of the presenter along with the public hearing at which the individual would like to speak, the general topic(s) the individual would like to address, and a general timeframe during which the individual would like to speak (for example, a presenter could indicate morning or afternoon, or before 11:00 a.m. or after 3:00 p.m.). We will make the determination on a first-come, first-served basis, based on the time and date the email was received. Each participant will be limited to five minutes. The Department will notify registrants of the date and time slot reserved for them. An individual may make only one presentation at the public hearings. If we receive more registrations than we are able to accommodate, the Department reserves the right to reject the registration of an entity or individual that is affiliated with an entity or individual that is already scheduled to present comments, and to select among registrants to ensure that a broad range of entities and individuals is allowed to present. We will accept registrations for any remaining time slots on a first-come, first-served basis, beginning at 8:30 a.m. on the day of the public hearing at the Department's on-site registration table. Registration is not required to observe the public hearings; however, space may be limited.

The Department will post transcripts of the hearings to *www2.ed.gov/policy/highered/reg/hearulemaking/2018/index.html.* Although the Department will not be video recording the hearings, speakers should be aware that, since these are public meetings, they may be filmed or recorded by members of the public.

Speakers may submit written comments at the public hearings. In addition, the Department will accept written comments via the Federal eRulemaking portal, and by postal mail, commercial delivery, or hand delivery. (See the **ADDRESSES** section of this document for submission information.)

Schedule for Negotiations

We anticipate that any committee established after the public hearings will begin negotiations in January of 2019, with the committee meeting for up to three sessions of three days each at roughly four- to eight-week intervals. The Department will post transcripts and audio of the sessions to *www2.ed.gov/policy/highered/reg/hearulemaking/2018/index.html.* We anticipate that any subcommittees established will begin meeting in January or February, after the first meeting of the committee. The committee and subcommittees will meet in the Washington, DC area. The dates and locations of these meetings will be published in a subsequent notice in the **Federal Register**, and will be posted on the Department's website at: *www2.ed.gov/policy/highered/reg/hearulemaking/2018/index.html.*

Accessible Format: Individuals with disabilities can obtain this document in an accessible format by contacting Aaron Washington, U.S. Department of Education, 400 Maryland Ave. SW, Room 281–13, Washington, DC 20202. Telephone: (202) 203–9155. Email: *Aaron.Washington@ed.gov.*

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Program Authority: 20 U.S.C. 1098a.

Diane Auer Jones,

Principal Deputy Under Secretary Delegated to Perform the Duties of Under Secretary and Assistant Secretary, Office of Postsecondary Education.

[FR Doc. 2018–15929 Filed 7–30–18; 8:45 am]

BILLING CODE 4000–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R02–OAR–2018–0549; FRL–9981–62—Region 2]

Approval and Promulgation of Implementation Plans; New Jersey; Elements for the 2008 8-Hour Ozone National Ambient Air Quality Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve several State Implementation Plan (SIP) revisions submitted by the State of New Jersey for purposes of implementing Reasonably Available Control Technology (RACT) for the 2008 8-hour ozone National Ambient Air Quality Standard (NAAQS). The EPA is proposing to approve New Jersey's SIP revision for the control and prohibition of air pollution by volatile organic compounds (VOCs) and control and prohibition of air pollution by oxides of nitrogen (NO_X), as they are intended to satisfy certain control technique guideline (CTG) and NO_X RACT categories. The EPA is proposing to approve New Jersey's certification that there are no sources within the State for the following CTGs: Manufacture of Vegetable Oils; Manufacture of Pneumatic Rubber Tires; Aerospace

Coatings; Shipbuilding and Ship Repair Operations; Metal Furniture Coatings; Large Appliance Coatings; and Auto and Light Duty Truck Original Equipment Manufacturer Assembly Coatings. In addition, the EPA is proposing to approve New Jersey's RACT SIP as it applies to non-CTG major sources of VOCs and major sources of NO_X. The EPA is also proposing to approve the other portions of the comprehensive SIP revision submitted by New Jersey that certify that the State has satisfied the requirements for an enhanced motor vehicle Inspection and Maintenance program, certify that the State has satisfied the requirements for an emission statement program, certify that the State has satisfied the requirements for an ozone specific provisions nonattainment new source review program, and show the State has adopted all NO_X RACT and VOC RACT, as it pertains to the 2008 8-hour ozone NAAQS. These actions are being taken in accordance with the requirements of the Clean Air Act.

DATES: Written comments must be received on or before August 30, 2018.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R02–OAR–2018–0549 at *http://www.regulations.gov.* Follow the online instructions for submitting comments. 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 *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Omar Hammad, Environmental Protection Agency, 290 Broadway, New York, New York 10007–1866, at (212) 637–3347, or by email at *Hammad.Omar@epa.gov.*

SUPPLEMENTARY INFORMATION: The Supplementary Information section is arranged as follows:

Table of Contents

I. What action is the EPA proposing?

The EPA is proposing to approve a State Implementation Plan (SIP) revision submitted by the State of New Jersey on June 11, 2015, for purposes of implementing Reasonably Available Control Technology (RACT) [1] for the 2008 8-hour ozone National Ambient Air Quality Standard (NAAQS or standard). New Jersey's June 11, 2015 SIP submittal consists of a showing that the State meets the RACT requirements for the two precursors for ground-level ozone, *i.e.,* oxides of nitrogen (NO_X) and volatile organic compounds (VOCs), set forth by the Clean Air Act (CAA or Act) with respect to the 2008 ozone standard.

This action addresses New Jersey SIP submittals dated June 11, 2015, December 14, 2017, and January 2, 2018. In the June 11, 2015 SIP submittal, the State indicates that the RACT requirements for the 2008 ozone NAAQS have been fulfilled with the exception of sources subject to four Control Techniques Guidelines (CTGs) for source categories represented in New Jersey: Industrial Cleaning Solvents (EPA 453/R–06–001); Paper, Film, and Foil Coatings (EPA 453/R–07–003); Miscellaneous Metal and Plastic Parts Coatings (EPA 453/R–08–003); and Fiberglass Boat Manufacturing Materials (EPA–453/R–08–004). The June 11, 2015 submittal also establishes new limits on NO_X emissions from existing simple cycle combustion turbines combusting natural gas and compressing gaseous fuel at major NO_X facilities and stationary reciprocating engines combusting natural gas and compressing gaseous fuel at major NO_X facilities. In a submission received by the EPA on December 14, 2017,[2] titled ''Control and Prohibition of Air Pollution by Volatile Organic Compounds and Oxides of Nitrogen,'' New Jersey indicates that the RACT requirements for the 2008 ozone NAAQS have been fulfilled for sources subject to the four CTGs identified above that were not addressed in the June 11, 2015 submittal. The EPA is proposing to approve New Jersey's June 11, 2015 RACT SIP as it applies to non-CTG major sources of VOCs and to major sources of NO_X. The EPA is proposing to approve New Jersey's December 14, 2017 submittal addressing the aforementioned four CTGs and establishing new limits on NO_X emissions.

Also, the EPA is proposing to approve the portions of New Jersey's SIP revision submitted on January 2, 2018,[3] that certifies the State has satisfied the requirements for a motor vehicle enhanced inspection and maintenance (I/M) program, an emission statement program, an ozone specific provisions nonattainment new source review (NNSR) program, and that the State has adopted all applicable NO_X RACT and VOC RACT, submitted in the ''1997 84 ppb and 2008 75 ppb 8-Hour Ozone Attainment Demonstration Northern New Jersey-New York-Connecticut Nonattainment Area and Nonattainment New Source Review (NNSR) Program Compliance Certification New Jersey Statewide'' SIP revision.

The EPA proposes that New Jersey's SIP submittals are consistent with the EPA's guidance documents as well as the EPA's CTG and Alternative Control Technique (ACT) documents and are fully approvable as SIP-strengthening measures for New Jersey's ozone SIP.

II. What is the background for this proposed rulemaking?

In 2008, the EPA revised the health based NAAQS for ozone, setting it at 0.075 parts per million (ppm), or 75 parts per billion (ppb), averaged over an 8-hour time frame. The EPA determined that the revised 8-hour standard would be more protective of human health, especially with regard to children and adults who are active outdoors and individuals with a pre-existing respiratory disease such as asthma.

On May 21, 2012 (77 FR 30087), the EPA finalized its attainment/nonattainment designations for areas across the country with respect to the 2008 8-hour ozone standard. This action became effective on July 20, 2012. The two 8-hour ozone marginal nonattainment areas located in New Jersey are the New York-Northern New Jersey-Long Island, NY–NJ–CT nonattainment area, also referred to as the New York Metropolitan Area

[1] The EPA has defined RACT as the lowest emission limitation that a particular source is capable of meeting by the application of control technology that is reasonably available considering technological and economic feasibility (44 FR 53762, September 17, 1979).

[2] Submission cover letter dated November 30, 2017.

[3] Submission cover letter dated December 22, 2017.

(NYMA), and the Philadelphia-Wilmington-Atlantic City, PA–NJ–MD–DE nonattainment area. The New Jersey portion of the NYMA is comprised of Bergen, Essex, Hudson, Hunterdon, Middlesex, Monmouth, Morris, Passaic, Somerset, Sussex, Union and Warren Counties. On May 4, 2016 (81 FR 26697), the EPA determined that the NYMA did not attain the 2008 ozone standard by the applicable attainment date and is reclassified from a marginal to a moderate nonattainment area. State attainment plans for moderate nonattainment areas were due by January 1, 2017. Since the NYMA has been reclassified to a moderate nonattainment area, New Jersey submitted a new RACT determination as part of the State's attainment demonstration for the 2008 ozone standard.

In areas classified as moderate or areas located in the Ozone Transport Region (OTR) (which includes all of New Jersey) under the 8-hour ozone standard, the definition for major sources is 50 tons per year for VOC and 100 tons per year for NO_X. New Jersey, however, has an emission threshold of 25 tons per year throughout the state for purposes of the RACT analysis which results in a more stringent evaluation of RACT.

Sections 172(c)(1) and 182(b)(2) of the CAA require states to implement RACT in areas classified as moderate (and higher) nonattainment for ozone, while section 184(b)(1)(B) of the CAA requires RACT in states located in the OTR. Specifically, these areas are required to implement RACT for all major VOC and NO_X emission sources and for all sources covered by a CTG. A CTG is a document issued by the EPA which establishes a ''presumptive norm'' for RACT for a specific VOC source category. A related set of documents, ACT documents, exists primarily for NO_X control requirements. States must submit rules or negative declarations when the State has no such sources for CTG source categories, but not for sources in ACT categories. However, RACT must be imposed on major sources of NO_X, and some of those major sources may be within a sector covered by an ACT document.

On March 6, 2015 (80 FR 12264), the EPA published a final rule, herein referred to as the ''2008 ozone implementation rule,'' that outlined the obligations that areas found to be in nonattainment of the 2008 ozone NAAQS needed to address. The 2008 ozone implementation rule contains, among other things, a description of the EPA's expectations for states with RACT obligations. The 2008 ozone implementation rule indicates that states could meet RACT through the establishment of new or more stringent requirements that meet RACT control levels, through a certification that previously adopted RACT controls in their SIP approved by the EPA under a prior ozone NAAQS represents adequate RACT control levels for attainment of the 2008 ozone NAAQS, or a combination of these two approaches. In addition, a state must submit a negative declaration in instances where there are no CTG sources. The 2008 ozone implementation rule requires that states with nonattainment areas to submit RACT SIPs to EPA within two years from the effective date of nonattainment designation or by July 20, 2014.

The 2008 ozone implementation rule also states, among other things, that an attainment demonstration should consist of a list of adopted measures (including RACT) with schedules for implementation and other means and techniques necessary and appropriate for demonstrating attainment as expeditiously as practicable but no later than the outside attainment date for the area's classification. New Jersey submitted an attainment demonstration SIP and EPA will act on it in a separate rulemaking.

III. What did New Jersey submit?

On June 11, 2015, the New Jersey Department of Environmental Protection (NJDEP) submitted to the EPA a formal revision to its SIP. The SIP revision consists of information documenting how New Jersey complied with the RACT requirements for the 2008 8-hour ozone NAAQS, pertaining to the former marginal classification for the NYMA. In its June 11, 2015 submittal, New Jersey certifies that the State's submittal addresses the RACT requirements for the 2008 8-hour ozone standard except that it does not fulfill the requirements of the CTGs for industrial cleaning solvents, paper film and foil coatings, fiberglass boat manufacturing materials, and miscellaneous metal and plastic parts coatings and the requirements of the ACTs for stationary reciprocating internal combustion engines and stationary gas turbines. In New Jersey's June 2015 RACT submittal, the State commits to revise New Jersey Administrative Code, Title 7, Chapter 27 (N.J.A.C 7:27) Subchapter 16 and Subchapter 19 to address those requirements in a timely manner.

On December 14, 2017, the EPA received New Jersey's SIP revision, ''New Jersey's Control and Prohibition of Air Pollution by Volatile Organic Compounds and Control and Prohibition of Air Pollution by Oxides of Nitrogen.'' [3] The December 14, 2017 submittal includes the amendment to N.J.A.C. 7:27, Subchapter 16, ''Control and Prohibition of Air Pollution by Volatile Organic Compounds'' and Subchapter 19, ''Control and Prohibition of Air Pollution by Oxides of Nitrogen'' that New Jersey committed to propose and adopt in their June 11, 2015 submittal.

On January 2, 2018, New Jersey submitted, for inclusion in the SIP, the ''1997 84 ppb and 2008 75 ppb 8-Hour Ozone Attainment Demonstration Northern New Jersey-New York-Connecticut Nonattainment Area and Nonattainment New Source Review (NNSR) Program Compliance Certification New Jersey Statewide.'' In the January 2, 2018 submission New Jersey certifies, among other things, that the State has satisfied the requirements for an enhanced motor vehicle I/M program, an emission statement program, an ozone specific provisions NNSR program, and that the State has adopted all applicable NO_X RACT and VOC RACT for the moderate NYMA.[4]

In New Jersey's June 11, 2015 RACT submittal, the State evaluated its existing RACT regulations which were adopted to meet the 1997 8-hour ozone standard to ascertain whether the same regulations constitute RACT for the 2008 8-hour ozone standard. In making its new 8-hour ozone RACT determination, New Jersey referenced EPA's RACT guidance (''Beyond Volatile Organic Compound-Reasonably Available Control Technology-Control Technology Guidelines Requirements, EPA–453/R–95–010, April 1995) and EPA's proposed rule ''Implementation of the 2008 National Ambient Air Quality Standards for Ozone: State Implementation Plan Requirements.'' 78 FR 34178 (June 2013).[5] Accordingly, the basic framework for New Jersey's June 11, 2015 RACT SIP determination is described as follows:

- Identify all source categories covered by Control Technique Guidelines (CTG) and Alternative Control Technique (ACT) documents.
- Identify applicable regulations that implement RACT.
- Certify that the existing level of controls for the 1997 8-hour ozone standard equals RACT under the 2008 8-hour ozone standard in certain cases.

[3] Effective date November 6, 2017 (49 N.J.R. 3518).

[4] The EPA will act on the remainder of New Jersey's January 2, 2018 SIP revision submittal, including the attainment demonstrations, Reasonable Further Progress (RFP) requirements and other portions at a later date.

[5] The EPA finalized the proposed rule. 80 FR 12264 (March 6, 2015).

• Declare that sources covered by a CTG and ACT do not exist within the state and/or that RACT is not applicable in certain cases.

• Identify and evaluate applicability of RACT to individual sources whose source category does not have a presumptive emission limit covered by a state-wide regulation.

• Identify potential RACT revisions.

In New Jersey's June 11, 2015 submittal, the State certified that all statewide RACT regulations, with the exception of four CTGs and two ACTs, with SIP approved state effective dates prior to the date when the RACT analysis was performed in 2015, are RACT for the 2008 8-hour ozone NAAQS, because the RACT determinations issued by the State are consistent with the most recent control technology and economic considerations. The State's December 14, 2017 submittal addressed the requirements for the four CTGs; the CTG for ''industrial cleaning solvents,'' ''paper film and foil coatings,'' ''fiberglass boat manufacturing materials,'' and ''miscellaneous metal and plastic parts coatings'' and the two ACTs for ''stationary reciprocating internal combustion engines'' and ''stationary gas turbines.'' The following discusses the results of New Jersey's analysis of RACT under the basic framework identified above.

CTGs and ACTs

New Jersey reviewed its existing RACT regulations adopted under the 1979 1-hour and 1997 8- hour ozone standard to identify source categories covered by the EPA's CTG and ACT documents. New Jersey's 2015 RACT SIP submittal lists the CTG and ACT documents and corresponding State RACT regulations that cover the CTG and ACT sources included in New Jersey's emissions inventory.

In 2009, New Jersey adopted VOC and NO_X RACT for major non-CTG sources located in the State. Those sources for which EPA guidance was not published, but for which the State established RACT, include:

1. High Electric Demand Day boilers serving EGUs [N.J.A.C. 7:27–19.4];

2. High Electric Demand Day turbines serving EGUs [N.J.A.C. 7:27–19.5];

3. Asphalt paving production plants [N.J.A.C. 7:27–19.9];

4. Alternative VOC control requirements [N.J.A.C. 7:27–16.17];

5. Alternative and facility-specific NO_X emission limits [N.J.A.C. 7:27–19.13];

6. Municipal solid waste (MSW) incinerators [N.J.A.C. 7:27–19.12]; and

7. Sewage sludge incinerators [N.J.A.C. 7:27–19.28].

New Jersey has determined that currently effective emission limits for these source categories still represent RACT in 2015 for the marginal classification in the NYMA for the 75 ppb ozone standard.

With the exception of the source categories for which New Jersey has made negative declarations, New Jersey has implemented RACT controls state-wide for all CTGs that the EPA has issued as of June 2015 to meet the requirements of the CAA. The following table lists the RACT controls that have been promulgated in N.J.A.C. 7:27 and the corresponding EPA SIP approval dates.

N.J.A.C. 7:27 subchapter	Title	EPA latest approval date
16.2	VOC stationary storage tanks	8/3/10, 75 FR 45483
16.3	Gasoline transfer operations	8/3/10, 75 FR 45483
16.6	Open top tanks and solvent cleaning operations	8/3/10, 75 FR 45483
16.7	Surface coating and graphic arts operations	8/3/10, 75 FR 45483
16.12	Surface coating operations at mobile equipment repair and refinishing facilities	8/3/10, 75 FR 45483
16.16	Other source operations	8/3/10, 75 FR 45483
16.18	Leak detection and repair	8/3/10, 75 FR 45483
16.19	Application of cutback and emulsified asphalts	8/3/10, 75 FR 45483
16.20	Petroleum solvent dry cleaning operations	8/3/10, 75 FR 45483
19.4	Boilers serving electric generating units	8/3/10, 75 FR 45483
19.5	Stationary combustion turbines	8/3/10, 75 FR 45483
19.7	Industrial/commercial/institutional boilers and other indirect heat exchangers	8/3/10, 75 FR 45483
19.8	Stationary reciprocating engines	8/3/10, 75 FR 45483
19.10	Glass manufacturing furnaces	8/3/10, 75 FR 45483
23	Prevention of Air Pollution from Architectural Coatings Standards	12/22/10, 75 FR 80340
24	Consumer products	12/22/10, 75 FR 80340
26	Prevention of Air Pollution from Adhesives, Sealants, Adhesive Primers and Sealant Primers.	12/22/10, 75 FR 80340

New Jersey's June 11, 2015 RACT submittal contains a table (see Table II–2: RACT Certifications Based on Existing EPA Guidance) listing all the CTG and ACT categories (67 categories in total) and the corresponding State regulations or negative declarations that address the requirements. The EPA previously approved and incorporated into the SIP all of the State's regulations identified in Table II–2 that address CTGs and ACTs. New Jersey's December 14, 2017 submittal fulfilled the requirement to submit for the four CTGs and two ACTs which are identified in Table II–2 as rules that had not yet been adopted.

For many source categories, the existing New Jersey rules have more stringent emission limits and/or lower thresholds of applicability than the recommendations contained in the CTG and ACT documents. New Jersey considers and certifies that its SIP approved regulations meet the RACT requirements for the 2008 8-hour ozone standard.

Source Categories Not Applicable in New Jersey

In New Jersey's 2015 submittal, by comparing the list of existing CTGs with New Jersey's effective rules, and researching the New Jersey Environmental Management System (NJEMS) emission statements and permitting database for source categories by Standard Industrial Code (SIC), the State certifies that the following source-specific categories either do not exist in this State, or fall below significant emission unit applicability thresholds in the CTGs: (1) Manufacture of Vegetable Oils; [6] (2)

[6] The CTG for the manufacturing of vegetable oils was published in June 1978 (see EPA–450/2–78–035) but in a March 1980 guidance document,

Continued

Manufacture of Pneumatic Rubber Tires; (3) Aerospace Coatings; (4) Shipbuilding and Ship Repair Operations; (5) Metal Furniture Coatings; (6) Large Appliance Coatings; and (7) Auto and Light Duty Truck Original Equipment Manufacturer (OEM) Assembly Coatings.

Source-Specific RACT Determinations

A source-specific RACT determination applies to sources that have obtained a facility-specific emission limit or an alternative emission limit, *i.e.,* a variance. A case-by-case RACT analysis is required for sources that are not defined by a specific source category covered by an existing state regulation, that are requesting a variance, or that are not addressed by a CTG. New Jersey's RACT regulations at N.J.A.C. 7:27 Subchapter 19.13 for NO_X and at Subchapter 16.17 for VOCs outline the process and conditions for granting a source-specific RACT determination. Under the CAA, these individual source-specific RACT determinations need to be submitted by the State as a SIP revision for the EPA's approval. Therefore, New Jersey included Table II–3 in its June 2015 RACT SIP submittal, a listing of VOC and NO_X source facilities that are subject to a RACT source-specific SIP revision under the 8-hour ozone SIP and the corresponding emission limits, control technology and applicable regulation governing the RACT determinations. Consistent with the CAA, New Jersey submitted to the EPA SIP revisions that included the source-specific RACT revisions identified in Table II–3 of the 2015 RACT SIP submittal. The EPA has approved some of those revisions and is performing its technical review of the remainder of the submittals and will take separate rulemaking actions for each of the source-specific determinations (see 40 CFR 52.1570 (d) ''*EPA approved State source-specific requirements*'').

New Jersey's Control and Prohibition of Air Pollution by Volatile Organic Compounds

New Jersey's December 14, 2017 submittal, which included amendments to N.J.A.C. 7:27, Subchapter 16, addresses sources subject to four CTGs for source categories represented in New Jersey: Industrial Cleaning Solvents (ICS), CTG issued September 2006 (EPA 453/R–06–001); Paper, Film, and Foil Coatings (PFFC), CTG issued September 2007 (EPA 453/R–07–003); Miscellaneous Metal and Plastic Parts Coatings (MMPPC), CTG issued September 2008 (EPA 453/R–08–003); and Fiberglass Boat Manufacturing Materials (FBMM), CTG issued September 2008 (EPA–453/R–08–004). The VOC emission limits adopted by New Jersey and set forth in Subchapter 16 are as effective in regulating the source categories as the EPA's CTG documents.

Industrial Cleaning Solvents (ICS)

The EPA issued a CTG for industrial cleaning solvents in 2006 that includes recommended control techniques. This category includes the industrial cleaning solvents used by many industries. It includes a variety of products that are used to remove contaminants such as adhesives, inks, paint, dirt, soil, oil and grease. The recommended measures for controlling VOC emissions from the use, storage and disposal of industrial cleaning solvents include work practice standards, limitations on VOC content of the cleaning materials, and an optional alternative limit on composite vapor pressure of the cleaning materials. They also include the use of add-on controls with an overall emission reduction of at least 85 percent by mass.

Based on the EPA CTG, New Jersey adopted new rules N.J.A.C. 7:27–16.24 which specifies VOC content and vapor pressure limits for solvents used in solvent cleaning activities conducted to remove material through wiping, flushing, or spraying. Facilities can be exempt by annual industrial cleaning solvent usage, based on a purchase limit, and by source operation type. Compliance can be achieved by meeting a maximum VOC content, a maximum VOC composite vapor pressure, or a minimum control efficiency. Applicable facilities must implement best management practices, which include keeping cleaning materials in closed containers when not in use. Recordkeeping must be maintained which demonstrates compliance. The EPA proposes to find that New Jersey's adopted ICS rules are as effective in regulating the source category as the EPA's CTG document.

Paper, Film, and Foil Coatings (PFFC)

The EPA issued a 2007 CTG for paper, film and foil coatings. Previous Federal actions that affected this source category included a 1977 CTG for controlling VOC emissions from surface coating of paper, the 1983 new source performance standards (NSPS) for surface coating of pressure sensitive tape and labels (a subset of this category), and a 2002 National Emissions Standards for Hazardous Air Pollutants (NESHAP) for paper and other web coating. The EPA recommends applying the control recommendations for coatings only to individual paper, film and foil surface coating lines with the potential to emit at least 25 tons per year (tpy) of VOC from coatings, prior to controls. The EPA recommends an overall VOC control efficiency of 90 percent as RACT for each coating line.

New Jersey adopted amendments to N.J.A.C. 7:27–16.7, based on the CTG, which requires paper, film, and foil coating operations to implement best management practices if the actual VOC emissions exceed 15 pounds per day for all coating operations. The EPA proposes to find that New Jersey's adopted PFFC rules are as effective in regulating the source category as the EPA's CTG document.

Miscellaneous Metal and Plastic Parts Coatings (MMPPC)

The EPA issued a 2008 CTG for miscellaneous metal and plastic parts coatings. The CTG recommended three options for controlling VOC emissions: (1) VOC content limits for each coating category based on the use of low-VOC content coatings and specified application methods to achieve good transfer efficiency; (2) equivalent VOC emission rate limits based on the use of a combination of low-VOC coatings, specified application methods, and add-on controls; or (3) an overall VOC control efficiency of 90 percent for facilities that choose to use add-on controls instead of low-VOC Content coatings and specified application methods. In addition, the EPA recommended work practices to further reduce VOC emissions from coatings as well as to minimize emissions from cleaning materials used in miscellaneous metal product and plastic part surface coating processes.

New Jersey adopted new rules at N.J.A.C. 7:27–16.15, based on the EPA CTG, which specify an applicability limit of 2.7 tons of actual VOC emissions during any consecutive 12-month period from all miscellaneous metal and plastic part coating operations, including related cleaning activities. Compliance can be achieved by either meeting the maximum allowable VOC content, achieving a minimum 90 percent overall control efficiency, or meeting a minimum overall control efficiency which is based upon the characteristics of the coating. Exemptions include surface coating

entitled ''Guidance for the Control of Volatile Organic Compounds Emitted by Ten Selected Source Categories,'' the EPA advised that the ''states are not required, at this time, to develop regulations for the vegetable oil manufacturing industry.'' The EPA guidance has not been revised since the March 1980 guidance. At this time, the EPA considers the vegetable oil CTG as only guidance for states when they need to develop attainment plans in nonattainment areas.

operations that exclusively use powder coating and metal parts coatings which must comply with a military specification that has been formulated to meet a higher, less stringent VOC content. Applicable facilities must implement best management practices, which include keeping cleaning materials in closed containers when not in use. Recordkeeping must be maintained which demonstrates compliance. The EPA proposes to find that New Jersey's adopted MMPPC rules are as effective in regulating the source category as the EPA's CTG document.[7]

Fiberglass Boat Manufacturing Materials (FBMM)

The EPA issued a CTG in 2008 that provides control recommendations for reducing VOC emissions from the use of gel coats, resins, and materials used to clean application equipment in fiberglass boat manufacturing operations. The CTG recommends the use of low-VOC content (monomer and non-monomer VOC) resin and gel coats with specified application methods. The CTG recommends the use of covers on mixing containers to further reduce VOC emissions from gel coats and resins. The CTG also recommends the use of low-VOC and low vapor pressure cleaning materials. Because the CTG recommendations are based on the 2001 National Emission Standards for Hazardous Air Pollutants (NESHAP) for boat manufacturing, those facilities that are major sources of HAP are already complying with the 2001 NESHAP and have already adopted these control measures. Because the 2001 NESHAP does not apply to area sources, area source fiberglass boat manufacturing facilities are not currently required to implement the measures provided in the NESHAP and recommended in the CTG. There are boat manufacturing facilities in ozone nonattainment areas that meet the applicability threshold in the CTG and would provide VOC emission reductions when the CTG recommended controls are applied. These control approaches are recommended for all fiberglass boat manufacturing facilities where total actual VOC emissions from all fiberglass boat manufacturing operations are equal to or exceed 15 pounds per day.

New Jersey adopted new rules at N.J.A.C. 7:27–16.14, based on the EPA CTG, which establish an applicability limit of actual VOC emissions, before add-on control, of 15 pounds per day from all fiberglass boat manufacturing operations. Exemptions include production of vessels that must meet military specifications and production of parts of boats that do not involve the manufacture of fiberglass. Compliance can be achieved by meeting a maximum monomer VOC content standard, meeting a maximum monomer VOC mass emission rate, or installation of a VOC control apparatus. Recordkeeping must be maintained which demonstrates compliance. The EPA proposes to find that New Jersey's adopted FBMM rules are as effective in regulating the source category as the EPA's CTG document.

New Jersey's Control and Prohibition of Air Pollution by Oxides of Nitrogen (Subchapter 19)

New Jersey's December 14, 2017 submittal, which included amendments to N.J.C.A. 7:27, Subchapter 19, establishes more stringent limits on NO_X emissions from existing simple cycle combustion turbines combusting natural gas and compressing gaseous fuel at major NO_X facilities and stationary reciprocating engines combusting natural gas and compressing gaseous fuel at major NO_X facilities. The EPA proposes to find that the NOx emission limits adopted by New Jersey and set forth in their December 14, 2017 submittal are as effective in regulating the source categories as the EPA's recommendations and guidance.

Stationary Natural Gas Compressor Turbines and Reciprocating Engines

In New Jersey's December 14, 2017 submittal, New Jersey adopted amendments to its rules for stationary gas turbines and engines. New Jersey amended N.J.A.C. 7:27–19.5 by adopting new standards for NO_X emissions from existing simple cycle combustion turbines combusting natural gas and compressing gaseous fuel at major NO_X facilities (compressor turbines). The standard provides, at 7:27–19.5(l) that, beginning November 6, 2019, any simple cycle combustion turbine combustion natural gas and compressing gaseous fuel at a major NO_X facility shall not emit more than 42 ppm by volume, dry basis (ppmvd), of NO_X corrected to 15 percent oxygen. NJDEP amended N.J.A.C. 7:27–19.8 by adopting new standards for NO_X emissions from stationary reciprocating engines combusting natural gas and compressing gaseous fuel at major NO_X facilities (compressor engines). The standard provides, at 7:27–19.8 (g), that beginning November 6, 2019, the owner or operator of a two-stroke lean burn engine capable of producing an output of 200 brake horsepower (bhp) or more but less than 500 bhp, combusting natural gas, and compressing gaseous fuel at a major NO_X facility shall cause it to emit no more than 3.0 grams NO_X/brake horsepower-hour (bhp-hr). The standard also provides, at 7:27–19.8 (h), that beginning November 6, 2019, the owner or operator of a four-stroke lean burn engine or four-stroke rich burn engine capable of producing an output of 200 bhp or more but less than 500 bhp, combusting natural gas, and compressing gaseous fuel at a major NO_X facility shall cause it to emit no more than 2.0 grams NO_X/bhp-hr.

The EPA proposes to find that the adopted rules are consistent with EPA guidance and address NO_X RACT requirements by establishing new limits on NO_X emissions from existing simple cycle combustion turbines combusting natural gas and compressing gaseous fuel at major NO_X facilities and stationary reciprocating engines combusting natural gas and compressing gaseous fuel at major NO_X facilities.

Nitrogen Oxide (NO_X) Reasonably Available Control Technology (RACT) and Volatile Organic Compounds (VOC) RACT Certification

In New Jersey's January 2, 2018 submittal, the State certified that they have addressed RACT requirements for the 2008 75 ppb 8-hour ozone NAAQS supported by their June 11, 2015 and December 14, 2017 submittals. EPA proposes to find that New Jersey has demonstrated that it has met the NO_X RACT and VOC RACT requirements. In some instances, New Jersey has gone beyond RACT by adopting control measures more stringent than the Federal rules and CTGs.

New Jersey's VOC RACT rules cover source categories such as VOC stationary storage tanks, gasoline transfer operations, VOC transfer operations other than gasoline, marine tank vessel loading and ballasting operations, open tanks and solvent cleaning operations, surface coating and graphic arts operations, boilers, stationary combustion turbines, stationary reciprocating engines, asphalt pavement production plants, surface coating operations at mobile equipment repair and finishing facilities, flares, other source operations, leak detection and repair, application of cutback and emulsified asphalts, petroleum solvent

[7] New Jersey's rule includes a partial exemption for military specification coatings from the new VOC limits for metal parts and products, at N.J.A.C. 7:27–16.15(c)(1). N.J.A.C. 7:27–16.15(c)(3)(vii) exempts any military specification coating that has been formulated to meet a higher, less stringent VOC content limit. Additional exceptions include less stringent VOC content limits for extreme high gloss topcoat (craft) and other substrate antifoulant coating than those recommended in the MMPPC CTG. This departure from the MMPPC CTG recommendation is based on EPA guidance memo ''Control Technique Guidelines for Miscellaneous Metal and Plastic Part Coatings—Industry Request for Reconsideration''.

dry cleaning operations, natural gas pipelines, and their NO_X RACT cover source categories such as boilers serving electric generating units, stationary combustion turbines, industrial/commercial/institutional boilers and other indirect heat exchangers, stationary reciprocating engines, asphalt pavement production plants, glass manufacturing furnaces, emergency generators, municipal solid waste (MSW) incinerators and sewage sludge incinerators. These RACT controls that have been promulgated in N.J.A.C. 7:27, have been approved by the EPA as part of New Jersey's SIP most recently on August 3, 2010 [8] and December 22, 2010.[9]

Enhanced Motor Vehicle Inspection and Maintenance (I/M) Program Certification

In New Jersey's January 2, 2018 submission, the State certifies that its state-wide rules at N.J.A.C. 7:27–14 and 15, N.J.A.C. 7:27B–4 and B–5 and the Motor Vehicle Commission (MVC) rules at N.J.A.C. 13:20–43, satisfy Federal requirements for an enhanced motor vehicle I/M Program for the 2008 75 ppb 8-hour ozone NAAQS.

Four categories of vehicles are subject to the enhanced I/M program: light-duty gasoline-fueled vehicles, heavy-duty gasoline-fueled vehicles, light-duty diesel-powered vehicles and heavy-duty diesel-powered vehicles. Within each category are commercial and non-commercial vehicles.

EPA approved New Jersey's enhanced I/M program as meeting applicable requirements of the CAA. 67 FR 2811. On April 3, 2009 and September 9, 2016, New Jersey adopted amendments to its enhanced I/M Program. The EPA approved these amendments into the SIP. 83 FR 21174 (May 9, 2018).

Emission Statement Program Certification

In New Jersey's January 2018 submittal, the State certifies that its state-wide rules at N.J.A.C. 7:27–21 satisfy Federal requirements for an emission statement program for the 2008 75 ppb 8-hour ozone NAAQS. The EPA most recently approved a revision to Subchapter 21 into the SIP on August 3, 2010.[10]

The EPA stated in the 2008 ozone implementation rule that if an area has a previously approved emission statement rule in force for the 1997 ozone NAAQS or the 1-hour ozone NAAQS that covers all portions of the nonattainment area for the 2008 ozone NAAQS, such rule should be sufficient for purposes of the emissions statement requirement for the 2008 ozone NAAQS.

N.J.A.C. 7:27–21 requires the submission of annual emission statements from major facilities. From these statements, the Department develops reports of emissions of all criteria pollutants and submits them to the EPA pursuant to the Federal Air Emission Reporting Requirements (AERR) Rule for uploading to the EPA's National Emission Inventory (NEI).

Federal Nonattainment New Source Review (NNSR) Program Certification

In New Jersey's January 2018 submission, the State certifies that its existing state-wide NNSR rules codified at N.J.A.C. 7:27–18, which regulate the New Jersey portions of the Northern NJ–NY–CT and Southern NJ–PA–DE–MD Nonattainment Areas for the 2008 75 ppb 8-hour ozone NAAQS are at least as stringent as the Federal requirements at 40 CFR 51.165 for ozone and its precursors. See 80 FR 12264 (March 6, 2015). The EPA most recently approved a revision to Subchapter 18 into the SIP on July 25, 1996.[11] New Jersey's demonstration that its NNSR rules comply with the ozone specific Federal provisions is provided in Table 8–2 of its submission.

IV. What is the EPA's evaluation of New Jersey's SIP submittals?

New Jersey submitted a state-wide RACT assessment on June 11, 2015. The RACT submission from New Jersey consists of: (1) A certification that previously adopted RACT controls in New Jersey's SIP for various source categories that were approved by the EPA under the 1-hour and the 1997 8-hour ozone standards are based on the currently available technically and economically feasible controls and that they continue to represent RACT for the 2008 8-hour ozone standard for implementation purposes; (2) New Jersey's 14 existing case-by-case source specific limits, approved by the EPA for the 1997 8-hour ozone standard, which New Jersey indicates continue to meet RACT for the 2008 8-hour ozone standard; (3) a negative declaration that for certain CTGs and/or ACTs there are no sources within New Jersey or that there are no sources within New Jersey above the applicability threshold; and (4) a commitment to revise and adopt, and submit as a SIP revision, a new or more stringent regulation(s), incorporating four CTGs, if determined to be more effective than current New Jersey requirements, and to consider further limiting NO_X emissions from natural gas compressor engines and turbines. New Jersey's December 14, 2017 submittal addresses the commitment for the four CTGs and two ACTs. New Jersey's January 8, 2018 SIP revision submittal certified, among other things, that the State's NO_X RACT, VOC RACT, enhanced I/M program, emission statement program and ozone specific provisions NNSR program satisfy Federal regulations and are at least as stringent as the Federal requirements.

The EPA has reviewed New Jersey's RACT analysis including the state-wide RACT analysis submitted on June 11, 2015, the December 14, 2017 revisions and the January 2, 2018 certification that the State has adopted all applicable NO_X RACT and VOC RACT. EPA proposes to find that these submissions fully address the OTR RACT requirements, the moderate RACT requirements for the NYMA and address the RACT requirements consistent with sections 172(c)(1), 182(b)(2) and 182(f) of the CAA, as interpreted by the EPA's regulations, guidance and policies. Also, the EPA has reviewed portions of New Jersey's January 2, 2018 SIP submittal that certify the State has satisfied the requirements for an enhanced motor vehicle I/M program, an emission statement program and an ozone specific provisions NNSR program, and the EPA is proposing to approve the State's certifications.

V. What action is the EPA proposing?

The EPA has evaluated the information provided by New Jersey and is proposing to approve New Jersey's state-wide RACT submittal dated June 11, 2015 and the State's December 14, 2017 SIP revision rule, which include a declaration that the following source-specific categories either do not exist in this State, or fall below significant emission unit applicability thresholds in the CTGs: (1) Manufacture of Vegetable Oils; (2) Manufacture of Pneumatic Rubber Tires; (3) Aerospace Coatings; (4) Shipbuilding and Ship Repair Operations; (5) Metal Furniture Coatings; (6) Large Appliance Coatings; and (7) Auto and Light Duty Truck Original Equipment Manufacturer (OEM) Assembly Coatings. The submittals also include amendments to N.J.A.C. 7:27, Subchapter 16, ''Control and Prohibition of Air Pollution by Volatile Organic Compounds,'' Subchapter 19, ''Control and Prohibition of Air Pollution by Oxides of

[8] 75 FR 45483.

[9] 75 FR 80340.

[10] 75 FR 45483.

[11] 61 FR 38591.

Nitrogen,'' [12] for purposes of satisfying the 2008 8-hour ozone standard RACT requirements, NO_X RACT for major sources, Non-CTG VOC RACT for major sources, all VOC CTG RACT sources and relevant OTR RACT requirements. The EPA is also proposing to approve portions of New Jersey's January 2, 2018 SIP revision that certifies the State has satisfied the requirements for an enhanced motor vehicle I/M program, an emission statement program, an ozone specific provisions NNSR program. As indicated in footnote 5, above, the EPA will address the remainder of the January 2, 2018 SIP submittal in a separate rulemaking.

The EPA is soliciting public comments on the issues discussed in this proposal. These comments will be considered before the EPA takes final action. Interested parties may participate in the Federal rulemaking procedure by submitting written comments as discussed in the **ADDRESSES** section of this rulemaking.

VI. Incorporation by Reference

In this rule, the EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference of revisions to Title 7, Chapter 27: Subchapters 16 and 19 of the New Jersey Administrative Code that implements New Jersey's RACT regulations for VOCs and NO_X, as described in section III of this preamble.

The EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and at the EPA Region 2 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

VII. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 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, this action merely proposes to approve state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 382, January 21, 2011);
- is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempt 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 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
- 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).

In addition, this proposed rulemaking action, pertaining to New Jersey's 2008 8-hour ozone RACT submission the 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 in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Nitrogen Dioxide, Intergovernmental Relations, Ozone, Reporting and recordkeeping requirements, Volatile Organic Compounds.

[12] State Effective dates for both rules is November 6, 2017 (49 N.J.R. 3518).

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

Dated: July 23, 2018.

Peter D. Lopez,

Regional Administrator, Region 2.

[FR Doc. 2018–16378 Filed 7–30–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2018–0550; FRL–9981–60—Region 3]

Approval and Promulgation of Air Quality Implementation Plans; West Virginia; 2018 Amendments to West Virginia's Ambient Air Quality Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a state implementation plan (SIP) revision submitted by the State of West Virginia. This revision updates the effective date by which the state incorporates by reference the national ambient air quality standards (NAAQS) as well as their monitoring reference and equivalent methods. This action is being taken under the Clean Air Act (CAA).

DATES: Written comments must be received on or before August 30, 2018.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R03–OAR–2018–0550 at *http://www.regulations.gov,* or via email to *spielberger.susan@epa.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. For either manner of submission, 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. 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, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For 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: Joseph Schulingkamp, (215) 814–2021, or by email at *schulingkamp.joseph@epa.gov.*

SUPPLEMENTARY INFORMATION: On June 8, 2018, the West Virginia Department of Environmental Protection (WVDEP) submitted a formal revision to its SIP pertaining to amendments of Legislative Rule, 45CSR8—Ambient Air Quality Standards. The SIP revision consists of revising the effective date of the incorporation by reference of the NAAQS and the associated monitoring reference and equivalent methods.

I. Summary of SIP Revision

This SIP revision is required by WVDEP in order to update the State's incorporation by reference of the primary and secondary NAAQS and the ambient air monitoring reference and equivalent methods, found in 40 CFR parts 50 and 53, respectively. Currently, 45CSR8 incorporates by reference 40 CFR parts 50 and 53 as effective on June 1, 2016. Since that date, EPA retained the standard for lead and made a technical correction to the particulate standard. *See* 81 FR 71906 and 82 FR 14325, respectively. EPA also designated one new ambient air monitoring reference method for measuring concentrations of sulfur dioxide, four new ambient air monitoring equivalent methods for measuring concentrations of fine and coarse particulate matter ($PM_{2.5}$ and $PM_{10,}$ respectively), and two new equivalent methods for measuring concentrations of nitrogen dioxide (NO_2) in ambient air.

The amendments to the legislative rule include the following changes: To section 45–8–1 (General), the filing, effective, and incorporation by reference dates are changed to reflect the update of the legislative rule; to section 45–8–3 (Adoption of Standards), the effective dates for the incorporation by reference of the primary and secondary NAAQS and the ambient air monitoring reference and equivalent methods are changed. The filing and effective dates of the legislative rule were updated to March 22, 2018 and June 1, 2018 respectively. The effective date of the incorporation by reference of 40 CFR parts 50 and 53 changed from June 1, 2016 to June 1, 2017.

II. Proposed Action

EPA is proposing to approve the West Virginia SIP revision updating the date of incorporation by reference, which was submitted on June 8, 2018. EPA is soliciting public comments on the issues discussed in this document. These comments will be considered before taking final action.

III. Incorporation by Reference

In this proposed rule, EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is proposing to incorporate by reference 45CSR8, as effective on June 1, 2018. EPA has made, and will continue to make, these materials generally available through *http://www.regulations.gov* and at the EPA Region III Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable federal regulations. 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, 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 proposed 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 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
- 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).

In addition, this proposed rule, updating the effective date of West Virginia's 45CSR8, does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Lead, Nitrogen dioxide, Ozone, Particulate matter, Sulfur oxides.

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

Dated: July 23, 2018.

Cosmo Servidio,

Regional Administrator, Region III.

[FR Doc. 2018–16375 Filed 7–30–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R10–OAR–2018–0238, FRL–9981–61—Region 10]

Air Plan Approval; Oregon: Lane County Permitting and General Rule Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) proposes to approve, and incorporate by reference, specific changes to the Oregon State Implementation Plan as it applies in Lane County, Oregon. The local air

agency in Lane County, Lane Regional Air Protection Agency, has revised its rules to align with recent changes to Oregon state regulations. The revisions, submitted on August 29, 2014 and March 27, 2018, are related to the criteria pollutants for which the EPA has established national ambient air quality standards—carbon monoxide, lead, nitrogen dioxide, ozone, particulate matter, and sulfur dioxide. The regulatory changes address federal particulate matter requirements, update the major and minor source pre-construction permitting programs, add state-level air quality designations, update public processes, and tighten emission standards for dust and smoke.

DATES: Comments must be received on or before August 30, 2018.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R10–OAR–2018–0238, at *https://www.regulations.gov.* Follow the online instructions for submitting comments. 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 the disclosure of which 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.*

FOR FURTHER INFORMATION CONTACT: Kristin Hall at (206) 553–6357, or *hall.kristin@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, wherever ''we,'' ''us,'' or ''our'' is used, it is intended to refer to the EPA.

Table of Contents

I. Background

Each state has a Clean Air Act (CAA) State Implementation Plan (SIP), containing the control measures and strategies used to attain and maintain the national ambient air quality standards (NAAQS) established for the criteria pollutants (carbon monoxide, lead, nitrogen dioxide, ozone, particulate matter, sulfur dioxide). The SIP contains such elements as air pollution control regulations, emission inventories, attainment demonstrations, and enforcement mechanisms. The SIP is a living compilation of these elements and is revised and updated by a state over time—to keep pace with federal requirements and to address changing air quality issues in that state.

The Oregon Department of Environmental Quality (ODEQ) implements and enforces the Oregon SIP through rules set out in Chapter 340 of the Oregon Administrative Rules (OAR). Chapter 340 rules apply in all areas of the state, except where the Oregon Environmental Quality Commission (EQC) has designated a local agency as having primary jurisdiction.

Lane Regional Air Protection Agency (LRAPA) has been designated by the EQC to implement and enforce state rules in Lane County, and also to adopt local rules that apply within Lane County. LRAPA may promulgate a local rule in lieu of a state rule provided: (1) It is as strict as the corresponding state rule; and (2) it has been submitted to and not disapproved by the EQC.[1] This delegation of authority in the Oregon SIP is consistent with CAA section 110(a)(2)(E) requirements for state and local air agencies.

On August 29, 2014 and March 27, 2018, LRAPA and ODEQ submitted specific revisions to the Oregon SIP as it applies in Lane County. These changes align local rules with recently revised state rules, approved by the EPA on October 11, 2017 and incorporated by reference into the Code of Federal Regulations (CFR) at 40 CFR part 52, subpart MM (82 FR 47122). The changes address federal particulate matter requirements, revise the major and minor source pre-construction permitting programs, add state-level air quality designations, update public processes, and tighten emission standards for dust and smoke.

We note that the March 27, 2018, revisions partially supersede the August 29, 2014, revisions. In this action, we are reviewing and taking action on the most recent version of the submitted rules applicable in Lane County, as described below. In describing our evaluation, we have focused on the substantive rule changes. We have not described typographical corrections, minor edits, and renumbering changes.

II. Evaluation of Revisions

A. Title 12: General Provisions and Definitions

Title 12 in LRAPA's rules contains generally-applicable provisions and definitions used throughout Lane County air quality rules. The submitted revisions align the definitions in Section 12–005 with the definitions in state rules, recently reviewed and approved by the EPA.[2] In this section of our evaluation, we discuss key changes to existing definitions and substantive new terms used in multiple titles. Terms used primarily in a single title are described in the discussion section for that particular title.

Key definition changes include narrowing the definition of ''adjacent'' by limiting the use of this defined term (''interdependent facilities that are nearby to each other'') to the ''major source'' and ''source'' terms in LRAPA's program for air contaminant discharge permits. Definitions of the terms ''capture efficiency,'' ''control efficiency,'' ''destruction efficiency,''

[1] *See* OAR 340–200–0010(3), state effective April 16, 2015, codified at 40 CFR 52.1970.

[2] *See* OAR 340–200–0020, state effective April 16, 2015, and approved by the EPA on October 11, 2017 (82 FR 47122).

and ''removal efficiency'' were added to differentiate amongst similar terms.

LRAPA revised the term ''categorically insignificant activities'' to narrow when emissions may be excluded from consideration—in some aspects of source permitting—as ''insignificant.'' For example, there is a cap on the aggregate emissions from fuel burning equipment that may be considered categorically insignificant, and there is also a restriction on when emergency generators may be considered categorically insignificant (limiting the exemption to no more than 3,000 horsepower, in the aggregate). We note that LRAPA adopted a *new* category of insignificant emissions, as Oregon did, namely, fuel burning equipment brought on site for six months or less for construction, maintenance, or similar purposes, provided the equipment performs the same function as the permanent equipment, and is operated within the source's existing plant site emission limit. Importantly, however, insignificant activity emissions must be included in determining whether a source is a ''federal major source'' or a ''major modification'' subject to federal major new source review (federal major NSR).[3] In addition, categorically insignificant activities must still comply with all applicable requirements.

LRAPA revised definitions to consistently use certain terms, such as ''construction,'' ''control device,'' ''federal major source,'' ''immediately,'' ''fugitive emissions,'' ''major modification,'' ''major source,'' ''PM_{10},'' ''$PM_{2.5}$,'' and ''stationary source.'' LRAPA added definitions to align with state rules, including ''continuous compliance determination method,'' ''emergency,'' ''emission limitation,'' ''excursion,'' ''greenhouse gases,'' ''Indian governing body,'' ''Indian reservation,'' ''potential to emit,'' and ''synthetic minor source.'' The term ''internal combustion engine'' was defined to clarify the universe of regulated fuel burning equipment under local rules.

In the definition of ''opacity,'' LRAPA spelled out that visual opacity determinations are to be made using EPA Method 203B. Method 203B is designed for time-exception regulations, such as those that establish a limit on the average percent opacity for a period or periods aggregating more than three minutes in any one hour. There are a small number of LRAPA visible emissions standards that are not time-exception regulations, and in those cases, LRAPA rules specify a different test method, including, for example, EPA Method 9. All specified methods are included in the March 2015 version of the Oregon Source Sampling Manual, approved by the EPA on October 11, 2017, for purposes of the limits in the Oregon SIP (82 FR 47122). Please see our discussion of opacity standards and methods for visual opacity determinations in Section H. below.

Consistent with the state definition, LRAPA defined the term ''portable'' as ''designed and capable of being carried or moved from one location to another.'' At the same time, the definition of ''stationary source'' was updated to include portable sources required to have permits under the air contaminant discharge permitting program at Title 37.

LRAPA changed the definition of ''modification'' to differentiate it from the terms ''major modification'', ''permit modification'', and ''title I modification'', and to make clear that it applies to a change in a portion of a source, as well as a source in its entirety. LRAPA also simplified the definition of ''ozone precursor'' to remove redundant language pointing to the reference method for measuring volatile organic compounds (VOCs). The term ''VOC'' was also updated to reflect changes to the federal definition of ''VOC'' at 40 CFR 51.100(s).

LRAPA formally defined ''wood fuel-fired device'', consistent with the definition in state rules. The term was added and defined as ''a device or appliance designed for wood fuel combustion, including cordwood stoves, woodstoves, and fireplace stove inserts, fireplaces, wood fuel-fired cook stoves, pellet stoves and combination fuel furnaces and boilers that burn wood fuels.'' The remainder of the new definitions established by LRAPA in Title 12 are common dictionary terms and are not discussed in this summary.

We have evaluated these Title 12 definition changes, and the changes to definitions discussed in the sections below, and we propose to find that LRAPA's defined terms are consistent with CAA requirements and the EPA's implementing regulations. We therefore propose to approve the submitted definitions into the Oregon SIP for Lane County.

Other Provisions

The revisions also include general rules in Title 12 submitted to be consistent with state rules in Division 200. LRAPA revised Section 12–001 *General* to align with OAR 340–200–0010 *Purpose and Application,* including repealing the SIP-approved version of Section 12–001(2), state effective March 8, 1994, and renumbering the section paragraphs. Section 12–001(2) stated that ''in cases of apparent conflict between rules and regulations within these titles, the most stringent regulation applies unless otherwise expressly stated,'' and is appropriately removed from the SIP.

Section 12–010 was added to spell out abbreviations and acronyms used throughout the Lane County air quality rules, consistent with OAR 340–200–0025. LRAPA also added Section 12–020 listing activities that are not subject to local air quality regulations, comparable to OAR 340–200–0030 and Oregon Revised Statutes (ORS) 468A–020. Section 12–020(2) makes clear, however, that the exceptions in subsection (1) do not apply to the extent such local air regulations are necessary to implement CAA requirements. We note that LRAPA added Section 12–025 identifying key reference materials, including the March 2015 version of the Oregon Source Sampling Manual, approved by the EPA into the Oregon SIP on October 11, 2017 (82 FR 47122). We propose to approve and incorporate by reference these changes to Title 12.

Consistent with our recent action on OAR 340–200–0050, LRAPA did not submit Section 12–030 *Compliance Schedules* for approval into the SIP. Any compliance schedule established by LRAPA under this provision must be specifically submitted to, and approved by the EPA, before it will be federally-enforceable or change the requirements of the EPA-approved SIP.[4]

B. Title 13: General Duties and Powers of Board and Director

Title 13 sets out general authority to adopt, implement and enforce regulations in Lane County, including issuing permits. These general authority provisions were first approved into the Oregon SIP in 1993 (58 FR 47385, September 9, 1993). We note, that at the time of that original approval, the general authority provisions were located in Title 12, and were later renumbered to Title 13. These provisions contain long-standing requirements for make-up of the LRAPA Board and disclosures of potential conflicts of interest for board members and director, approved as meeting CAA

[3] This includes both the prevention of significant deterioration (PSD) new source review permitting program that applies in attainment and unclassifiable areas (40 CFR 51.166) and the nonattainment major source new source review permitting program that applies in nonattainment areas (40 CFR 51.165).

[4] 40 CFR 51.102(a)(2) and (c) and 260; 82 FR 47122, October 11, 2017.

state board requirements under section 128.[5]

We propose to find that the submitted updates to Title 13 remain consistent with CAA section 110 requirements for permit issuance, enforcement authority, state and local agencies, and state boards. In this action, we are proposing to approve Title 13 to the extent the provisions relate to the implementation of requirements in the SIP, but we note we are not incorporating these provisions by reference into 40 CFR part 52, subpart MM. These types of rules are generally not incorporated by reference into the CFR because they may conflict with the EPA's independent administrative and enforcement procedures under the CAA.

C. Title 14: Rules of Practice and Procedures

The submissions revise Title 14 to align with Oregon's SIP-approved state rules in Division 11. LRAPA's revisions follow the Oregon Attorney General Model Rules, as do the comparable Oregon rules, and address procedures for filing and serving documents in contested cases (appeals of LRAPA and ODEQ actions). Title 14 was revised to improve the clarity and completeness of contested case appeals coming before the LRAPA Board. This title provides authority needed to implement the SIP in Lane County, and is consistent with the CAA requirements for the issuance of permits and enforcement authority. The EPA therefore proposes to approve the submitted revisions to Title 14 *Rules of Practice and Procedures,* to the extent it relates to implementation of requirements contained in the Oregon SIP. We are not incorporating these rules by reference into the CFR, however, because we rely on the EPA's independent administrative and enforcement procedures under the CAA.

D. Title 29: Designation of Air Quality Areas

This division contains rules for the designation of air quality areas in Lane County. In Section 29–0010, LRAPA culled definitions to leave only those directly related to designated areas in Lane County, including Eugene-Springfield and Oakridge. Sections 29–0020, 0050, and 0060 were added to mirror state air quality region and prevention of significant deterioration area rules in OAR 340–204–0020, 0050, and 0060, respectively. Section 29–0030 addresses the two nonattainment areas in Lane County, namely the Oakridge Urban Growth Boundary (coarse particulate matter (PM_{10})) and the Oakridge Nonattainment Area (fine particulate matter ($PM_{2.5}$)). In addition, LRAPA added Sections 29–0070 *Special Control Areas,* 29–0080 *Motor Vehicle Inspection Boundary Designations,* and 29–0090 *Oxygenated Gasoline Control Areas,* to correspond to state rule sections OAR 340–204–0070, 0080, and 0090, respectively.

A significant change in this title is the introduction of three concepts: ''sustainment areas,'' ''reattainment areas,'' and ''priority'' sources.[6] Both sustainment and reattainment areas are state-level designations designed to add to federal requirements. We note that LRAPA and Oregon have both implemented a state-level designation in the past—specifically, the maintenance area designation. Following Oregon's lead, LRAPA is now defining two added state designations intended to help areas address air quality problems by further regulating emission increases from major and minor sources.

To designate an area as sustainment or reattainment, the LRAPA rule revisions create a similar process as was used in the past to designate a maintenance area. The process includes public notice, a rule change, and approval by the LRAPA Board. Oregon and LRAPA designed the new designations and associated requirements with the stated intent to help solve air quality issues while not changing attainment planning requirements or federal requirements for major stationary sources.

The sustainment area designation is designed to apply to an area where monitored values exceed, or have the potential to exceed, ambient air quality standards, but which has not been formally designated nonattainment by the EPA.[7] To construct or modify a major or minor source in a sustainment area, the owner or operator may need to offset new emissions with reductions from other sources, including the option of targeting ''priority'' sources, in that area. Priority sources are defined as sources causing or contributing to elevated emissions levels in the area. This is determined using local airshed information, such as emissions inventories and modeling results. A new major or minor stationary source seeking to construct in a sustainment area may obtain more favorable offsets from priority sources.

The reattainment area designation is designed to apply to an area that is formally designated nonattainment by the EPA, but that has achieved three years of quality-assured/quality-controlled monitoring data showing the area is attaining the relevant standard.[8] When an area has met attainment planning requirements and has attained the standard, the CAA requires that a state submit, and the EPA approve, a maintenance plan demonstrating attainment for the next ten years. The state may then request that the EPA redesignate the area to attainment. In the interim, LRAPA may designate the area a reattainment area. The submitted rules require that all elements of the area's attainment plan continue to apply with a reattainment designation. However, minor sources will be subject to less stringent state new source review permitting requirements—unless the source has been specifically identified as a significant contributor to air quality problems in the area, or the source has control requirements that are relied on as part of the attainment plan. The federal requirements for redesignation remain in place and are unchanged.

In the submissions, LRAPA included the Oakridge area as a state-designated reattainment area with respect to $PM_{2.5}$.[9] We note that at the federal level, the EPA has approved the Oakridge $PM_{2.5}$ attainment plan, determined the Oakridge area attained the 2006 24-hour $PM_{2.5}$ NAAQS by the applicable attainment date, and achieved clean data for the most recent three years of valid, certified monitoring data (83 FR 5537, February 8, 2017). However, the Oakridge area remains a federal nonattainment area for the 2006 24-hour $PM_{2.5}$ NAAQS until LRAPA and Oregon submit a maintenance plan to the EPA to ensure the area can continue to meet the standard for the next 10 years, and the EPA approves the maintenance plan and redesignates the Oakridge area to attainment.[10] We propose to determine that designation of the Oakridge area as a state reattainment area does not change federal requirements for the area, and that the Oakridge $PM_{2.5}$ attainment plan remains in effect.

We propose to approve these revisions to Title 29 because the submitted rules for state-level designations are consistent with CAA requirements and the EPA's implementing regulations for attainment planning and major source pre-construction permitting. The related changes to LRAPA's major and minor source permitting program—and our

[5] LRAPA Section 12–025, renumbered to Section 13–025; 58 FR 47385, September 9, 1993.

[6] *See* Sections 29–0300 through 0320 and the corresponding state provisions at OAR 340–204–0300 through 0320.

[7] As codified at 40 CFR part 81.

[8] *See* Section 29–0310.

[9] *See* Section 29–0310(2)(a).

[10] *See* 40 FR 81.338.

evaluation of those changes—are discussed in detail in Section M. below.

E. Title 30: Incinerator Regulations

The submissions made changes to LRAPA's incinerator regulations consistent with those in state rule at Division 230. Most changes were minor; however, a significant change was made to tighten limits and clarify the appropriate method of compliance for crematory incinerators. Consistent with our previous action on August 3, 2001, we propose to approve the revisions to Title 30, except as those rules relate to hazardous air pollutants and odors that are not also criteria pollutants or precursors (66 FR 40616).

F. Title 31: Public Participation

Title 31 governs public participation in the review of proposed permit actions. This title corresponds to Division 209 in state rules. LRAPA submitted this title for SIP approval, consistent with recent changes to Oregon's public participation rules. Title 31 provides four different levels of public process, depending on the type of permitting action, with Category I having the least amount of public notice and opportunities for public participation, and Category IV having the most. The majority of new source review permitting actions are subject to category III, for which LRAPA provides public notice and an opportunity for a hearing at a reasonable time and place if requested, or if LRAPA otherwise determines a public hearing is necessary. Category IV public process apply to major new source review permitting actions, and LRAPA provides an informational meeting before issuing a draft permit for public review and comment.

LRAPA has aligned the requirements for informational meetings with state rules in Division 209, to provide at least a 14-day public notice, before the scheduled informational meeting. The submitted rules also make clear that although LRAPA accepts, and will consider, comments from the public during the informational meeting, LRAPA does not maintain an official record of the informational meeting, or respond in writing to comments provided at the informational meeting. This same approach to informational meetings in state rules was approved by the EPA into the Oregon SIP on October 11, 2017 (82 FR 47122).

The submissions also addressed public participation requirements for permitting in state-designated sustainment and reattainment areas, detailed the option of email notification, and identified where public comment records are made available for review. Hearing procedures, laid out at Section 31–0070, correlate with hearing provisions at OAR 340–209–0070. We propose to approve the hearing procedures, but not incorporate them by reference, to avoid confusion or potential conflict with the EPA's independent authorities.

In sum, we have concluded that the submitted LRAPA public participation rules are consistent with the CAA and federal requirements for public notice of new source review actions in 40 CFR 51.161 *Public availability of information,* 40 CFR 51.165 *Permit requirements,* and 40 CFR 51.166 *Prevention of significant deterioration of air quality,* and we propose to approve them.

G. Title 32: Emission Standards

This title contains emission standards and provisions of general applicability, including requirements for highest and best practicable treatment and control, operating and maintenance, typically achievable control technology, additional requirements imposed on a permit by permit basis, particulate emission limits for process equipment and other sources (other than fuel or refuse burning equipment or fugitive emissions), and alternative emission limits (bubbles).

LRAPA made changes to Section 32–001 to clarify what definitions apply to this section (those in Titles 12 and 29) in addition to more specific definitions for ''distillate fuel oil'' and ''residual fuel oil.'' In Section 32–007, LRAPA clarified that pressure drop and ammonia slip are operational, maintenance, and work practice requirements that may be established in a permit condition or notice of construction approval. Section 32–008 *Typically Achievable Control Technology* was also updated by moving procedural requirements from the definitions section to this section, and revising them to account for Oregon's changes to NSR, Major NSR and Type A State NSR, discussed below in Section M.

Notably, LRAPA retained its general, SIP-approved visible emission standards in the form of an aggregate exception of three minutes in a 60-minute period. Three-minute aggregate periods are to be measured by EPA Method 203B, a continuous opacity monitoring system, or an alternative monitoring method approved by LRAPA and that has been determined by the EPA to be equivalent to Method 203B. While LRAPA's form and method for evaluating visible emissions from sources are different than those in Oregon's corresponding SIP-approved rules (OAR 340–208–0110 was recently revised to a 6-minute block average as measured by EPA Method 9), both forms and their associated test methods are equally-valid means to measure opacity and determine compliance with standards.[11]

LRAPA also made changes to phase in tighter visible emission limits granted to wood-fired boilers in operation before 1970. These sources are required to meet a 40% visible emission limit. However, starting in 2020, these sources must meet a 20% visible emissions limit, except for certain, limited situations where a boiler-specific, short-term limit may be established in a source's operating permit, if appropriate and allowed under the SIP-approved permitting program.

Notably, LRAPA revised particulate emission limits under Section 32–015 to reduce emissions from certain non-fuel-burning sources built before June 1970. The rules in this section phase in tighter standards for older sources, generally tightening grain loading standards for existing sources from 0.2 grains per dry standard cubic foot (gr/dscf) to between 0.10 and 0.15 gr/dscf, depending on whether there is existing source test data for the source, and what that data shows. Timelines to achieve these rates depend on whether sources were built before or after June 1, 1970. Existing sources that operate equipment less frequently (less than 867 hours a year) must meet less stringent standards. For new sources, LRAPA has increased the stringency of the grain loading standard by adding a significant digit, revising the standard from 0.1 gr/dscf to 0.10 gr/dscf. Compliance with the grain loading standards is determined using test methods specifically identified in the March 2015 version of the Oregon Source Testing Manual, approved on October 11, 2017 (82 FR 47122).

LRAPA also tightened grain loading standards for fuel burning equipment (Sections 32–020 and 025) in the same manner as described above. Process weight provisions in Section 32–045 were aligned with state rules, and the listing of process weight limitations was moved to Section 32–8010. Sulfur content of fuels and sulfur dioxide emission limits in Section 32–065 were also updated by removing a coal space-heating exemption that expired in 1983, and clarifying that recovery furnaces are regulated in Title 33.

We propose to approve the revisions to Title 32 because they are consistent with the CAA and strengthen the SIP.

[11] The EPA approved OAR 340–208–0110, state effective April 16, 2015 on October 11, 2017 (82 FR 47122).

We note we are taking no action on Sections 32–050, and 32–055 because they are nuisance provisions related to concealment and masking of emissions and particle fallout. We are also taking no action on the acid rain provision in Section 32–075. These types of provisions are generally not appropriate for SIP approval because they are not related to attainment and maintenance of the NAAQS under CAA section 110 and the SIP.

H. Title 33: Prohibited Practices and Control of Special Classes of Industry

Title 33 establishes controls on specific sectors, including board products facilities, charcoal plants, Kraft pulp mills, and hot mix asphalt plants. LRAPA clarified that Title 12 definitions apply to this section, except where specific definitions are established in Title 33. Throughout this title, LRAPA removed open burning provisions made obsolete now that LRAPA limits open burning through regulations established in Title 47, most recently approved by the EPA on October 23, 2015 (80 FR 64346).

In Section 33–060, LRAPA made changes to improve the enforceability of opacity limits on veneer dryers and hardboard manufacturing operations. Section 33–070 was updated to ensure local rules for Kraft pulp mills are as stringent as the state equivalent. LRAPA also revised what was formerly referred to as ''replacement or significant upgrading'' of equipment for purposes of determining whether more restrictive standards apply. Alternative temperatures for hardboard tempering ovens must be approved using the procedures in the federal NESHAP for *Plywood and Composite Wood Products,* 40 CFR part 63, subpart DDDD. LRAPA added source test methods for particulate matter and demonstrations of oxygen concentrations in recovery furnace and lime kiln gases. Under the reporting section, LRAPA removed the alternative sampling option where transmissometers are not feasible because all pulp mills in Oregon now have transmissometers. Minor changes were made under a provision in this section authorizing LRAPA to determine that upset conditions at a subject source are chronic and correctable by the installation of new or modified process or control equipment, and the establishment of a program and schedule to effectively eliminate the deficiencies causing the upset conditions. This provision is consistent with the corresponding state provision at OAR 340–234–0270.[12]

LRAPA revised Section 33–075 *Hot Mix Asphalt Plants* to specify the appropriate test method to determine compliance. In addition, LRAPA added a requirement that hot mix asphalt plants must develop a fugitive emissions control plan if requested.

Except for the requirements relating to total reduced sulfur, odor, and reduction of animal matter, we propose to approve the submitted changes to Title 33 because they strengthen the SIP and are consistent with CAA requirements. Total reduced sulfur, odor, and reduction of animal matter requirements are not appropriate for SIP approval because they are not criteria pollutants, not related to the criteria pollutants regulated under title I of the CAA, not essential for meeting and maintaining the NAAQS, nor related to the requirements for SIPs under section 110 of the CAA. We are therefore excluding from the SIP the following parts of Section 33–070: The definitions of ''Other sources'' and ''Total Reduced Sulfur (TRS)'' in paragraph (1), and paragraphs (3)(a), (4)(b), (5)(b), (6)(a), and (6)(b); and Section 33–080 *Reduction of Animal Matter.*

I. Title 34: Stationary Source Notification Requirements

Title 34 contains a registration program for sources not subject to one of LRAPA's operating permit programs, as well as some of the requirements for the construction of new and modified sources. In Section 34–010, LRAPA broadened the applicability of this title, as Oregon did in Division 210, so that it applies to ''air contaminant sources'' and to ''modifications of existing portable sources that are required to have permits under title 37'', in addition to stationary sources. Sections 34–016 and 34–017 were added for recordkeeping and reporting, and enforcement, respectively.[13] LRAPA also added a new section for general source registration requirements and detailed the information an owner or operator must submit to register and re-register. Sections 34–034, 035, and 036 were added to clarify when a *Notice of Construction* application is required, how the construction/modification is categorized for purposes of process and public review, and what to include in a notice to construct.

LRAPA added Sections 34–037 and 038 to spell out when sources may proceed with construction or modification, and that construction approval does not mean approval to operate the source, unless the source is not required to obtain an ACDP under Title 37.

We propose to approve the revisions to Title 34 because we have determined they are consistent with CAA requirements and correct or clarify existing source notification requirements to help ensure that changes to sources go through the appropriate approval process. We note that Section 34–170 through 200 are not appropriate for SIP approval because they are related to title V of the CAA, not title I and the SIP.

J. Title 35: Stationary Source Testing and Monitoring

This title contains general requirements for source testing and monitoring. Title 35 was recently established to correlate closely with state provisions in Division 212. LRAPA clarified the term ''stationary source'' to include portable sources that require permits under Title 37. This change is consistent with the term as used in other titles. LRAPA also clarified, with respect to stack height and dispersion technique requirements, the procedures referenced in 40 CFR 51.164 are the major and minor NSR review procedures used in Oregon, as applicable.

Section 35–0140 sets forth test methods, and requires that sampling, testing, or measurements performed pursuant to this title conform to the methods in Oregon's March 2015 revised versions of the *Source Sampling Manual, Volumes I and II,* and *Continuous Monitoring Manual.* The revised manuals were approved by the EPA into the Oregon SIP on October 11, 2017 (82 FR 47122). In that action we concluded that the revised manuals are consistent with the EPA's monitoring requirements for criteria pollutants and we approved them for the purpose of the limits approved into the SIP.

We note that the submitted provisions in Section 35–0200 through 0280 are related to compliance assurance monitoring, and are not appropriate for SIP approval. The specified rules apply to title V sources only and implement the requirements of 40 CFR parts 64 and 70. We are taking no action on these rules because they are not appropriate for SIP approval under section 110 of title I of the CAA.

K. Title 36: Excess Emissions

LRAPA made several revisions to the excess emissions and emergency provision requirements in Title 36 and

[12] *See* EPA proposed approval of OAR 340–234–0270, state effective April 16, 2015 (March 22, 2017, 82 FR 14654 at page 14667).

[13] *See* OAR 340–214–0114, and OAR 340–214–0120.

submitted them for approval into the SIP. We are deferring action on the Title 36 revisions. We intend to address the submitted provisions of Title 36 in a separate, future action.

L. Title 37: Air Contaminant Discharge Permits

The Air Contaminant Discharge Permit (ACDP) program is both the federally-enforceable non-title V state operating permit program, and also the administrative mechanism used to implement the notice of construction and new source review programs. There are six types of ACDPs under state and LRAPA rules: Construction, General, Short Term Activity, Basic, Simple, and Standard. The types of ACDPs have not changed, but LRAPA has made some changes and clarifications to the criteria and requirements for the various ACDPs. LRAPA also revised application requirements to set application renewal deadlines, and to clarify the required contents of applications.

The applicability rules at Section 37–0020 reference the table of applicability criteria for the types of permits in Section 37–8010 *Table 1.* The associated fees are listed at Section 37–8020 *Table 2.* These sections are consistent with OAR 340–216–8010 *Table 1* and OAR 216–8020 *Table 2,* respectively, including the type of ACDP (Basic, General, Simple, or Standard) each source category is required to obtain prior to construction and operation. Overall, the list of sources required to obtain Basic, General, Simple, or Standard ACDPs was slightly expanded, with one exception. LRAPA removed the requirement that greenhouse gas-only sources obtain a Standard ACDP, and pay the associated permitting fees, consistent with the federal court decision described below in Section M.

For Construction ACDPs at Section 37–0052, LRAPA added a qualifier to the rule that construction commence within 18 months after the permit is issued. This deadline now applies only if a source is subject to federal major NSR and certain state major NSR permitting, which we have discussed in more detail below. LRAPA also added language to the public notice requirements for a modified Construction ACDP, making clear when public notice as a Category I permit action is appropriate, as opposed to a Category II permit action under Title 31. Although the construction permit itself expires, the requirements remain in effect and must be added to the subsequent operating permit.[14]

General ACDP requirements at Section 37–0060 were updated to refer to the appropriate public notice procedures, reference the fee class for specific source categories, and confirm the procedures that will be used to rescind a source's General ACDP, if the source no longer qualifies and must obtain a Simple or Standard ACDP instead. LRAPA also changed the rule section to make clear that the agency may rescind an individual source's assignment to a General Permit. When notified, the source has 60 days to submit an application for a Simple or Standard ACDP. *General ACDP Attachments,* Section 37–0062, was updated to clarify public notice requirements and fees.

For Simple ACDPs, it is now clear that LRAPA may determine a source ineligible for a Simple ACDP with generic emission limits, and instead, require the source obtain a Standard ACDP with source-specific emission limits, as necessary. LRAPA also clarified the public notice requirements and fees for Simple ACDPs and removed redundant requirements from the section that are also in Section 37–0020.

The requirements at Section 37–0066 were updated to lay out the different application requirements for sources seeking a Standard ACDP permit when they are subject to federal major versus minor NSR. LRAPA also changed this section to allow sources with multiple activities or processes at a single site, covered by more than one General ACDP or that has multiple processes, to obtain a Standard ACDP.

For processing permits, LRAPA's provision at Section 37–0082 now expressly provide that sources with expired ACDP permits may continue operating under the expired permit if they have submitted a timely and complete renewal application. Sources may also request a contested case hearing, if LRAPA revokes a permit or denies a permit renewal. We have determined in our review that LRAPA's Title 37 provisions are consistent with the Division 216 rule sections recently approved by the EPA on October 11, 2017 (82 FR 47122). Therefore, we find Title 37 is consistent with CAA requirements and propose to approve the submitted provisions.

M. Title 38: New Source Review

Parts C and D of title I of the CAA, 42 U.S.C. 7470–7515, set forth preconstruction review and permitting program requirements that apply to new and modified major stationary sources of air pollutants, known as major new source review (major NSR). The CAA major NSR programs include a combination of air quality planning and air pollution control technology program requirements. States adopt major NSR programs as part of their SIP. Part C is the Prevention of Significant Deterioration (PSD) program, which applies in areas that meet the NAAQS (attainment areas), as well as in areas for which there is insufficient information to determine whether the area meets the NAAQS (unclassifiable areas). Part D is the nonattainment new source review (nonattainment NSR) program, which applies in areas that are not in attainment of the NAAQS (nonattainment areas).

The EPA regulations for SIPs implementing these programs are contained in 40 CFR 51.165 and 51.166, and appendix S to part 51. Regulations addressing the EPA's minor new source review (NSR) requirements are located at 40 CFR 51.160 through 164. We note that states generally have more flexibility in designing minor NSR programs. Minor NSR programs, however, must still ensure that emissions from the construction or modification of a facility, building, structure, or installation (or any combination thereof) will not interfere with attainment and maintenance of the NAAQS, or violate an applicable portion of a control strategy approved into the SIP.

Oregon and LRAPA's major NSR program has long differed from the federal major NSR programs in several respects. The program does not subject the same sources and modifications to major NSR as would the EPA's rules. It also has had lower major source thresholds for sources in nonattainment and maintenance areas. The program requires fugitive emissions to be included in applicability determinations for all new major sources and modifications to existing major sources. However, Oregon and LRAPA also utilize a Plant Site Emission Limit, or ''PSEL,'' approach to defining ''major'' modifications, rather than the contemporaneous net emissions increase approach used in the EPA's main major NSR program (not the EPA's plant-wide applicability limit (PAL) option). The EPA has previously determined that, overall, the major NSR program in Oregon is at least as stringent as the EPA's major NSR program and meets the requirements of 40 CFR 51.165 and 51.166.[15]

Under the previous SIP-approved program, both federal major sources and large minor sources have been covered

[14] *See* Section 37–0082.

[15] *See* 76 FR 80747, 80748 (December 27, 2011) (final action); 76 FR 59090, 59094 (Sept. 23, 2011) (proposed action).

by Title 38. The submitted changes to Title 38 revise this approach and establish distinct components within Title 38, referred to as Major New Source Review (LRAPA Major NSR—Sections 38–0045 through 0070) and State New Source Review (State NSR—Sections 38–0245 through 0270) to help clarify the requirements that apply to federal major sources and large minor sources. Pre-construction review and permitting of other minor sources continue to be covered in Title 34 *Stationary Source Notification Requirements,* Title 37 *Air Contaminant Discharge Permits,* and Title 42 *Plant Site Emission Limits.*

As discussed above, Oregon and LRAPA have created two new state designations. ''Sustainment'' areas are state-designated areas that are violating or close to violating the NAAQS but which are not formally designated nonattainment by the EPA. ''Reattainment'' areas are state-designated areas that have been designated nonattainment by the EPA, but that have achieved improved air quality, and data shows the area is attaining the NAAQS. Key changes to the LRAPA Major NSR and State NSR programs are discussed below.

Section 38–0010 Applicability, General Prohibitions, General Requirements, and Jurisdiction

LRAPA has narrowed the scope of sources that are subject to LRAPA Major NSR in nonattainment and maintenance areas by increasing the thresholds, from the significant emission rate (SER) to the major source thresholds in the CAA specified for the current nonattainment areas in Lane County.[16] At the same time, LRAPA's State NSR requirements under Title 38 apply to the construction of new sources with emissions of a regulated air pollutant at or above the SER, as well as increases in emissions of a regulated pollutant from existing sources that equal or exceed the SER over the netting basis. This is consistent with Oregon's rules in Division 224.

LRAPA has divided the State NSR program into two parts: Type A, which generally applies in nonattainment, reattainment, and maintenance areas, and Type B, for attainment, unclassifiable, and sustainment areas. Sources subject to Type A State NSR remain subject to many of the same requirements that apply to such sources under the current SIP-approved program in nonattainment [17] and maintenance areas, whereas sources subject to Type B State NSR are subject to requirements equivalent to the minor NSR requirements under the PSEL rules in the current SIP.[18] Because LRAPA's changes to the definition of ''federal major source'' in nonattainment areas are consistent with the federal definition of ''major stationary source'' at 40 CFR 51.165 for the designated areas in Lane County, and because LRAPA has retained most of the characteristics of the previous Major NSR permitting program for Type A State NSR, the EPA proposes to approve these revisions.

LRAPA also made revisions here, and in several other places in its rules, to be consistent with changes to the federal PSD rules made in response to a Supreme Court decision on greenhouse gases (May 7, 2015, 80 FR 26183).[19] Specifically, LRAPA revised definitions and procedures in Titles 12, 36, 37, 38, and 42 to remove greenhouse gas-only sources from PSD applicability. Therefore, as required by the federal PSD program, a source is now subject to the LRAPA Major NSR requirements for greenhouse gases in attainment and unclassifiable areas only when the source is subject to LRAPA Major NSR requirements anyway, for one or more criteria pollutants. As specified in the federal PSD regulations, LRAPA's rules continue to require that sources of greenhouse gases subject to LRAPA Major NSR in attainment and unclassifiable areas for a criteria pollutant, are also subject to LRAPA Major NSR for greenhouse gases.

LRAPA also made clear in this section that a source is subject to Title 38 requirements for the designated area in which the source is located—for each regulated pollutant, including precursors. Finally, revisions clarify that a subject source must not begin actual construction, continue construction, or operate without complying with the requirements of Title 38 and obtaining an ACDP permit authorizing construction or operation.

Section 38–0025 Major Modification

LRAPA moved the definition of ''major modification'' from Title 12 to Title 38, to reflect that the former definition was really a procedure for determining whether a major modification has, or will occur, rather than a true definition. The revised definition and procedure are intended to better explain how emissions increases and decreases are tracked and factored into calculations for major modifications.

LRAPA also specified that emissions from categorically insignificant activities, aggregate insignificant emissions, and fugitive emissions must be included in determining whether a major modification has occurred. In addition, LRAPA clarified that major modifications for ozone precursors, or $PM_{2.5}$ precursors, also constitute major modifications for ozone and $PM_{2.5}$, respectively. Finally, language was added stating that the PSEL, netting basis, and emissions changes must be recalculated when more accurate or reliable emissions information becomes available, to determine whether a major modification has occurred.

Section 38–0030 New Source Review Procedural Requirements

LRAPA revised this section to account for differing LRAPA Major NSR and State NSR procedures. Included are: When LRAPA will determine whether an application is complete; when a final determination will be made; when construction is permitted; how to revise a permit and extend it; and when and how LRAPA will terminate an NSR permit.

With respect to the provision in the federal PSD regulations authorizing extensions to the 18-month construction time limitation in 40 CFR 52.21(r)(2) ''upon a satisfactory showing that an extension is justified,'' LRAPA revised its extension provisions to be consistent with recent EPA guidance. This guidance sets out the EPA's views on what constitutes an adequate justification for an extension of the 18-month timeframe under 40 CFR 52.21(r)(2) for commencing construction of a source that has been issued a PSD permit.[20] LRAPA also extended the time period for making a final determination on an LRAPA Major NSR or Type A State NSR permit from six months to one year, to reflect the more complex nature of such permitting actions. The one-year time-frame for permit issuance is consistent with the EPA's requirements for major NSR permitting.[21]

Section 38–0038 Fugitive and Secondary Emissions

This section was moved and amended to account for State NSR requirements.

[16] *See* Title 12.

[17] Key changes are discussed below in the discussion of State NSR.

[18] Sources in sustainment areas subject to Section 38–0245(2) are also subject to Type A NSR.

[19] *Utility Air Regulatory Group* v. *Environmental Protection Agency,* 134 S.Ct. 2427 (2014).

[20] Memorandum from Stephen D. Page, Director of EPA's Office of Air Quality Planning and Standards, to Regional Air Division Directors, Region 1–10, entitled Guidance on Extension of Prevention of Significant Deterioration (PSD) Permits under 40 CFR 52.21(r)(2), dated January 31, 2014.

[21] *See* 40 CFR 52.21(q)(2).

For sources subject to LRAPA Major NSR and Type A State NSR, fugitive emissions are included in the calculation of emission rates and subject to the same controls and analyses required for emissions from identifiable stacks or vents. Secondary emissions are not included in potential to emit calculations for LRAPA Major NSR or Type A State NSR, but once a source is subject to LRAPA Major NSR or Type A State NSR, secondary emissions must be considered in the required air quality impact analysis in Titles 38 and 40.

Sections 38–0045 Through 0070 Major NSR

LRAPA has made changes consistent with Oregon's corresponding rules and has specified LRAPA Major NSR requirements for each of the following designations: Sustainment, nonattainment, reattainment, maintenance, and attainment/unclassifiable.

Major NSR in Sustainment Areas

New sources and modifications subject to LRAPA Major NSR in sustainment areas (areas that are classified as attainment/unclassifiable by the EPA but have air quality either violating the NAAQS or just below the NAAQS) must meet PSD requirements for each sustainment pollutant, but must also satisfy additional requirements for obtaining offsets and demonstrating a net air quality benefit to address the air quality problems in the area, as discussed in more detail below. Because such areas are designated as attainment/unclassifiable by the EPA, requiring compliance with LRAPA's PSD requirements meets federal requirements. The additional requirements for obtaining offsets and demonstrating a net air quality benefit go beyond CAA requirements for attainment/classifiable areas and are thus approvable.

Major NSR in Nonattainment Areas

For new sources and modifications subject to LRAPA Major NSR in nonattainment areas, LRAPA reorganized and clarified the requirements, aligning with state rules, including that they apply for each pollutant for which the area is designated nonattainment. Lowest Achievable Emission Rate (LAER) and offsets continue to be required for such sources and modifications. In addition, LRAPA's submitted revisions tighten offsets required in nonattainment areas (except with respect to ozone). LRAPA rules now initially require 1.2:1 offsets to emissions in non-ozone areas. If offsets are obtained from priority sources, the ratio may be reduced to 1:1, equivalent to the federal requirement in 40 CFR 51.165(a)(9)(i).

The submitted changes also tighten requirements for sources seeking construction permit extensions, and limit extension requests to two 18-month periods, with certain additional review and re-evaluation steps. We note that, beyond the federal rules, the rules applicable in Lane County extend best available control technology (BACT) and offset requirements to new and modified minor sources in nonattainment areas.

Major NSR in Reattainment Areas

In reattainment areas (areas meeting the NAAQS but not yet redesignated to attainment), new sources and modifications subject to LRAPA Major NSR must continue to meet all nonattainment LRAPA Major NSR requirements for the reattainment pollutant. In addition, to ensure air quality does not again deteriorate, LRAPA requires that sources subject to LRAPA Major NSR also meet other requirements for each reattainment pollutant. Specifically, the owner or operator of the source must demonstrate the source will not cause or contribute to a new violation of the ambient air quality standard, or PSD increment, by conducting an air quality analysis as outlined in Title 40.

Major NSR in Maintenance Areas

In maintenance areas, new sources and modifications subject to LRAPA Major NSR must continue to comply with LRAPA Major NSR requirements for attainment/unclassifiable areas (*i.e.,* PSD), and also conduct a demonstration or obtain allowances to ensure a net air quality benefit in the area. Rather than setting out the specific PSD requirements in this section, however, this section simply references the PSD requirements at Section 38–0070.

Major NSR in Attainment/Unclassifiable Areas (PSD)

For the construction of new sources and modifications subject to LRAPA Major NSR in attainment or unclassifiable areas, LRAPA revised its rules to address court decisions impacting federal PSD rules. First, as discussed above, LRAPA revised definitions and procedures in Titles 12, 36, 37, 38, and 42 to remove greenhouse gas-only sources from PSD applicability. Therefore, as required under the EPA's federal PSD program, a source is now subject to the LRAPA Major NSR requirements for greenhouse gases only when the source also is subject to LRAPA PSD requirements for one or more criteria pollutants.

Second, LRAPA revised its requirements for preconstruction monitoring to address another court decision and the resulting revisions to the EPA's PSD rules. On October 20, 2010, the EPA promulgated the 2010 PSD $PM_{2.5}$ Implementation Rule, revising the federal significant monitoring concentration (SMC) and significant impact levels (SILs) for $PM_{2.5}$ (75 FR 64864). On January 22, 2013, the U.S. Court of Appeals for the District of Columbia, in *Sierra Club* v. *EPA,*[22] issued a judgment that, among other things, vacated the provisions adding the $PM_{2.5}$ SMC to the federal regulations at 40 CFR 51.166(i)(5)(i)(c) and 52.21(i)(5)(i)(c). In its decision, the court held that the EPA did not have the authority to use SMCs to exempt permit applicants from the statutory requirement in CAA section 165(e)(2) that ambient monitoring data for $PM_{2.5}$ be included in all PSD permit applications. Although the $PM_{2.5}$ SMC was not a required element, where a state program contained an SMC and applied it to allow new permits without requiring ambient $PM_{2.5}$ monitoring data, the provision would be inconsistent with the court's opinion and CAA section 165(e)(2).

At the EPA's request, the decision also vacated and remanded the portions of the 2010 PSD $PM_{2.5}$ Implementation Rule that revised 40 CFR 51.166 and 40 CFR 52.21 related to SILs for $PM_{2.5}$. The EPA requested this vacatur and remand of two of the three provisions in the EPA regulations that contain SILs for $PM_{2.5}$ because the wording of these two SIL provisions (40 CFR 51.166(k)(2) and 40 CFR 52.21(k)(2)) was inconsistent with the explanation of when and how SILs should be used by permitting authorities, that we provided in the preamble to the **Federal Register** publication when we promulgated these provisions. Specifically, the EPA erred because the language promulgated in 2010 did not provide permitting authorities the discretion to require a cumulative impact analysis notwithstanding that the source's impact is below the SIL, where there is information that shows the proposed source would lead to a violation of the NAAQS or increments. The third SIL provision (40 CFR 51.165(b)(2)) was not vacated and remains in effect. On December 9, 2013, the EPA removed the vacated $PM_{2.5}$ SILs and SMC provisions from federal PSD regulations (78 FR 73698). On April 17, 2018, the EPA issued guidance to states on

[22] 703 F.3d 458 (D.C. Cir. 2013).

recommended $PM_{2.5}$ (and ozone) SILs.[23] As stated in this guidance, the EPA intends to use information yielded from application of this guidance by permitting authorities to determine whether a future rulemaking to codify SILs is appropriate.

In response to the vacatur and remand, LRAPA submitted revisions to several titles. LRAPA revised the $PM_{2.5}$ SMC to zero, as the EPA did, to address this issue in the federal PSD regulations. LRAPA also revised the definition of ''significant impact levels'' or ''SIL'' in state rules, removed the vacated language and added text to make clear that ''no source may cause or contribute to a new violation of an ambient air quality standard or PSD increment even if the single source impact is less than the significant impact level.'' We propose to approve LRAPA's revisions as consistent with the court decision.

LRAPA also aligned local rules with state rules to remove language allowing the substitution of post-construction monitoring for preconstruction monitoring. LRAPA added an exemption from the preconstruction ambient air monitoring requirement, with LRAPA's approval, if representative or conservative background concentration data is available, and the source demonstrates that such data is adequate to determine that the source would not cause or contribute to a violation of an ambient air quality standard or any applicable PSD increment. These revisions, along with the other existing provisions regarding preconstruction monitoring in LRAPA's PSD regulations, are consistent with 40 CFR 51.166(m)(iii) and therefore we propose to approve them.

Finally, LRAPA added the requirement to demonstrate a net air quality benefit for subject sources that will have a significant impact on air quality in a designated area other than the area in which the source is located. This demonstration of net air quality benefit is beyond federal PSD requirements, and will be discussed in more detail below.

Sections 38–0245 Through 0270 State NSR

Title 38 now also specifies State NSR requirements for sustainment, nonattainment, reattainment, maintenance, and attainment/unclassifiable areas. For sources that emit between the SER and 100 tons per year in nonattainment and maintenance areas (Type A State NSR sources), LRAPA has relaxed some of the requirements, as compared to the current SIP, that historically went beyond federal requirements. In nonattainment areas, if the increase in emissions from the source is the result of a major modification,[24] BACT rather than LAER is now required. In maintenance areas, Type A State NSR sources are no longer required to conduct preconstruction monitoring to support the ambient air impact analysis for the source.

In both nonattainment and maintenance areas, LRAPA's State NSR rules allow a reduction of the offset ratio if some of the offsets come from sources that are contributing to air quality problems in the area (which historically have been woodstoves). As we found in our 2017 action on the Oregon SIP, the State NSR requirements in sustainment and reattainment areas go beyond CAA requirements for minor NSR programs by requiring a demonstration of a net air quality benefit (discussed below).[25] (October 11, 2017, 82 FR 47122).

Because BACT, LAER, pre-construction monitoring, and offsets are not required components of a State's SIP-approved minor NSR program, and because the offset requirements now provide sources with incentives to obtain offsets from sources found to be specifically contributing to air quality problems in the area, we propose to find that LRAPA's minor NSR program continues to meet CAA requirements for approval.

Sections 38–0500 Through 0540 Net Air Quality Benefit Emission Offsets

The CAA requires that, for nonattainment NSR, the proposed major source or major modifications must obtain emissions reductions of the affected nonattainment pollutant from the same source or other sources in the area to offset the proposed emissions increase.[26] Consistent with that requirement, the EPA's nonattainment NSR regulations require that major sources and major modifications in nonattainment areas obtain emissions offsets at a ratio of at least 1 to 1 (1:1) from existing sources in the area to offset emissions from the new or modified source.[27]

LRAPA revised the criteria for demonstrating a net air quality benefit, in line with Oregon's rule revisions approved by the EPA on October 11, 2017 (82 FR 47122). In addition to the incentives provided to sources subject to Type A State NSR in sustainment and reattainment areas (to obtain offsets from priority sources discussed above) LRAPA made an additional change. Rules were revised to provide incentives for major sources to use priority source offsets for LRAPA Major NSR sources in nonattainment and reattainment areas by increasing the required offset ratio for major sources to 1.2:1 from the current 1:1. If a source subject to LRAPA Major NSR obtains offsets of some emissions increases from priority sources, the ratio may be reduced to no less than 1:1, the minimum offset level under the federal nonattainment NSR program.

We note that LRAPA did not submit Section 38–0510(3) for SIP approval because the submissions do not also include a demonstration for inter-pollutant offset ratios as recommended by the EPA's inter-pollutant offset policy.[28] LRAPA also did not submit Section 38–0520 for SIP approval, in this case because the section addresses ozone nonattainment areas, of which Lane County has none. We propose to approve the revisions to LRAPA's net air quality benefit emissions rules, except Sections 38–0510(3) and 38–0520, for which LRAPA did not request approval.

Summary

We propose to approve the submitted revisions to Title 38 because we have determined that, in conjunction with other provisions including but not limited to rules in Titles 12, 31, 34, 35, 40, 42, and 50, the revisions are consistent with the requirements of the federal PSD and minor NSR permitting programs applicable statewide. We have also determined that the submitted changes are consistent with the federal requirements for nonattainment NSR for the current designated nonattainment areas in Lane County.[29]

N. Title 40: Air Quality Analysis Requirements

This title contains the air quality analysis requirements, which are

[23] Memorandum from Peter Tsirigotis, Director of EPA's Office of Air Quality Planning and Standards, to Regional Air Division Directors, Region 1–10, entitled Guidance on Significant Impact Levels for Ozone and Fine Particles in the Prevention of Significant Deterioration Permitting Program, dated April 17, 2018.

[24] Oregon and LRAPA use the term ''major modification'' for physical and operational changes that result in significant increases to both existing major and existing minor sources.

[25] October 11, 2017, 82 FR 47122.

[26] *See* CAA section 173(c).

[27] *See* 40 CFR 51.165(a)(9)(i).

[28] Gina McCarthy, EPA Administrator. ''Revised Policy to Address Reconsideration of Inter-pollutant Trading Provisions for Fine Particles ($PM_{2.5}$),'' Memorandum to Regional Administrators, July 21, 2011.

[29] *See* 40 CFR 51.160 through 161, 51.165, and 51.166. *See* also EPA proposed approval of Oregon nonattainment NSR program (March 22, 2017, 82 FR 14654 at page 14663).

primarily used in Title 38 *New Source Review.* By its terms, this title does not apply unless a rule in another section refers to Title 40. Substantive changes include revising the definition of ''allowable emissions'' at Section 40–0020(1) to add ''40 CFR part 62'' to the list of referenced standards and clarifying the definition of ''baseline concentration year'' at Section 40–0020(2), that varies depending on the pollutant for a particular designated area. LRAPA also revised the definitions of ''competing PSD increment consuming source impacts'' and ''competing NAAQS [national ambient air quality standards] source impacts'' [30] to broaden the reference to include all of LRAPA's ambient air quality standards at Title 50 (which include the NAAQS) [31] and to specify that in calculating these concentrations, sources may factor in the distance from the new or modified source to other emission sources (range of influence or ROI), spatial distribution of existing emission sources, topography, and meteorology.

LRAPA also clarified and reorganized the defined ROI formula at Section 38–0020(10). The ROI is the distance from the new or modified source or source impact area to other emission sources that could impact that area. The ROI and source impact area are used to predict the air quality impacts of a new or modified source. LRAPA continues to limit the maximum ROI to 50 kilometers and has moved the constant values in the ROI formula from the table at the end of the division into the text of the rule.

PSD requirements were revised to align with the court decision vacating and remanding the $PM_{2.5}$ SIL. Please see Section M. above for a discussion of the court decision. This title now includes language stating that application of a SIL as a screening tool does not preclude LRAPA from requiring additional analysis to evaluate whether a proposed source or modification will cause or contribute to a violation of an air quality standard or PSD increment.

PSD requirements for demonstrating compliance with air quality related values were also updated. LRAPA made clear that, if applicable, the analysis applies to each emission unit that increases the actual emissions of a regulated pollutant above the portion of the netting basis attributable to that emission unit. In addition, the term ''air quality related values'' includes visibility, deposition, and ozone impacts. A visibility analysis for sources impacting the Columbia River Gorge National Scenic Area, is now required, where applicable, to evaluate potential impacts on that area. We propose to approve Title 40 into the LRAPA SIP as meeting CAA requirements, including the EPA's major NSR permitting regulations at 40 CFR 51.165 and 51.166, and the regional haze requirements at 40 CFR part 51, subpart P.

O. Title 41: Emission Reduction Credits

In Title 41, LRAPA submitted revisions to clarify when reductions in criteria pollutant emissions that are also hazardous air pollutant emissions are creditable. Emission reductions required to meet federal NESHAP standards in 40 CFR parts 61 or 63 are not creditable reductions for purposes of Major NSR in nonattainment or reattainment areas in Lane County. However, criteria pollutant reductions that are in excess of, or incidental to, the required hazardous air pollutant reductions can potentially earn credits—as long as all conditions are met. LRAPA also lowered the threshold for banking credits in the Oakridge area—from ten tons to one ton—to encourage trading activity. Finally, the rules were revised to specify when such credits are considered used up, and when they expire. The revisions are consistent with the CAA and the EPA's implementing regulations and we propose to approve them.

P. Title 42: Criteria for Establishing Plant Site Emission Limits

This division contains a regulatory program for managing airshed capacity through a PSEL. PSELs are used in Oregon, including Lane County, to protect ambient air quality standards, prevent significant deterioration of air quality, and to ensure protection of visibility. Establishing such a limit is a mandatory step in the Oregon and LRAPA source permitting process. A PSEL is designed to be set at the actual baseline emissions from a source plus approved emissions increases and minus required emissions reductions. This design is intended to maintain a more realistic emissions inventory. Oregon and LRAPA use a fixed baseline year of 1977 or 1978 (or a prior year if more representative of normal operation) and factor in all approved emissions increases and required emissions decreases since baseline, to set the allowable emissions in the PSEL. Increases and decreases since the baseline year do not affect the baseline, but are included in the difference between baseline and allowable emissions.

''Netting basis'' is a concept in this program that defines both the baseline emissions from which increases are measured—to determine if changes are subject to review—as well as the process for re-establishing the baseline, after changes have been through the new source review permitting process.

As noted above, the PSEL program is used, in part, to implement NSR permitting. For major NSR, if a PSEL is calculated at a level greater than an established SER over the baseline actual emission rate, an evaluation of the air quality impact and major NSR permitting are required. If not, the PSEL is set without further review (a construction permit may also be required). For minor NSR (State NSR), a similar calculation is conducted. If the difference is greater than the SER, an air quality analysis is required to evaluate whether ambient air quality standards and increments are protected. The air quality analysis results may require the source to reduce the airshed impact and/or comply with a tighter emission limit.

LRAPA submitted a number of changes to the PSEL requirements in this title, to align with similar changes to state rules. Many of the changes are organizational, centralizing requirements related to PSELs in Title 42. Other changes are more substantive. LRAPA revised the criteria for establishing PSELs at Sections 42–0035 through 0090 by consolidating requirements from other sections into these provisions, and revising them to take into account the differentiated major and State NSR requirements. LRAPA also updated the source-specific annual PSEL provision, at Section 42–0041, to account for $PM_{2.5}$ and major and State NSR requirements. We note that as previously written, the PSEL rule included provisions for PSEL increases that were not subject to New Source Review. The submissions revoke those provisions and instead make these PSEL increases subject to the State New Source Review requirements in Title 38. The comprehensive requirements for approval of such PSEL increases in sustainment, nonattainment, reattainment, maintenance, and attainment/unclassifiable areas are as stringent as the current requirements.

LRAPA updated the short-term PSEL requirements at Section 42–0042 to spell out the process a source must follow to request an increase in a short-term PSEL—and when that source must obtain offsets, or an allocation, from an available growth allowance in the area.

[30] *See* Sections 40–0020(4) and (5), respectively.

[31] Our approval of Section 38–0020(4) and (5) would not extend to those ambient standards in Title 50 that we have excluded from our approval.

At Section 42–0046, LRAPA clarified how the initial netting basis for $PM_{2.5}$ is set and how potential increases are limited. Changes were made to spell out how a source's netting basis may be reduced—when a rule, order or permit condition requires the reductions—and how unassigned emissions and emissions reduction credits are to be addressed. In addition, the submitted revisions clarify that a source may retain a netting basis if that source relocates to a different site, as opposed to an adjacent site. However, it is only allowed if LRAPA determines the different site is within or affects the same airshed, and that the time span between operation at the old site and new sites is less than six months.

At Section 42–0048, LRAPA consolidated baseline period and baseline emission rate provisions, and indicated when a baseline emission rate may be recalculated—limited to circumstances when more accurate or reliable emission factor information becomes available, or when regulatory changes require additional emissions units be addressed. Changes were also made to Section 42–0051, which addresses actual emissions, and how to appropriately calculate the mass emissions of a pollutant from an emissions source during a specified time period. LRAPA revised this provision to account for the changes in the program that differentiate major NSR from State NSR.

We note that Section 42–0055 unassigned emissions procedures were clarified. The rule section was revised to state that a source may not use emissions that are removed from the netting basis—including emission reductions required by rule, order or permit condition—for netting any future permit actions. LRAPA also updated Section 42–0090, addressing the impact on PSEL calculations and permitting requirements when sources combine, split, and change primary Standard Industrial Code. The changes make clear that sources must qualify to combine, and that it will impact the netting basis and SER, and trigger new source review and recordkeeping requirements, if applicable.

Except for Section 42–0060, we propose to approve Title 42 into the SIP because we believe the revisions to the PSEL requirements are intended to clarify and strengthen the rules. Section 42–0060 is not appropriate for SIP approval because it is applicable to sources of hazardous air pollutants addressed under CAA section 112, rather than sources of criteria pollutants addressed under CAA section 110.

Q. Title 48: Rules for Fugitive Emissions

LRAPA submitted fugitive emission requirements in Title 48 for SIP approval, consistent with Oregon's fugitive emissions rules in Division 208. This title requires sources to take reasonable precautions to prevent fugitive emissions, and may require a fugitive emissions control plan to prevent visible emissions from leaving a facility property for more than 18 seconds in a six-minute period. Compliance is based on EPA Method 22, *Visual Determination of Fugitive Emissions from Material Sources and Smoke Emissions from Flares.* We propose to approve Title 48 into the SIP because we have determined that these fugitive emissions rules are consistent with CAA requirements.

R. Title 50: Ambient Air Standards and PSD Increments

Title 50 contains ambient air quality standards and Prevention of Significant Deterioration (PSD) increments applicable in Lane County. Most notably, LRAPA updated Title 50 for all current federal national ambient air quality standards and federal reference methods.[32]

At Section 50–005(2), LRAPA added language expressly stating that no source may cause or contribute to a new violation of an ambient air quality standard or a PSD increment, even if the single source impact is less than the significant impact level. This change was made to address a court decision vacating and remanding regulatory text for the $PM_{2.5}$ significant impact level. Please see Section M for a detailed discussion of the basis for our determination that this change, along with other related changes, adequately addresses the court decision.

LRAPA updated the table of PSD increments, also known as maximum allowable increases and clarified that PSD increments are compared to aggregate increases in pollution concentrations from the new or modified source over the baseline concentration.[33] LRAPA included ambient air quality thresholds for pollutants in this title, moved from Title 38, to centralize ambient standards and thresholds. Finally, LRAPA consolidated requirements for areas subject to an approved maintenance plan, moving ambient standards and thresholds from Title 38 into Section 50–065. We propose to approve the submitted revisions to Title 50 as being consistent with CAA requirements and implementing regulations at 40 CFR parts 50 and 51.

S. Title 51: Air Pollution Emergencies

This title establishes criteria for identifying and declaring air pollution episodes at levels below the levels of significant harm. LRAPA submitted mostly minor changes to this title. However, significant changes were made to establish a significant harm level for $PM_{2.5}$, and $PM_{2.5}$ trigger levels corresponding with alert, warning, and emergency episodes. We propose to approve the submitted revisions to Title 51 because this title remains consistent with the EPA's rules at 40 CFR part 51, subpart H *Prevention of Air Pollution Emergency Episodes.*

III. Proposed Action

We propose to approve, and incorporate by reference into the SIP, specific rule revisions submitted by Oregon and LRAPA on August 29, 2014 (state effective March 31, 2014) and March 27, 2018 (state effective March 23, 2018), to apply in Lane County. We also propose to approve, but not incorporate by reference, specific provisions that provide LRAPA with authority needed for SIP approval.

As requested by LRAPA and the state, we are removing certain rules from the SIP, because they are obsolete, redundant, or replaced by equivalent or more stringent local rules. We are also deferring action on a section of rules because we intend to address them in a separate, future action.

We note that the submissions include changes to OAR 340–200–0040, a rule that describes the Oregon procedures for adopting its SIP and references all of the state air regulations that have been adopted by LRAPA and ODEQ for approval into the SIP (as a matter of state law), whether or not they have yet been submitted to or approved by the EPA. We are not approving the changes to OAR 340–200–0040 because the federally-approved SIP consists only of regulations and other requirements that have been submitted by LRAPA and ODEQ and approved by the EPA.

A. Rules Approved and Incorporated by Reference

We propose to approve into the Oregon SIP, and incorporate by reference at 40 CFR part 52, subpart MM, revisions to the following LRAPA rule sections. Each rule section listed is state effective March 23, 2018, unless marked with an asterisk, denoting it is effective March 31, 2014:

- Title 12—Definitions (001, 005, 010, 020, 025);

[32] *See* Sections 50–015 through 045.

[33] *See* Section 50–055.

• Title 29—Designation of Air Quality Areas (0010, 0020, 0030, 0040, 0050, 0060, 0070*, 0080*, 0090*, 0300, 0310, 0320);
• Title 30—Incinerator Regulations (010, 015*, 020*—except (2) and (8), 025*—except (9), 030*—except (1)(I) and (2)(E), 035*, 040*, 045*—except (3), 050*, 055*, 060*);
• Title 31—Public Participation (0010, 0020, 0030, 0040, 0050, 0060, 0070, 0080);
• Title 32—Emission Standards (001, 005, 006, 007, 008, 009, 010, 015, 020, 030, 045, 050, 060, 065, 070, 090*, 100, 8010);
• Title 33—Prohibited Practices and Control of Special Classes of Industry (005, 060, 065, 070—except, in (1), the definitions of ''non-condensables'', ''other sources'', and ''TRS'', (3)(a), (4)(b), (5)(b), (6)(a), (6)(b), 500);
• Title 34—Stationary Source Notification Requirements (005, 010, 015, 016, 017, 020, 025, 030, 034, 035, 036, 037, 038);
• Title 35—Stationary Source Testing and Monitoring (0010, 0110, 0120, 0130, 0140, 0150*);
• Title 37—Air Contaminant Discharge Permits (0010, 0020, 0025, 0030, 0040, 0052, 0054, 0056, 0060, 0062, 0064, 0066, 0068, 0070, 0082, 0084, 0090, 0094, 8010, 8020);
• Title 38—New Source Review (0010, 0020, 0025, 0030, 0034, 0038, 0040, 0045, 0050, 0055, 0060, 0070, 0245, 0250, 0255, 0260, 0270, 0500, 0510—except (3), 0530, 0540);
• Title 40—Air Quality Analysis Requirements (0010, 0020, 0030, 0040, 0045, 0050, 0060, 0070);
• Title 41—Emission Reduction Credits (0010*, 0020, 0030);
• Title 42—Stationary Source Plant Site Emission Limits (0010, 0020, 0030, 0035, 0040, 0041, 0042, 0046, 0048, 0051, 0055, 0080, 0090);
• Title 48—Rules for Fugitive Emissions (001, 005, 010, 015);
• Title 50—Ambient Air Standards and PSD Increments (001, 005, 015, 025, 030, 035, 040, 045, 050, 055, 060*, 065); and
• Title 51—Air Pollution Emergencies (005, 007, 010, 011, 015, 020, 025, Table I, Table II, Table III).

B. Rules Approved But Not Incorporated by Reference

We propose to approve, but not incorporate by reference, the following LRAPA rule sections. Each rule section is state effective March 23, 2018, unless marked with an asterisk, denoting the rule is effective March 31, 2014:
• Title 13—General Duties and Powers of Board and Director (005*, 010*, 020*, 025*, 030*, 035*); and
• Title 14—Rules of Practice and Procedures (110, 115, 120, 125, 130, 135, 140, 145, 147, 150, 155, 160, 165, 170, 175, 185, 190, 200, 205).

C. Rules Removed

We are removing the following rules from the current federally-approved Oregon SIP at 40 CFR part 52, subpart MM, because they have been repealed, replaced by rules noted in paragraph A. above, or the state has asked that they be removed:
• Title 12—Definitions (001(2)), state effective March 8, 1994;
• Title 30—Incinerator Regulations (005), state effective March 8, 1994;
• Title 33—Prohibited Practices and Control of Special Classes of Industry (030, 045), state effective November 10, 1994; and
• Title 34—Stationary Source Notification Requirements (040), state effective June 13, 2000.

We also are removing the following rules in the table entitled, ''Rules Also Approved for Lane County'', state effective April 16, 2015, because LRAPA has submitted equivalent or more stringent local rules to apply in place of those requirements:

Table 5—EPA-Approved Oregon Administrative Rules (OAR) Also Approved for Lane County

• Division 200—General Air Pollution Procedures and Definitions (0020);
• Division 202—Ambient Air Quality Standards and PSD Increments (0050);
• Division 204—Designation of Air Quality Areas (0300, 0310, 0320);
• Division 208—Visible Emissions and Nuisance Requirements (0110, 0210);
• Division 214—Stationary Source Reporting Requirements (0114)(5);
• Division 216—Air Contaminant Discharge Permits (0040, 8010);
• Division 222—Stationary Source Plant Site Emission Limits (0090);
• Division 224 –New Source Review (0030, 0530);
• Division 225—Air Quality Analysis Requirements (0010, 0020, 0030, 0040, 0045, 0050, 0060, 0070);
• Division 226—General Emissions Standards (0210); and
• Division 228—Requirements for Fuel Burning Equipment and Fuel Sulfur Content (0210).

D. Rules Deferred

We are deferring action on the following rules, state effective March 23, 2018, because we intend to address them in a separate, future action:
• Title 36—Excess Emissions (001, 005, 010, 015, 020, 025, 030).

IV. Incorporation by Reference

In this rule, we are proposing to include in a final rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, we are proposing to incorporate by reference the provisions described above in Section III. Proposed Action. The EPA has made, and will continue to make, these documents generally available electronically through *https://www.regulations.gov* and in hard copy at the appropriate EPA office (see the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Oregon Notice Provision

Oregon Revised Statute 468.126 prohibits ODEQ from imposing a penalty for violation of an air, water or solid waste permit unless the source has been provided five days' advanced written notice of the violation and has not come into compliance or submitted a compliance schedule within that five-day period. By its terms, the statute does not apply to Oregon's title V program or to any program if application of the notice provision would disqualify the program from federal delegation. Oregon has previously confirmed that, because application of the notice provision would preclude EPA approval of the Oregon SIP, no advance notice is required for violation of SIP requirements.

VI. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA 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 proposed 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 proposed 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 Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because this action does not involve technical standards; and

• does not provide the 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 the 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.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

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

Dated: July 23, 2018.

Chris Hladick,

Regional Administrator, Region 10.

[FR Doc. 2018–16371 Filed 7–30–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 68

[EPA–HQ–OEM–2015–0725; FRL–9981–66–OLEM]

RIN 2050–AG95

Accidental Release Prevention Requirements: Risk Management Programs Under the Clean Air Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; notification of data availability and extension of comment period; correction.

SUMMARY: The Environmental Protection Agency (EPA) issued a proposed rule in the **Federal Register** on May 30, 2018 to request public comment on several proposed changes to the final Risk Management Program Amendments rule (Amendments rule) issued on January 13, 2017. This document is being issued to correct technical errors in the Regulatory Impact Analysis and the Notification of Data Availability and Extension of Comment Period for the proposed rule.

DATES: Comments on the proposed rule (83 FR 24850, May 30, 2018), as extended by the Notification of Data Availability and Extension of Comment Period (83 FR 34967, July 24, 2018) must be received by August 23, 2018.

ADDRESSES: Submit comments and additional materials, identified by docket EPA–HQ–OEM–2015–0725 to the Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the online instructions for submitting comments. 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.*

FOR FURTHER INFORMATION CONTACT: James Belke, United States Environmental Protection Agency, Office of Land and Emergency Management, 1200 Pennsylvania Ave. NW (Mail Code 5104A), Washington, DC 20460; telephone number: (202) 564–8023; email address: *belke.jim@epa.gov,* or Kathy Franklin, United States Environmental Protection Agency, Office of Land and Emergency Management, 1200 Pennsylvania Ave. NW (Mail Code 5104A), Washington, DC 20460; telephone number: (202) 564–7987; email address: *franklin.kathy@epa.gov.*

SUPPLEMENTARY INFORMATION: Detailed background information describing the proposed RMP Reconsideration rulemaking may be found in a previously published document: Accidental Release Prevention Requirements: Risk Management Programs Under the Clean Air Act; Proposed Rule (83 FR 24850, May 30, 2018).

I. What action is EPA taking?

EPA is correcting incorrect date references to the version of the Risk Management Plan (RMP) database used to extract accident history information for the years 2014 through 2016. EPA used this accident information to update the trend of accidents from RMP facilities discussed in the Regulatory Impact Analysis for the proposed Reconsideration rule (EPA. Regulatory Impact Analysis, Reconsideration of the 2017 Amendments to the Accidental Release Prevention Requirements: Risk Management Programs Under the Clean Air Act, Section 112(r)(7), April 27, 2018). EPA also referred to the 2014–2016 accident information in the Accidental Release Prevention Requirements: Risk Management Programs Under the Clean Air Act; Notification of Data Availability and Extension of Comment Period (83 FR 34967, July 24, 2018). In both documents, EPA made incorrect references to the date of the RMP database version used to extract these accident data. This document serves to correct the incorrect date references.

II. What does this correction do?

This document corrects incorrect date references to the RMP database in two locations in the regulatory record for the Accidental Release Prevention Requirements: Risk Management Programs Under the Clean Air Act; Proposed Rule (83 FR 24850, May 30, 2018). One location is on page 33 of the

Regulatory Impact Analysis (RIA). Page 33 of the RIA discusses the availability of annual accident data for 2014–2016, and includes a footnote (footnote 32) indicating the source of the accident data. The footnote states: ''EPA. April 2018. Risk Management Plan (RMP) Facility Accident Data, 2014–2016. USEPA, Office of Emergency Management.'' This footnote should read ''EPA. March 2018. Risk Management Plan (RMP) Facility Accident Data, 2014–2016. USEPA, Office of Emergency Management.''

The other location is on page 34968 of ''Accidental Release Prevention Requirements: Risk Management Programs Under the Clean Air Act; Notification of Data Availability and Extension of Comment Period,'' 83 FR 34967, 34968 (July 24, 2018), in the **SUPPLEMENTARY INFORMATION** section. Column two of this page also discusses the 2014–2016 accident data, but incorrectly indicates that EPA developed the docketed spreadsheet containing these data from the November 2017 version of the RMP database. The last sentence of the carryover paragraph at the top of column two should read: ''EPA developed the latter spreadsheet from the March 2018 version of the database.''

While the facility count information discussed in the Notification of Data Availability was based on the November 2017 version of the RMP database, EPA extracted the 2014–2016 accident data from the March 2018 version of the RMP database, as indicated above. EPA notes that the previously docketed 2014–2016 accident spreadsheet contains an additional 25 accident records for the 2014–2016 period that were not available when the November 2017 version of the database was created. By using a later version of the database to extract accident records, EPA provided more up-to-date accident information to support the regulatory record. However, users who attempt to replicate EPA's 2014–2016 accident spreadsheet by extracting accident data from the November 2017 version of the RMP database (which was recently added to the rulemaking docket as EPA–HQ–OEM–2015–0725–0989) would not see the additional 25 accident records.

EPA has added a memo to the rulemaking docket dated July 25, 2018, with the subject line: *Corrections to References to Risk Management Plan Accident Information for 2014–2016.* This memo explains the corrections discussed above and includes a list of the 25 accidents that are included in the 2014–2016 spreadsheet but not in the November 2017 version of the RMP database.

Dated: July 25, 2018.

Reggie Cheatham,

Director, Office of Emergency Management.

[FR Doc. 2018–16372 Filed 7–30–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–SFUND–1983–0002; FRL–9981–39—Region 6]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List: Partial Deletion of the South Valley Superfund Site

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; notice of intent.

SUMMARY: The Environmental Protection Agency (EPA) Region 6 is issuing a Notice of Intent to Delete Operable Units 1, 2, and 5 of the South Valley Superfund Site (Site) located in Albuquerque, New Mexico, from the National Priorities List (NPL) and requests public comments on this proposed action. The NPL, promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is an appendix of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). The EPA and the State of New Mexico, through the New Mexico Environment Department, have determined that all appropriate response actions at these identified parcels under CERCLA have been completed, other than five-year reviews and operation and maintenance activities. However, this deletion does not preclude future actions under Superfund. This partial deletion pertains to Operable Units 1, 2, and 5. The remaining Operable Units 3, 4, and 6 will remain on the NPL and are not being considered for deletion as part of this action.

DATES: Comments must be received by August 30, 2018.

ADDRESSES: Submit your comments, identified by Docket ID no. EPA–HQ–SFUND–1983–0002, by one of the following methods:

- *http://www.regulations.gov* . Follow the online instructions for submitting comments. 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 *http://www2.epa.gov/dockets/commenting-epa-dockets.*
- *Email: hebert.michael@epa.gov.*
- *Mail:* Michael A. Hebert, Remedial Project Manager, EPA Region 6, Mail Code—6SF–RL, 1445 Ross Avenue, Dallas, Texas 75202–2733.
- *Hand delivery:*
  - Michael A. Hebert, Remedial Project Manager, EPA Region 6, Mail Code—6SF–RL, 7th Floor Reception Area, 1445 Ross Avenue, Dallas, Texas 75202–2733.
  - Such deliveries are only accepted during the Docket's normal hours of operation (Monday through Friday, 7 a.m. to 4 p.m.) and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID no. EPA–HQ–SFUND–1983–0002. The *http://www.regulations.gov* website is an ''anonymous access'' system, which means 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 EPA without going through *http://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, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not 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 the hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at:

Zimmerman Library, Government Information Department, University of New Mexico, Albuquerque NM 87131, 505.277.9100, Monday–Thursday—7 a.m.–2 a.m., Friday—7 a.m.–9 p.m., Saturday—10 a.m.–6 p.m., Sunday—12 p.m.–2 a.m.

New Mexico Environment Department, Harold Runnels Building, 1190 St. Francis Drive, Santa Fe, NM 87505, 505.827.2855, Monday–Friday—8 a.m.–5 p.m.

FOR FURTHER INFORMATION CONTACT: Michael A. Hebert, Remedial Project Manager, U.S. Environmental Protection Agency, Region 6, Mail Code—6SF–RL, 1445 Ross Avenue, Dallas, Texas, 75202–2733, (214) 665–8315, email: *hebert.michael@epa.gov*.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

EPA Region 6 announces its intent to delete Operable Units 1, 2, and 5 of the South Valley Superfund Site (Site), from the National Priorities List (NPL) and requests public comment on this proposed action. The NPL constitutes Appendix B of 40 CFR part 300 which is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), which EPA promulgated pursuant to Section 105 of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) of 1980, as amended. EPA maintains the NPL as those sites that appear to present a significant risk to public health, welfare, or the environment. Sites on the NPL may be the subject of remedial actions financed by the Hazardous Substance Superfund (Fund). This partial deletion of the South Valley Superfund Site is proposed in accordance with 40 CFR 300.425(e) and is consistent with the Notice of Policy Change: Partial Deletion of Sites Listed on the National Priorities List. 60 FR 55466 (Nov. 1, 1995). As described in § 300.425(e)(3) of the NCP, a portion of a site deleted from the NPL remains eligible for Fund-financed remedial action if future conditions warrant such actions.

EPA will accept comments on the proposal to partially delete this site for 30 days after publication of this document in the **Federal Register**.

Section II of this document explains the criteria for deleting sites from the NPL. Section III discusses procedures that EPA is using for this action. Section IV discusses Operable Units 1, 2, and 5 of the South Valley Superfund Site and demonstrates how the operable units meet the deletion criteria.

II. NPL Deletion Criteria

The NCP establishes the criteria that EPA uses to delete sites from the NPL. In accordance with 40 CFR 300.425(e), sites may be deleted from the NPL where no further response is appropriate. In making such a determination pursuant to 40 CFR 300.425(e), EPA will consider, in consultation with the State, whether any of the following criteria have been met:

i. Responsible parties or other persons have implemented all appropriate response actions required;

ii. all appropriate Fund-financed response under CERCLA has been implemented, and no further response action by responsible parties is appropriate; or

iii. the remedial investigation has shown that the release poses no significant threat to public health or the environment and, therefore, the taking of remedial measures is not appropriate.

Pursuant to CERCLA section 121(c) and the NCP, EPA conducts five-year reviews to ensure the continued protectiveness of remedial actions where hazardous substances, pollutants, or contaminants remain at a site above levels that allow for unlimited use and unrestricted exposure. EPA conducts such five-year reviews even if a site is deleted from the NPL. EPA may initiate further action to ensure continued protectiveness at a deleted site if new information becomes available that indicates it is appropriate. Whenever there is a significant release from a site deleted from the NPL, the deleted site may be restored to the NPL without application of the hazard ranking system.

III. Deletion Procedures

The following procedures apply to deletion of Operable Units 1, 2, and 5 of the Site:

(1) EPA consulted with the State of New Mexico before developing this Notice of Intent for Partial Deletion.

(2) EPA has provided the State of New Mexico 30 working days for review of this notice prior to publication of it today.

(3) In accordance with the criteria discussed above, EPA has determined that no further response is appropriate.

(4) The State of New Mexico, through the New Mexico Environment Department, has concurred with the deletion of Operable Units 1, 2, and 5 of the South Valley Superfund Site, from the NPL.

(5) Concurrently, with the publication of this Notice of Intent for Partial Deletion in the **Federal Register**, a notice is being published in a major local newspaper, the *Albuquerque Journal, http://www.abqjournal.com.* The newspaper announces the 30-day public comment period concerning the Notice of Intent for Partial Deletion of the Site from the NPL.

(6) The EPA placed copies of documents supporting the proposed partial deletion in the deletion docket, made these items available for public inspection, and copying at the Site information repositories identified above.

If comments are received within the 30-day comment period on this document, EPA will evaluate and respond accordingly to the comments before making a final decision to delete Operable Units 1, 2, and 5. If necessary, EPA will prepare a Responsiveness Summary to address any significant public comments received. After the public comment period, if EPA determines it is still appropriate to delete Operable Units 1, 2, and 5 of the South Valley Superfund Site, the Regional Administrator will publish a final Notice of Partial Deletion in the **Federal Register**. Public notices, public submissions and copies of the Responsiveness Summary, if prepared, will be made available to interested parties and included in the site information repositories listed above.

Deletion of a portion of a site from the NPL does not itself create, alter, or revoke any individual's rights or obligations. Deletion of a portion of a site from the NPL does not in any way alter EPA's right to take enforcement actions, as appropriate. The NPL is designed primarily for informational purposes and to assist EPA management. Section 300.425(e)(3) of the NCP states that the deletion of a site from the NPL does not preclude eligibility for future response actions, should future conditions warrant such actions.

IV. Basis for Partial Site Deletion

The following information provides EPA's rationale for deleting Operable Units 1, 2, and 5 of the South Valley Superfund Site from the NPL:

Site Background and History

The EPA ID for the South Valley Superfund Site is NMD980745558. The South Valley Superfund Site is in the southern portion of Albuquerque, in Bernillo County, New Mexico, directly across Interstate 25 from the Albuquerque International Airport and the University of New Mexico Golf Course. The South Valley Superfund Site consists of an area of approximately one square mile proximate to the intersection of South Broadway Boulevard and Woodward Road and is divided into two properties: the former Air Force Plant 83 site and the Univar site. The Air Force Plant 83 site is further divided into two parcels located north and south of Woodward Road known as North Plant 83 and South Plant 83, respectively. Various manufacturing operations occurred at the Air Force Plant 83 site from the 1940s until 1967, when the United States Air Force took ownership of the property and its contractor, General Electric Aircraft Engines (GEA), began manufacturing aircraft engine components at the property. GEA purchased the Air Force Plant 83 in 1983 and continued operations until October 1997, when North Plant 83 was closed, and until October 2010, when South Plant 83 was closed. Groundwater beneath the Site is in the Santa Fe Group which is comprised of several layers within the formation. The shallow zone aquifer (approximately 175–225 below ground surface [bgs]) beneath the North Plant 83 area has a continuous silty clay layer underneath it and is therefore primarily perched and does not have a uniform flow direction. The shallow groundwater in the South Plant 83 area flows east to west. Unlike North Plant 83, the silty clay layer beneath the South Plant 83 area is discontinuous and therefore is in hydraulic connection with the deeper aquifer zones. The deeper aquifer sand zones (approximately 225–355 bgs, 255–415 bgs, and 415–515 bgs) have discontinuous silts and clays interbedded within them which are not laterally extensive but may limit downward movement through the formation. Groundwater flows generally east to west in all the deeper aquifer zones.

Groundwater contamination was first suspected in the late 1970s in two municipal wells—San Jose No. 6 and San Jose No. 3. The wells were taken out of service after subsequent sampling indicated contamination. Groundwater monitoring results in the vicinity of the wells indicated the potential for a number of sources, including several industrial operations located in close proximity to the contaminated wells. When the Site was proposed to the NPL on December 30, 1982, (47 FR 58476), it was the number one priority of the State of New Mexico. EPA finalized the NPL listing on September 8, 1983, (48 FR 40658).

The Operable Units at the South Valley Superfund Site are as follows:

Operable Unit 1 (OU1) (included in partial deletion)—OU1 consists of the City of Albuquerque San Jose 6 (SJ–6) and San Jose 3 (SJ–3) wells, which were contaminated with volatile organic compounds (VOCs). EPA signed the Record of Decision (ROD) for OU1 on March 22, 1985 but did not identify a Potentially Responsible Party (PRP). The remedial goal was to eliminate the threat to human health posed by introducing water from the San Jose 6 and San Jose 3 wells into the City of Albuquerque drinking water supply. The objective was achieved by EPA replacing wells SJ–6 and SJ–3 with the Burton No. 4 well, which was completed in April 1987.

Operable Unit 2 (OU2) (included in partial deletion)—The remedial goals of OU2 were to eliminate the conduit(s) for contaminant migration from the shallow to the deeper aquifers and to restrict groundwater use under the Site. EPA signed the OU2 ROD on September 30, 1988 and identified GEA as a PRP. GEA implemented the remedial action by plugging SJ–6 and SJ–3 and any shallow wells that could act as conduits for contaminant transport from the shallow to the deeper aquifers, restricting groundwater use, and implementing groundwater monitoring. GEA integrated the OU2 groundwater monitoring program into Operable Unit 6 and continues the monitoring program today.

Operable Unit 3 (OU3)—The remedial goal of OU3 included reducing the concentrations of site-related VOCs in groundwater to acceptable levels (aquifer restoration) via a pump-treat-injection system. EPA signed the ROD on June 28, 1988 and identified Univar as the Potentially Responsible Party. Univar initiated groundwater recovery system in April 1992 and a vapor recovery system in November 1999. Univar shut off both systems in November 2006. Subsequent monitoring has shown that the groundwater and vapor recovery systems reduced the dissolved chlorinated VOC concentrations to levels below and compliant with applicable or relevant and appropriate requirements as defined in the ROD. On June 10, 2014, the EPA acknowledged that Univar completed all requirements of the Consent Decree dated March 27, 1990, as they relate to the constituents of concern in groundwater identified in the ROD and the subsequent Explanation of Significant Differences dated September 26, 2006, except for addressing 1,4-dioxane contamination. The EPA acknowledged that Univar is addressing 1,4-dioxane in groundwater at OU3 pursuant to Section XVI(D) of the above Consent Decree.

Operable Unit 4 (OU4)—OU4 consists of the vadose zone at the Univar site. As the PRP, Univar was required to investigate the soil around a pit on its property to establish the source of the solvents under their plant. The investigation found no evidence in the vadose zone that a release occurred at this location. EPA signed the ROD on June 28, 1988 and specified No Further Action.

Operable Unit 5 (OU5) (included in partial deletion)—OU5 consists of the unsaturated and saturated portion of the shallow zone aquifer at North Plant 83 and South Plant 83. EPA signed the ROD on September 30, 1988, and identified GEA as the PRP. The remedial goals for this operable unit were remediating shallow zone groundwater and eliminating source materials via enhanced dewatering, soil flushing, and soil vapor extraction (SVE) to result in aquifer restoration. GEA conducted soil vapor surveys and collected soil borings in the South Plant 83 area and the North Plant 83 area to identify VOC contamination. The result of these investigations indicated that the concentrations of VOCs would best be remediated using SVE. GEA operated SVE systems at the North Plant 83 and South Plant 83 areas in 1992 and 1993. Prior to remediation, the groundwater contamination encompassed approximately twelve acres at North Plant 83 and approximately seven acres at South Plant 83. GEA initiated shallow groundwater recovery systems at the North Plant 83 and South Plant 83 areas in May 1994 and completely shut down the groundwater recovery systems in July 2010. GEA completed compliance groundwater monitoring and on September 22, 2014 requested closure of OU5 stating that GEA had satisfactorily completed all requirements of the Administrative Order dated July 3, 1989. All wells and infrastructure associated with the OU5 groundwater treatment system have been plugged and

abandoned or removed as approved by EPA.

After the closure of South Plant 83 in October 2010, GEA performed additional remedial activities associated with OU5 soils. Specifically, GEA performed investigations within the North Plant 83 and South Plant 83 building footprints and excavated and disposed of hexavalent chromium contaminated soil from the East and West Tank Line area in South Plant 83. In addition, GEA filed a deed restriction in the Bernalillo County records covering areas where semi-volatile organic compounds (*i.e.,* polyaromatic hydrocarbons) or hexavalent chromium contamination remained above industrial soil screening levels.

Operable Unit 6 (OU6)—OU6 consists of the deep aquifer at North Plant 83 and South Plant 83. EPA signed the ROD on September 30, 1988 and identified GEA as the PRP. The remedial goals of OU6 are hydraulically containing the plume to protect the City of Albuquerque's water supply wells and reducing the concentrations of site-related VOC compounds in groundwater to acceptable levels (aquifer restoration). The original plume was approximately 100 acres in size but as of 2018, only two wells have constituents above cleanup levels. The groundwater remediation system at OU6 began operation in March 1996. Remedial action activities have hydraulically contained the plume and shrunk it significantly from its former volume and mass. To date, over 7.5 billion gallons of contaminated water have been recovered, treated, and reinjected back into the deep aquifer.

The South Valley area of Albuquerque has experienced ongoing development and redevelopment for decades. The proposed extension of Sunport Boulevard from east of Interstate 25 to west of Interstate 25, if constructed, is expected to spur local economic growth and redevelopment.

Remedial Investigation and Feasibility Study

Operable Unit 1 (OU1)—Other than the sampling that established that San Jose No. 6 and San Jose No. 3 municipal water supply wells had been impacted, there was no remedial investigation performed for OU1. Upon detection of contamination, the City of Albuquerque discontinued use of the water supply wells. Subsequently, the EPA, the City of Albuquerque, and other stakeholders conducted several meetings to discuss potential sites for a replacement municipal well, which culminated in the final design and ultimate installation of a replacement municipal water supply well, Burton Well No. 4. In addition, a remedial investigation was initiated which provided information utilized to develop remedial activities for the remaining operable units at the Site.

Operable Unit 2 (OU2)—GEA conducted a remedial investigation for OU2 because of the contamination identified in OU1. As part of the remedial investigation, GEA compiled existing investigative information and collected additional soil, groundwater, surface water, and sediment information associated with the one-square-mile boundary area of the South Valley Superfund Site. In addition, GEA identified contamination associated with several different sources. Based upon the remedial investigation data, GEA determined in the feasibility study that contaminated groundwater in the shallow zone was potentially migrating into the intermediate zone throughout the Site through improperly constructed groundwater wells. The contaminants of concern identified in the remedial investigation were VOCs, with the main contaminant being trichloroethylene (TCE).

Operable Unit 5 (OU5)—GEA conducted a remedial investigation for OU5 because of the contamination identified in OU1. As part of the remedial investigation GEA, compiled existing investigative information and collected additional soil, groundwater, surface water, and sediment information associated with the one-square-mile boundary area of the South Valley Superfund Site. Further, GEA identified contamination associated with several different sources. The contaminants of concern identified in the remedial investigation were VOCs, with the main contaminant being TCE.

Based upon the remedial investigation data, GEA determined in the feasibility study that OU5 soil contamination occurs in areas associated with the two areas, North Plant 83 and South Plant 83, and groundwater contamination occurs in the shallow aquifer below portions of both the North Plant 83 and South Plant 83 areas. GEA also identified groundwater contamination comprising of similar constituents of concerns as in OU5 in several other hydrogeological units beneath the Site, which are addressed in OU6.

After the closure of South Plant 83 in October 2010, GEA performed additional remedial activities associated with OU5, including soil investigations within the North Plant 83 and South Plant 83 building footprints. GEA identified 68 separate areas as a potential concern with 41 of these locations being identified for investigation. In addition, GEA sampled soil borings for VOCs, semi-volatile organic compounds, polychlorinated biphenyls, and selected metals. GEA did not detect VOCs above industrial soil screening levels and did not detect any polychlorinated biphenyls. GEA detected semi-volatile organic compounds (*i.e.,* polyaromatic hydrocarbons) and hexavalent chromium in a few of the 41 locations investigated. In addition, GEA inspected, investigated, and cleaned out sanitary sewer lines for both North Plant 83 and South Plant 83. While GEA detected concentrations of metal contaminants in sediments within the sewer lines, it did not identify impacts in the soils adjacent and beneath the sewer lines.

Selected Remedy

Operable Unit 1 (OU1)—EPA signed the ROD for OU1 on March 22, 1985. The selected remedy was installation of a new water supply well to replace the capacity of the contaminated well San Jose No. 6. The remedial goal was to eliminate the threat to human health posed by introducing water from this well into the City of Albuquerque drinking water supply.

Operable Unit 2 (OU2)—EPA signed the ROD for OU2 on September 30, 1988. The selected remedy consisted of cleaning out and sealing abandoned wells that were acting as conduits for contaminant migration, groundwater quality monitoring during and after implementation of any remedial action, and the imposition of access restrictions regarding well construction specifications and depth of completions through the State Engineer's office. The remedial goals were eliminating conduit(s) for contaminant migration from the shallow to intermediate aquifers and preventing the use of contaminated groundwater in the site area.

Operable Unit 5 (OU5)—EPA signed the ROD for OU5 on September 30, 1988. The selected remedy consisted of further investigation to define the extent of soil and groundwater contamination, soil remediation utilizing SVE on portions of North Plant 83 and South Plant 83, groundwater remediation through extraction, treatment with air stripping followed by carbon adsorption, and reinjection into the aquifer for shallow (OU5) groundwater contaminated zones located under portions of North Plant 83 and South Plant 83 along with intermediate/deep (OU6) groundwater contaminated zones on-site and off-site. The remedial goals for OU5 were remediating shallow zone groundwater and eliminating source

materials via enhanced dewatering, soil flushing, and SVE. Further, as a result of the investigations performed by GEA after closure of South Plant 83 in October 2010, GEA conducted removal of soil proximate to the East and West Tank Line area in South Plant 83 in 2011.

Response Actions

Operable Unit 1 (OU1)—The United State Corps of Engineers completed a final design for a new municipal water supply well in late 1986. The remedial action performed at OU1 was the replacement of wells SJ–6 and SJ–3 with the Burton No. 4 well, which was completed in April 1987.

Operable Unit 2 (OU2)—GEA completed a final design dated July 20, 1990, that contained plans to install monitoring wells, clean out and plug abandoned wells including the SJ–6 well (OU1), and conduct a groundwater monitoring program. GEA completed the installation of new monitoring wells and the plugging and abandonment of wells that could act as conduits for contaminant transport to lower groundwater zones by the end of 1992. GEA initiated an OU2 groundwater monitoring program, which in 1996 was combined with the OU6 groundwater monitoring program to simplify groundwater monitoring and reporting at the Site. The New Mexico State Engineer's office issued a restriction concerning groundwater well construction within the boundaries of the South Valley Superfund Site on December 19, 1988.

Operable Unit 5 (OU5)—Because the remedial investigation identified both soil and groundwater contamination, the response actions for OU5 were separated by media into soil and groundwater actions. For soils, GEA finalized the remedial design for the SVE systems in late 1991, which EPA subsequently approved on January 24, 1992. GEA installed and operated SVE systems on both the North Plant 83 and South Plant 83 areas. The North Plant 83 SVE system operated for approximately four months from June 1992 to June 1993. The South Plant 83 SVE system operated for approximately five months from October 1992 to March 1993. For groundwater, GEA's contractor, Canonie Environmental, completed a final design dated July 21, 1993, that contained construction details for the remedial systems for the shallow zone groundwater remediation on the North Plant 83 and South Plant 83 areas. The North Plant 83 system initially was comprised of seven extraction wells, and the South Plant 83 system was comprised of three wells. These systems were augmented through their operational lifetime to adapt to changes in groundwater concentrations and flow patterns.

After the closure of South Plant 83 in October 2010, GEA performed additional remedial activities associated with OU5. GEA conducted removal of soil proximate to the East and West Tank Line area in South Plant 83 in 2011. Approximately 3.5 tons of contaminated soil and concrete were removed and transported for final disposal at an off-site hazardous waste disposal facility. Following removal, GEA backfilled the area with clean fill and capped the area with a five-inch-thick, 3,000 pounds/square inch layer of reinforced concrete. GEA filed a deed restriction in the Bernalillo County records covering areas where semi-volatile organic compounds (*i.e.,* polyaromatic hydrocarbons) or hexavalent chromium contamination remained present above industrial soil screening levels. GEA removed approximately 1,750 feet of primary 4-inch to 8-inch diameter cast iron process sewer lines, 435 feet of similar smaller branch lines, and seven manholes and disposed these materials at a Resource Conservation and Recovery Act treatment, storage, and disposal facility. Finally, GEA cleaned and abandoned in place the South Plant 83 sewer system piping and plugged the connection to the City of Albuquerque sewer system.

Cleanup Levels

Operable Unit 1 (OU1)—There were no cleanup levels established for OU1, as the remedy was simply replacement of a municipal water supply well to replace the capacity lost by the contaminated SJ–6 well.

Operable Unit 2 (OU2)—There were no cleanup levels established for OU2, as the remedy was simply the installation of additional groundwater monitoring wells, the plugging and abandonment of wells that could act as conduits for contaminant transport to lower groundwater zones, the imposition of access restrictions regarding well construction specifications and depth of completions through the State Engineer's office, and the establishment of a groundwater monitoring program to obtain data concerning groundwater contamination.

Operable Unit 5 (OU5)—The investigations and remediation work for OU5 was separated by media into soil and groundwater work. For soil, the ROD required the utilization of SVE for soil remediation but did not specify cleanup levels. The ROD stated, ''Soils treatment will continue until the vapor extraction system ceases to produce volatile contaminants and will be followed by sampling to confirm soil remediation.'' GEA obtained post remediation soil samples after the SVE systems ceased operations and proposed cleanup levels for soils in April 1993. The proposed cleanup levels considered soil exposure pathways including dermal contact, inhalation, and ingestion (*i.e.,* by children ages 2 to 6) as well as the potential for contaminants to leach from soil into groundwater that would exceed drinking water standards. GEA based the cleanup levels on the assumption of an operating manufacturing facility with restricted access but also on the worst-case exposure scenario that the site could be converted to residential use. During a meeting with GEA on November 2, 1993, EPA verbally agreed to the proposed cleanup levels. In a letter dated June 21, 1994, EPA indicated that the levels of contaminants found in the soils were below limits that required removal. In addition, out of an abundance of caution, as part of the 2017 Remedial Action Report for OU5, GEA performed a comparison of the post remediation soil concentrations to the EPA Industrial and Residential Soil Screening Levels (November 2015) which indicated all the post soil remediation soil concentrations were below the EPA Industrial and Residential Soil Screening Levels. For groundwater, the ROD specified that cleanup levels would be maximum contaminant limits from the Safe Drinking Water Act and levels in the New Mexico Water Quality Control Commission regulations, whichever was more stringent. These levels were updated in an Explanation of Significant Differences dated October 16, 2006, which added a level for tetrachloroethylene promulgated under the Safe Drinking Water Act in 1992. GEA implemented and conducted a groundwater monitoring program throughout the operation of the shallow zone groundwater remediation systems. After six years of monitoring indicating that none of the off-site wells of the North Plant 83 system well network exceeded cleanup levels, EPA approved closure of the off-site wells and conveyance system. GEA flushed, cleaned, and abandoned conveyance piping in place and plugged and abandoned wells in 2010. One on-site well associated with the North Plant 83 system remained slightly above cleanup levels. In 2010, GEA performed in-situ chemical oxidation around this well which subsequent sampling confirmed that contaminant concentrations fell and

remained below cleanup levels. The South Plant 83 system experienced a similar history to the North Plant 83 system. By 1999, all wells associated with the South Plant 83 system except for two wells were below cleanup levels. By 2006, only one well had concentrations above cleanup levels. Like the North Plant 83 system, GEA performed in-situ chemical oxidation in 2010 around this well, which subsequent sampling confirmed that contaminant concentrations fell below cleanup levels shortly after the in-situ treatment and remained below cleanup levels through 2012.

After the closure of South Plant 83 in October 2010, GEA performed additional remedial activities associated with OU5. Utilizing investigations results, GEA completed an assessment of the risk for the contaminants identified in the investigation. This assessment indicated that hexavalent chromium contamination in deep soils would not pose a risk to human health and the environment assuming that an impermeable cover remained in place and institutional controls were implemented. The assessment also indicated that the semi-volatile organic compounds (*i.e.,* polyaromatic hydrocarbons) identified in soils would not pose a risk to human health and the environment if the existing concrete cap was left in place. GEA removed soil with concentrations of hexavalent chromium above 50 milligrams per kilogram (mg/kg) but did not remove soil with hexavalent chromium contamination ranging from 5.6 to 50 mg/kg at depths between 5 to 14 feet below the existing concrete slab. GEA filed a deed restriction in the Bernalillo County records covering areas where semi-volatile organic compounds or hexavalent chromium contamination remained above industrial soil screening levels.

Operation and Maintenance

Operable Unit 1 (OU1)—The operation and maintenance concerning the Burton No. 4 replacement well is performed by the City of Albuquerque.

Operable Unit 2 (OU2)—There is no operation and maintenance associated with OU2. The restriction concerning groundwater well construction within the boundaries of the South Valley Superfund Site issued by the New Mexico State Engineer's office on December 19, 1988, remains in effect but is now monitored under OU6. This restriction is not needed and does not affect the protectiveness of the actions performed at OU2.

Operable Unit 5 (OU5)—Since the soil and groundwater remediation systems associated with OU5 have met their associated cleanup levels and have been dismantled, there are no operation and maintenance activities required or ongoing for the OU5 SVE and groundwater remediation systems. In addition, while still in effect, the New Mexico State Engineer's restriction concerning groundwater well construction is no longer required for the protectiveness of the OU5 remedy because groundwater concentrations are below the maximum contaminant limits from the Safe Drinking Water Act and levels in the New Mexico Water Quality Control Commission regulations. After ceasing operations in September 2010 and completing demolition of the South Plant 83 buildings in May 2011, GEA performed investigations of the South Plant 83 property which included evaluating soil impacts near any existing sub-grade foundation features as well as the North Plant 83 and South Plant 83 sewer systems. In addition, GEA cleaned out and abandoned in place the sewer systems. Because of the soil investigation, GEA removed hexavalent chromium contamination near the location of the East and West Tank Line on the South Plant 83 property. Some contamination remained in place and, as a result, GEA filed a declaration of restrictive covenants on September 9, 2014 in the Bernalillo County property records. The declaration identified five areas where semi-volatile organic compounds or hexavalent chromium contamination exceed industrial soil screening levels. The declaration also contained the following: Identification of the abandoned sanitary sewer lines and existing sewer line locations; restriction that the property use is limited to commercial and industrial; restriction that groundwater beneath the site cannot be used; and engineered barriers must remain in place on portions of the property where semi-volatile organic compounds and hexavalent chromium remain above industrial soil screening levels. GEA performs normal property maintenance inspections of the North Plant 83 and South Plant 83 to identify fencing integrity issues and to maintain weed control. These inspections also observe the integrity of the concrete cap over the East and West Tank Line removal area to ensure it is competent. GEA also ensures that the deed restriction remains in the Bernalillo County records.

Five Year Review

Operable Unit 1 (OU1)—A five-year review is not necessary for OU1 because no hazardous substances, pollutants, or contaminants remain at the site above levels that allow for unlimited use and unrestricted exposure.

Operable Unit 2 (OU2)—A five-year review is not necessary for OU2 because no hazardous substances, pollutants, or contaminants remain at the site above levels that allow for unlimited use and unrestricted exposure. While still in effect, the New Mexico State Engineer's restriction concerning groundwater well construction is no longer required for the protectiveness of the OU5 remedy because groundwater concentrations are below the maximum contaminant limits from the Safe Drinking Water Act and levels in the New Mexico Water Quality Control Commission regulations. In 1996, the OU2 groundwater monitoring program was combined with the OU6 groundwater monitoring program, which is and has been the subject of ongoing five-year reviews associated with the Site. The next five-year review for the Site is due in July 2020.

Operable Unit 5 (OU5)—A statutory five-year review is necessary for OU5 because hazardous substances, pollutants, or contaminants remain at the site above levels that allow for unlimited use and unrestricted exposure. OU5 has been the subject of ongoing five-year reviews with the next review due in July 2020. No issues and/or recommendations were identified in the 2015 five-year review for OU5.

Community Involvement

The major community involvement activities associated with the operable units proposed for deletion are as follows:

- Open Houses and Workshops: September 1988; November 1993; July 1995; October 1997; September 1998; November 1999, October 2000; November 2001; January 2013.
- Original Proposed Plan Fact Sheet and Public Meetings: June 1988; July 1988; August 1988; February 1989.
- Public Meetings: October 2000; November 2001.
- Original ROD Fact Sheets: July 1988; November 1988; April 1989.
- Milestone Fact Sheets: May 1989; March 1990; April 1990; June 1990; March 1991; November 1993; June 1995; April 1996; December 2011; January 2013; June 2015; July 2015; June 2018.
- Citizens on Site Mailing List: 590.

Other notable community involvement activities are:

- Pre Five-Year Review public notices published in local newspapers indicating Five-Year Reviews were being initiated.
- Post Five-Year Review public notices published in local newspapers indicating Five-Year Reviews were

completed and available in the local repository or from the State or EPA.

- Monthly site status summaries that were made available to the public or more recently, updates to site activities made on the site web page available on the internet.
- September 23, 2010, newspaper article in the Albuquerque Journal concerning the closure of the General Electric plant.
- Discussion of the site at public meetings associated with the Sunport Boulevard Extension from approximately 2010 to the present.
- Fact sheets and public notices have been provided in both English and Spanish.

Determination That the Criteria for Deletion Have Been Met

The implemented remedies have achieved the degree of cleanup or protection specified in the OU1, OU2, and OU5 RODs for the portions of the Site proposed for deletion. The selected remedial action goals and associated cleanup levels for the OU1, OU2, and OU5 portions of the Site proposed for deletion are consistent with EPA policy and guidance. No further Superfund response for the OU1, OU2, and OU5 portions of the Site proposed for deletion are needed to protect human health and the environment. The State of New Mexico, in an August 11, 2017, letter from the New Mexico Environment Department, concurred with the proposed partial deletion of the OU1, OU2, and OU5 portions of the Site from the NPL.

The NCP specifies that EPA may delete a site from the NPL if all appropriate response under CERCLA has been implemented and no further response action is appropriate. 40 CFR 300.425(e)(1)(ii). EPA, with the concurrence of the State of New Mexico, through NMED, believes that this criterion for the deletion of the OU1, OU2, and OU5 portions of the Site has been met and the OU1, OU2, and OU5 portions of the Site no longer pose a threat to public health or the environment. Consequently, EPA is proposing to delete the OU1, OU2, and OU5 portions of the Site from the NPL. Documents supporting this action are available in the Docket.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous waste, Hazardous substances, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Authority: 33 U.S.C. 1321(d); 42 U.S.C. 9601–9657; E.O. 13626, 77 FR 56749, 3 CFR, 2013 Comp., p. 306; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

Dated: July 19, 2018.

Arturo Blanco,

Acting Regional Administrator, Region 6.

[FR Doc. 2018–16257 Filed 7–30–18; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–SFUND–2002–0001; FRL–9981–51—Region 4]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List: Deletion of the Reasor Chemical Company Superfund Site

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; notice of intent.

SUMMARY: The Environmental Protection Agency (EPA) Region 4 is issuing a Notice of Intent to Delete the Reasor Chemical Company Superfund Site (site) located in Castle Hayne, New Hanover County, North Carolina, from the National Priorities List (NPL) and requests public comments on this proposed action. The NPL, promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is an appendix of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). The EPA and the State of North Carolina, through the North Carolina Department of Environmental Quality (NCDEQ), have determined that all appropriate response actions under CERCLA have been completed. However, this deletion does not preclude future actions under Superfund.

DATES: Comments must be received by August 30, 2018.

ADDRESSES: Submit your comments, identified by Docket ID no. EPA–HQ–SFUND–2002–0001, by one of the following methods:

- *http://www.regulations.gov.* Follow the online instructions for submitting comments. 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 *http://www2.epa.gov/dockets/commenting-epa-dockets.*
- *Email: URQUHART-FOSTER.SAMANTHA@EPA.GOV.*
- *Mail:* Samantha Urquhart-Foster, Remedial Project Manager, Remediation and Site Evaluation Branch, Superfund Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960.
- *Hand delivery:* U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID no. EPA–HQ–SFUND–2002–0001. The *http://www.regulations.gov* website is an ''anonymous access'' system, which means 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 EPA without going through *http://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, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not 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 the hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at:

- U.S. EPA Record Center, attention: Ms. Tina Terrell, Atlanta Federal Center, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. Phone: 404–562–8835. Hours: 8 a.m.–4 p.m., Monday through Friday by appointment only; and
- New Hanover County Library, 201 Chestnut Street, Wilmington, North Carolina 28401. Phone: 910–798–6391. Hours: 9 a.m.–5 p.m., Monday through Saturday.

FOR FURTHER INFORMATION CONTACT: Samantha Urquhart-Foster, Remedial Project Manager, Remediation and Site Evaluation Branch, Superfund Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. Phone: 404–562–8760, email: *URQUHART-FOSTER.SAMANTHA@EPA.GOV.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

EPA Region 4 announces its intent to delete the Reasor Chemical Company Superfund Site from the National Priorities List (NPL) and requests public comment on this proposed action. The NPL constitutes Appendix B of 40 CFR part 300 which is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), which EPA promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) of 1980, as amended. EPA maintains the NPL as the list of sites that appear to present a significant risk to public health, welfare, or the environment. Sites on the NPL may be the subject of remedial actions financed by the Hazardous Substance Superfund (Fund). As described in 40 CFR 300.425(e)(3) of the NCP, sites deleted from the NPL remain eligible for Fund-financed remedial actions if future conditions warrant such actions.

EPA will accept comments on the proposal to delete this site for thirty (30) days after publication of this document in the **Federal Register**.

Section II of this document explains the criteria for deleting sites from the NPL. Section III discusses procedures that EPA is using for this action. Section IV discusses the Reasor Chemical Company Superfund Site and demonstrates how it meets the deletion criteria.

II. NPL Deletion Criteria

The NCP establishes the criteria that EPA uses to delete sites from the NPL. In accordance with 40 CFR 300.425(e), sites may be deleted from the NPL where no further response is appropriate. In making such a determination pursuant to 40 CFR 300.425(e), EPA will consider, in consultation with the State, whether any of the following criteria have been met:

i. Responsible parties or other persons have implemented all appropriate response actions required;

ii. all appropriate Fund-financed response under CERCLA has been implemented, and no further response action by responsible parties is appropriate; or

iii. the remedial investigation has shown that the release poses no significant threat to public health or the environment and, therefore, the taking of remedial measures is not appropriate.

III. Deletion Procedures

The following procedures apply to deletion of the Site:

(1) EPA consulted with the State before developing this Notice of Intent to Delete;

(2) EPA has provided the State 30 working days for review of this notice prior to publication of it today;

(3) In accordance with the criteria discussed above, EPA has determined that no further response is appropriate;

(4) The State of North Carolina, through the NCDEQ, has concurred with deletion of the Site from the NPL.

(5) Concurrently with the publication of this Notice of Intent to Delete in the **Federal Register**, a notice is being published in a major local newspaper, the *Wilmington Star-News.* The newspaper notice announces the 30-day public comment period concerning the Notice of Intent to Delete the site from the NPL.

(6) The EPA placed copies of documents supporting the proposed deletion in the deletion docket and made these items available for public inspection and copying at the Site information repositories identified above.

If comments are received within the 30-day public comment period on this document, EPA will evaluate and respond appropriately to the comments before making a final decision to delete. If necessary, EPA will prepare a Responsiveness Summary to address any significant public comments received. After the public comment period, if EPA determines it is still appropriate to delete the Site, the Regional Administrator will publish a final Notice of Deletion in the **Federal Register**. Public notices, public submissions and copies of the Responsiveness Summary, if prepared, will be made available to interested parties and in the site information repositories listed above.

Deletion of a site from the NPL does not itself create, alter, or revoke any individual's rights or obligations. Deletion of a site from the NPL does not in any way alter EPA's right to take enforcement actions, as appropriate. The NPL is designed primarily for informational purposes and to assist EPA management. Section 300.425(e)(3) of the NCP states that the deletion of a site from the NPL does not preclude eligibility for future response actions, should future conditions warrant such actions.

IV. Basis for Site Deletion

The following information provides EPA's rationale for deleting the Site from the NPL:

Site Background and History

The Reasor Chemical Company Site (EPA ID: NCD986187094) is located at 5100 North College Road (Hwy. 132), in Castle Hayne, New Hanover County, North Carolina. Castle Hayne is approximately 13 miles north of Wilmington, NC. The site is an abandoned stump rendering facility, which operated from 1959 to 1972 under the name of Reasor Chemical Company. The site property consists of one parcel of 25.59 acres. A fire and possible explosion occurred on the property on April 7, 1972, which damaged and destroyed the remaining buildings and material on the site property. The property currently is unused, unoccupied, and covered with native brush and secondary growth forest.

The former Reasor Chemical Company reportedly produced turpentine, pine resin, pitch, tall oil, pine oil, camphor, pine tar, and charcoal from pine tree stumps. It is believed that the facility used various solvents to extract raw product from chipped stumps, distilling the extract into separate product fractions. The solvents used in the extraction process were likely stored on-site in 55-gallon drums, the remains of which were in a surface drum disposal area near the center of the property. It is thought that four of the five onsite ponds were used in the manufacturing process. Those four ponds contained sediments with elevated concentrations of volatile organic compounds (VOCs), semi-

volatile organic compounds (SVOCs) including polycyclic aromatic hydrocarbons (PAHs), and inorganic compounds. An area thought to have been used to store scrap copper metal was also present, which had elevated concentrations of copper and lead.

EPA proposed listing the site on the NPL on September 13, 2001 (66 FR 47612), and finalized the listing on September 5, 2002 (67 FR 56757). The property is currently undeveloped. The Site is currently zoned industrial.

Remedial Investigation and Feasibility Study (RI/FS)

During 1996 through 2002, Roy F. Weston, Inc. (WESTON) performed the Remedial Investigation/Feasibility Study (RI/FS) for EPA. During 2000 through 2002, EPA Region 4's Science and Ecosystem Support Division (SESD) completed the Ecological Risk Assessment (ERA). Investigations at the site revealed the presence of metals, VOCs, and SVOCs above risk-based screening values.

The human health risk assessment identified risks for potential future on-site workers and residents. These risks were primarily associated with drinking shallow groundwater and ingestion of or dermal contact with soils. The ecological risk assessment indicated that risks were posed to ecological receptors from contact with or ingestion of surface water, soil, and sediment.

Selected Remedy

EPA's Record of Decision (ROD) was signed on September 26, 2002, and the North Carolina Department of Environment and Natural Resources, (now known as the North Carolina Department of Environmental Quality (NCDEQ)), concurred with the selected remedy. EPA revised the remedy in a ROD Amendment dated June 1, 2007. The amended selected remedy included the following:

- *Soil and sediment:* Excavation and off-site disposal, backfill the excavated soil areas and vegetate with native plant species, and return the former ponds to wetland habitats.
- *Surface water:* On-site treatment and disposal.
- *Groundwater:* Backfill the drum disposal area with an alkaline substance to raise the pH of shallow groundwater, perform annual monitoring of groundwater to determine if contaminants of concern (COCs) continue to be elevated, and attach a ''Declaration of Perpetual Land Use Restrictions'' to the property title that prohibits the use of shallow groundwater for any purpose.

The Remedial Action Objectives (RAOs) for the site were:

- *Sediment:* Prevent further migration of contaminants from sediment to groundwater and surface water above levels exceeding groundwater and surface water clean-up goals; eliminate exposure of ecological receptors to contaminated sediment; achieve ecological risk-based sediment clean-up goals for: Methyl ethyl ketone, toluene, (3 and/or 4)-methylphenol, total PAHs, and copper.
- *Surface water:* Prevent further migration of contaminants above clean-up goals from Ponds 1, 2, 3 and 4, to soil, groundwater and down-gradient surface water bodies; eliminate exposure to contaminated surface water above levels exceeding clean-up goals by aquatic receptors; achieve the North Carolina Surface Water Quality Standards (NCAC Title 15A, Chapter 2, Subchapter 2B.0100 and 2B.0200) in Ponds 1, 2, 3 and 4 for: Copper, lead, iron and zinc.
- *Soil:* Prevent further migration of contaminants from soil to groundwater and surface water above levels exceeding groundwater and surface water clean-up goals; eliminate unacceptable risk to human health and the environment; achieve the human health and ecological risk based clean-up goals for: Benzo(a)pyrene, benzo(b &/or k)fluoranthene, dibenzo(a,h) anthracene, antimony, copper and lead.
- *Groundwater:* Prevent human consumption of contaminated groundwater until risk-based standards for aluminum, and Safe Drinking Water Act's Maximum Contaminant Levels (MCLs) for beryllium, chromium and nickel, are attained.

Response Actions

The Remedial Design (RD) was completed by EPA between September 2002 and January 2004. EPA and the Potentially Responsible Parties (PRPs) entered a Consent Decree in which the PRPs agreed to conduct the Remedial Action (RA). The PRPs began the RA on June 4, 2007 utilizing the remedial actions outlined in the 2007 ROD Amendment. Apex Companies, LLC (Apex) was retained by the PRPs and performed all the of the RA work described below. The RA for soil, sediment and surface water was completed in July 2007 and the Preliminary Close-Out Report was issued in September 2007. The *Interim Remedial Action and Final Remediation Report, Revision 3,* was issued in August 2008.

Approximately 140,000 gallons of contaminated water was treated and discharged on site. Approximately 2,000 tons of contaminated soils and sediments were excavated and disposed of in off-site landfills. After excavation and confirmation sampling, the ponds were allowed to naturally refill with water and vegetate. The soil excavation areas were backfilled and allowed to naturally vegetate. Lime was applied in the area of monitoring wells MW–7S and MW–7D in order to increase the groundwater pH. Increasing the pH of groundwater is intended to lower concentrations of metals in the groundwater in this area. Institutional controls in the form of a Declaration of Perpetual Land Use Restriction were filed with the property deed in 2008.

Annual sampling of groundwater monitoring wells MW–7S and MW–7D was performed when appropriate pH and turbidity levels permitted. Collection of samples for laboratory analysis was only required if the pH was between 7.2 and 8.5 using best efforts to reduce turbidity. Annual sampling events were attempted on February 11, 2008, January 28, 2009, December 7, 2009, and November 2, 2010. However, samples were not collected during any of the annual sampling events due to pH conditions recorded below 7.2 units.

Apex returned to the site on May 18, 2011, to complete a groundwater sampling event in accordance with the Amended ROD, which stated that regardless of the pH levels, samples were to be collected within five years after initiation of remedial action. The sampling event was conducted with the intent that EPA could determine if the clean-up goals had been achieved.

Based on the groundwater quality results from the May 18, 2011, sampling event, remedial actions had been successful in achieving the cleanup goals for beryllium and nickel in groundwater. However, elevated concentrations of aluminum and chromium were still present above the cleanup goals. Based on past groundwater sampling results at the site, there is a direct correlation between low sample pH, high sample turbidity, and elevated metal concentrations. Apex returned to the site on November 12, 2012, to sample for metals in MW–7D and MW–7S, collecting both an unfiltered and filtered sample to address turbidity. Due to a malfunctioning pump at MW–7S, only MW–7D could be sampled on November 12, 2012. Elevated concentrations of aluminum and chromium were still present above the Amended ROD RAOs established for the site in the unfiltered sample; however, metal concentrations were below Amended ROD RAOs established for the site in the filtered sample.

Apex conducted groundwater assessment activities at the site in December 2015 and January 2016 to fulfill the requirements of the Amended ROD. The activities included the advancement of two groundwater monitoring wells installed immediately adjacent to MW–7D and MW–7S, in addition to the collection and analysis of groundwater samples, both filtered and unfiltered.

Replacement wells MW–7SR and MW–7DR were installed to address elevated turbidity levels. It was suspected that there could have been some damage to the existing well screens which resulted in the influx of sediment. Quarterly sampling was conducted at MW–7SR and MW–7DR. Results indicated that the COCs are not present at concentration at or above applicable Amended ROD clean up goals. Based on the cancer slope factor and oral reference dose for hexavalent chromium being more stringent, chromium was speciated during the January 2016 sampling event and was not detected above laboratory detection limits in either MW–7SR or MW–7DR.

It was determined that hexavalent chromium is not a COC and concentrations of total chromium are also below the Amended ROD clean up goals. Apex completed the Final Remedial Action Report Addendum in November 2017.

As prescribed in the 2007 Amended ROD, institutional controls (ICs) were implemented in September 2008 with the placement of a Declaration of Perpetual Land Use Restrictions (DPLUR) on the property deed. The DPLUR requires annual notification to NCDEQ and EPA confirming that the DPLUR is still recorded in the Office of the New Hanover County Register of Deeds and that activities and conditions at the site remain in compliance with the land use restrictions. The land use restrictions in the DPLUR state that groundwater from the surficial aquifer underlying the site may not be used for any purpose. Groundwater located beneath the confining layer shall not be used as a source of potable water. Any groundwater well or other device for access to groundwater for any purpose other than monitoring groundwater quality must include an isolation seal between the surficial aquifer and the Peedee Formation aquifer located below. The installation of groundwater wells or other devices for access to groundwater for any purpose other than monitoring groundwater quality requires prior approval by NCDEQ, or its successor in function. The owner(s) of the property must provide written notification to EPA prior to seeking approval from NCDEQ for the installation of groundwater wells.

Cleanup Levels

Cleanup goals were established to achieve a 10^{-5} (one in 100,000) excess carcinogenic risk level for potential future resident children (most conservative risk category evaluated) and/or a hazard quotient (HQ) of 1 for potential resident children or ecological receptors.

Surface Water: Although the treatment system did not reduce contaminant concentrations in surface water to below cleanup goals during its operation in 2007, the RAOs were achieved for the following reasons:

- Migration of and aquatic receptor exposure to contaminated surface water was halted by
  - treating all surface water in ponds and land applying treated water;
  - excavating contaminated soils to residential cleanup standards;
  - excavating contaminated sediments to ecological cleanup goals and placing 18 to 60 inches of non-contaminated soil over the base of the excavated ponds; and
  - allowing the ponds to refill naturally.

Soil: Cleanup goals specified in the 2007 ROD Amendment for soil were attained.

All confirmation sample results from the soil excavation areas were below the ROD-specified cleanup goals.

Sediment: Ten samples were collected and analyzed to determine if cleanup goals were met in the four sediment excavation areas. Six confirmation samples were collected from the four excavated ponds in June 2007. One sample was a duplicate of another sample in Pond 3. The duplicate sample result was within the same order of magnitude as the sample from which it was split. Because the laboratory detection limits for (3 and/or 4)-methylphenol and methyl ethyl ketone (also known as butanone) were higher than the cleanup goals, the four ponds were resampled in August 2007 and analyzed for these two COCs.

Cleanup goals for toluene and copper were attained in all four ponds. The cleanup goal for methyl ethyl ketone (also known as 2-butanone) was attained in ponds 1–3, and possibly pond 4. The original confirmation sample collected in June 2007 from pond 4 had a concentration less than the laboratory reporting limit of 100 micrograms per kilogram (µg/kg), which is less than the cleanup goal established in the 2007 ROD Amendment. However, the sample collected in pond 4 in August 2007 did not have a detectable concentration of methyl ethyl ketone but the laboratory detection limit (268 µg/kg) was greater than the cleanup goal of 137 µg/kg. Methyl ethyl ketone was not detected in any of the ponds. All ponds had at least one sample which had a laboratory detection limit that was lower than the cleanup goal.

All samples collected from the excavated ponds had concentrations of (3 and/or 4)-methylphenol above cleanup goals or the laboratory detection limit was greater than the cleanup goal. The low-level presence of (3 and/or 4)-methylphenol in the soil does not present a significant risk to human health or the environment, and further sampling and assessment is not needed for the following reasons:

- Methylphenol is a naturally occurring substance. Cresols (methylphenols) are found in many foods and in wood in this region of North Carolina. The contaminant presence at low-levels may be naturally occurring and not site-related.
- The impacted soil was removed from the lagoons and capped with 18 to 60 inches of clean fill. Therefore, the surface water within the lagoons is not in direct contact with impacted soil.
- The ROD clean-up goal of 50 µg/kg for (3 and/or 4)-methlyphenol was established based on ecological risk, not human health risk. Any residual contamination is at depths greater than 18 inches, and therefore there is no exposure route for ecological receptors. There is no obvious or adverse impact to the ecology within the lagoons as observed through the thriving aquatic flora and fauna present within lagoons over the last 11 years, since the time the lagoons were remediated in 2007.
- The concentrations present in the soil are below the EPA Regional Screening Levels (RSLs) for residential soils for methylphenol of 3,200 milligrams per kilogram (mg/kg), which is protective of human health.

The RAOs were achieved for the following reasons:

- All confirmatory samples obtained from ponds 1–4 were collected from each basin's clay liner.
- Each basin was subsequently capped with 18 inches to 60 inches of clean soil backfill.
- The RAs performed removed the contaminated ecological exposure medium, sediment, and subsequently capped the underlying clay liner with clean soil, thereby eliminating the ecological exposure pathway for sediments in the ponds and exposure to remaining residual levels in the clay layer, and thus any associated risk.

Soil or sediment samples have not been collected since the RA. For the soil

excavation areas, restoration included backfilling with soil, grading the areas to provide drainage away from the areas, revegetation with native rye grass and spreading of wood chips over the area for erosion control. Pond restoration consisted of backfilling a portion of the ponds, covering the banks of the excavation and surrounding disturbed areas with straw matting for erosion control, and seeding with native rye grass. During the final site inspection conducted in April 2017, it was observed that the excavation areas are now restored with native brush and secondary growth forest.

Groundwater: No COCs were detected at concentrations above the Amended ROD clean up goals in either sample MW–7DR or MW–7SR during 2016 quarterly groundwater sampling. The detected concentrations of these compounds are generally significantly less than the concentrations previously identified in groundwater samples collected at the Site in May 2011 and November 2012. Aluminum, beryllium, chromium, and nickel were either detected at estimated concentrations that are below the applicable criteria, or were not detected above laboratory detections limits in both the filtered and unfiltered samples.

Due to the low turbidity of the samples, the concentrations reported for both filtered and unfiltered samples were very similar. In addition to the reductions in the observed concentrations of the COCs, the pH values were also higher than historic values. The pH was measured at 3.81 in MW–7SR versus historic values ranging from 2.31 to 3.55 in MW–7S. The pH of the sample collected at MW–7DR was 6.47 versus historic values measured as low as 3.21.

In addition, pH values measured in the newly installed wells are similar to other sites in the Castle Hayne area. Based on the findings of the January 2016 sampling event, Apex conducted three additional quarterly sampling events in April, July, and October 2016 to obtain sufficient data for site closure. During these quarterly sampling events, since the January 2016 sampling results demonstrated that hexavalent chromium was not a COC, the samples were only analyzed for total chromium.

The monitoring data demonstrates that remedial action objectives and cleanup levels specified in the 2007 ROD Amendment are achieved. There are no additional monitoring or Operations and Maintenance of the remedy required.

Five-Year Reviews

The purpose of a five-year review (FYR) is to evaluate the implementation and performance of a remedy to determine if the remedy is and will continue to be protective of human health and the environment. In addition, FYR reports identify issues found during the review, if any, and document recommendations to address them. EPA completed two policy FYRs for the site in September 2012 and September 2017. The 2017 FYR determined that the remedy was protective of human health and the environment, and there were no issues or recommendations. The 2017 FYR concluded that no further FYRs are planned for the site because all impacted media have reached Unlimited Use/Unrestricted Exposure (UU/UE) categorization.

Community Involvement

EPA has communicated with the public through Fact Sheets, meetings, internet postings, newspaper ads, and answering email and phone inquiries. Current Site information can be found at *https://cumulis.epa.gov/supercpad/cursites/csitinfo.cfm?id=0405590.*

Public participation activities have been satisfied as required in CERCLA Section 113(k), 42 U.S.C. 9613(k) and CERCLA Section 117, 42 U.S.C. 9617. Documents in the deletion docket, which the EPA relied on for recommendation of the deletion from the NPL, are available to the public in the information repositories identified above.

Determination That the Site Meets the Criteria for Deletion in the NCP

Region 4 has followed the procedures required by 40 CFR 300.425(e) as mentioned above and the implemented remedy achieves the degree of cleanup specified in the ROD for all pathways of exposure. The information presented in the Final Close-Out Report verifies that the site has achieved the ROD Amendment's RAOs, and that all cleanup actions specified in the ROD Amendment were implemented. All selected remedial action objectives and associated cleanup levels are consistent with agency policy and guidance. This site meets all the site completion requirements as specified in Office of Solid Waste and Emergency Response (OSWER) Directive 9320.22, *Close-Out Procedures for National Priorities List Sites.* No further Superfund response is needed to protect human health and the environment.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous waste, Hazardous substances, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Authority: 33 U.S.C. 1321(d); 42 U.S.C. 9601–9657; E.O. 13626, 77 FR 56749, 3 CFR, 2013 Comp., p. 306; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

Dated: July 17, 2018.

Onis ''Trey'' Glenn, III,

Regional Administrator, Region 4.

[FR Doc. 2018–16244 Filed 7–30–18; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Chapter I

[CB Docket No. 18–31; DA 18–115]

Possible Revision or Elimination of Rules

AGENCY: Federal Communications Commission.

ACTION: Review of regulations; comments requested.

SUMMARY: This document invites members of the public to comment on the Commission's rules to be reviewed pursuant to section 610 of the Regulatory Flexibility Act of 1980, as amended (RFA). The purpose of the review is to determine whether Commission rules whose ten-year anniversary dates are in the years 2015–2016, as contained in the Appendix, should be continued without change, amended, or rescinded in order to minimize any significant impact the rules may have on a substantial number of small entities. Upon receipt of comments from the public, the Commission will evaluate those comments and consider whether action should be taken to rescind or amend the relevant rule(s).

DATES: Comments may be filed on or before October 29, 2018.

FOR FURTHER INFORMATION CONTACT: Sharon K. Stewart, Women's Outreach Specialist, Office of Communications Business Opportunities (OCBO), Federal Communications Commission, (202) 418–0990. People with disabilities may contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by email: *fcc504@fcc.gov* or phone: 202–418–0530 or TTY: 202–418–0432.

ADDRESSES: You may submit comments, identified by CB Docket No. 18–31, by any of the following methods:

- *Federal Communications Commission's Website: http://apps.fcc.gov/ecfs//.* Follow the instructions for submitting comments.
- *People with Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by email: *FCC504@fcc.gov* or phone: 202–418–0530 or TTY: 888–835–5322.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

SUPPLEMENTARY INFORMATION: Each year the Commission will publish a list of ten-year old rules for review and comment by interested parties pursuant to the requirements of section 610 of the RFA.

Synopsis

1. Pursuant to the Regulatory Flexibility Act (RFA), *see* 5 U.S.C. 610, the FCC hereby publishes a plan for the review of rules adopted by the agency in calendar years 2005–2006 which have, or might have, a significant economic impact on a substantial number of small entities. The purpose of the review is to determine whether such rules should be continued without change, or should be amended or rescinded, consistent with the stated objective of section 610 of the RFA, to minimize any significant economic impact of such rules upon a substantial number of small entities.

2. This document lists the FCC regulations to be reviewed during the next twelve months. In succeeding years, as here, the Commission will publish a list for the review of regulations promulgated ten years preceding the year of review.

3. In reviewing each rule in a manner consistent with the requirements of section 610, the FCC will consider the following factors:

(a) The continued need for the rule;

(b) The nature of complaints or comments from the public concerning the rule;

(c) The complexity of the rule;

(d) The extent to which the rule overlaps, duplicates, or conflicts with other federal rules and, to the extent feasible, with state and local governmental rules; and

(e) The length of time since the rule has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule.

4. Appropriate information has been provided in the Appendix for each rule, as chosen for review by the FCC according to the requirements of section 610, including a *Brief Description* of the rule and the need for, and *Legal Basis* of, the rule. The public is invited to comment on these rules, and all relevant and timely comments will be considered by the FCC before final action is taken in this proceeding.

5. Pursuant to sections 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated on the first page of this document. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS). *See Electronic Filing of Documents in Rulemaking Proceedings,* 63 FR 24121 (1998).

- *Electronic Filers:* Comments may be filed electronically using the internet by accessing the ECFS: *http://apps.fcc.gov/ecfs/.*
- *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number. Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.
- All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th St. SW, Room TW–A325, Washington, DC 20554. The filing hours are 8:00 a.m. to 7:00 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes and boxes must be disposed of *before* entering the building.
- Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9050 Junction Drive, Annapolis Junction, MD 20701.
- U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street SW, Washington, DC 20554.

People with Disabilities: To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).

6. The proceeding this Notice initiates shall be treated as a ''permit-but-disclose'' proceeding in accordance with the Commission's *ex parte* rules.[1] Persons making *ex parte* presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the *ex parte* presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during *ex parte* meetings are deemed to be written *ex parte* presentations and must be filed consistent with rule 1.1206(b). In proceedings governed by rule 1.49(f) or for which the Commission has made available a method of electronic filing, written *ex parte* presentations and memoranda summarizing oral *ex parte* presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (*e.g.,* .doc, .xml, .ppt, searchable .pdf). Participants in this proceeding should familiarize themselves with the Commission's *ex parte* rules.

7. For information on the requirements of the RFA, the public may contact Sharon K. Stewart, Women's Outreach Specialist, Office of Communications Business Opportunities, 202–418–0990 or visit *www.fcc.gov/ocbo.*

Federal Communications Commission.

Sanford S. Williams,

Director, Office of Communications Business Opportunities.

List of rules for review pursuant to the Regulatory Flexibility Act of 1980, 5 U.S.C. Section 610, for the ten-year

[1] 47 CFR 1.1200 *et seq.*

period beginning in the year 2005 and ending in the year 2006. All listed rules are in title 47 of the Code of Federal Regulations.

PART 1—PRACTICE AND PROCEDURE

Subpart E—Complaints, Applications, Tariffs, and Reports Involving Common Carriers

Brief Description: Section 1.767 sets forth the application filing requirements for submarine cable landing licenses. Section 1.768 sets forth the notification and prior approval requirements for submarine cable landing licensees that are or propose to become affiliated with a foreign carrier.

Need: The rules are needed to implement the Commission's policies that facilitate the expansion of capacity and facilities-based competition in the submarine cable market. These measures are designed to enable international carriers to respond to the demands of the market with minimal regulatory oversight and delay, saving time and resources for both the industry and government, while preserving the Commission's ability to guard against anticompetitive behavior.

Legal Basis: 47 U.S.C. 151, 154(i), 154(j), 155, 225, 303(r), 309 and 325(e).

Section Number and Titles:

1.767(a), (a)(5), (a)(7)–(11), (g)–(n) Cable landing licenses.

1.768, (h)–(j) Notification by and prior approval for submarine cable landing licensees that are or propose to become affiliated with a foreign carrier.

Subpart F—Wireless Radio Services Applications and Proceedings

Brief Description: Part 1 states the general rules of practice and procedure before the Federal Communications Commission. Subpart F sets forth the requirements and conditions under which entities may be licensed in the Wireless Radio Services as described in parts 1, 13, 20, 22, 24, 26, 27, 74, 80, 87, 90, 95, 97 and 101.

Need: These recodifications of Part 22 rules (1.958 and 1.959) establish the required distance and terrain elevation calculation methods applicable to all Wireless Radio Services (except Parts 21 and 101) (Parts 1, 20, 22, 24, 27, 80 87, 90, 95, and 97); implement the Commission's policies with regard to the processing of applications (1.913(a)(6) and 1.919(b)(5)) and the protection of Federal Government operations (1.924(e)); and revise the procedures for the amateur service vanity call sign system (1.934(d)(5)). The need for these rules is ongoing.

Legal Basis: 15 U.S.C 79 *et seq.;* 47 U.S.C. 151, 154, 154(i), 154(j), 155, 157, 225, 227, 303, 303(r), 307, 309 and 332.

Section Number and Titles:

1.913(a)(6) Application and notification forms; electronic and manual filing.

1.919(b)(5) Ownership Information.

1.924(e)(4) Quiet zones. (Revised 2015)

1.934(d)(5) Defective applications and dismissal.

1.958 Distance computation. (Revised 2014)

1.959 Computation of average terrain elevation.

Subpart G—Schedule of Statutory Charges and Procedures for Payment

Brief Description: These rules specify the schedule of annual regulatory fees and filing locations for the designated payors.

Need: Congress sets the amount the Commission must collect each year in the Commission's fiscal year appropriations. Section 9(a)(2) of the Communications Act of 1934, as amended (Communications Act or Act) requires the Commission to collect fees sufficient to offset the amount appropriated.[2] These rules specify the fees for the Commission's regulatees.

Legal Basis: 47 U.S.C. 159.

Section Number and Titles:

1.1102 Table amended—Schedule of charges for applications and other filings in the wireless telecommunications services.

1.1107 Table corrected—Schedule of charges for applications and other filings for the international services.

1.1152 Table amended—Schedule of annual regulatory fees and filing locations for wireless radio services.

1.1153 Revised—Schedule of annual regulatory fees and filing locations for mass media services.

1.1154 Revised—Schedule of annual regulatory charges for common carrier services.

1.1155 Revised—Schedule of regulatory fees for cable television services.

1.1156 Revised—Schedule of regulatory fees for international services.

Subpart Q—Competitive Bidding Proceedings

Brief Description: Part 1 states the general rules of practice and procedure before the Federal Communications Commission. Subpart Q sets forth the provisions implementing Section 309(j) of the Communications Act of 1934, as amended, authorizing the Commission to employ competitive bidding procedures to resolve mutually exclusive applications for certain initial licenses.

Need: These rules are needed on an ongoing basis to implement the Commission's competitive bidding authority under Section 309(j) of the Communications Act of 1934, as amended, including the designated entity and tribal land bidding credit programs.

Legal Basis: 47 U.S.C. 151, 154(i), 154(j), 155, 157, 225, 303(r) and 309(j).

Section Number and Titles:

1.2104(j)(1)–(2) Competitive bidding mechanisms. (Renumbered 2014)

1.2107(g) Submission of down payment and filing of long-form applications.

1.2111(b)(2)(ii) Assignment or transfer of control: Unjust enrichment. (Renumbered 2015)

1.2112(b)(1)(iii)–(iv) Ownership disclosure requirements for applications. (Revised 2016)

1.2114 Reporting of eligibility event. (Revised 2015)

Subpart Y—International Bureau Filing System

Brief Description: Subpart Y describes the procedures for electronic filing of international and satellite services applications using the International Bureau Filing System (IBFS).

Need: Subpart Y is necessary as it codifies the use of the International Bureau Filing System (IBFS) as an official method of filing applications related to satellite and international telecommunications services with the Commission. Electronic filing improves the speed and efficiency of application processing and also expedites the availability of application information for public use and inspection.

Legal Basis: 47 U.S.C. 151, 154(i), 154(j), 155, 225, 303(r), 309 and 325(e).

Section Number and Titles: (originally codified at 1.9000–9018).

1.10000 What is the purpose of these rules?

1.10001 Definitions.

1.10002 What happens if the rules conflict?

1.10003 When can I start operating?

1.10004 What am I allowed to do if I am approved?

1.10005 What is IBFS?

1.10006 Is electronic filing mandatory?

1.10007, (a)–(c) What applications can I file electronically?

1.10008 What are IBFS file numbers?

1.10009 What are the steps for electronic filing?

[2] 47 U.S.C. 159(a)(2).

1.10010 Do I need to send paper copies with my electronic applications?
1.10011 Who may sign applications?
1.10012 When can I file on IBFS?
1.10013 How do I check the status of my application after I file it?
1.10014 What happens after officially filing my application?
1.10015 Are there exceptions for emergency filings?
1.10016 How do I apply for special temporary authority?
1.10017 How can I submit additional information?
1.10018 May I amend my application?

PART 2—FREQUENCY ALLOCATIONS AND RADIO TREATY MATTERS; GENERAL RULES AND REGULATIONS

Subpart J—Equipment Authorization Procedures

Brief Description: An application for certification of a software defined radio must include the information required by section 2.944.

Need: Section 2.1033 ensures that applications for certification include information sufficient to demonstrate compliance with all pertinent requirements. Paragraph (c)(18) requires an application for certification of a software defined radio to include an exhibit that addresses the specific requirements of Section 2.944, Software defined radios. Pursuant to that section, in order to assure that the device may only operate within the radio parameters for which it was approved, manufacturers must take steps to ensure that only software that has been approved for use with the software defined radio can be loaded into the radio. This rule affects small entities that are identified as manufacturers.

Legal Basis: 47 U.S.C. 154, 302a, 303, and 336, unless otherwise noted.

Section Number and Title:

2.1033 Application for certification.

PART 15—RADIO FREQUENCY DEVICES

Subpart B—Unintentional Radiators

Brief Description: All TV broadcast receivers shipped in interstate commerce or imported into the United States, for sale or resale to the public, shall comply with the provisions of this section, except that paragraphs (f) and (g) of this section shall not apple to the features of such sets that provide for reception of digital television signals.

Need: This rule contains requirements adopted pursuant to the All-Channel Receiver Act, 47 U.S.C. 303(s), to ensure that that TV receivers are capable of adequately receiving all channels allocated for the TV broadcast service.

Legal Basis: 47 U.S.C. 154, 302a, 303, 304, 307, 336, 544a, and 549.

Section Number and Title:

15.117 TV broadcast receivers.

Subpart C—Intentional Radiators

Brief Description: Client devices that operate in a master/client network may be certified if they have the capability of operating outside permissible part 15 frequency bands, provided they operate on only permissible part 15 frequencies under the control of the master device with which they communicate.

Need: This rule benefits equipment manufacturers by allowing the certification of transmitters that can be used in multiple countries, thus reducing equipment costs, while minimizing the likelihood that these devices will operate outside permissible frequency bands within the United States and cause interference to authorized services.

Legal Basis: 47 U.S.C. 154, 302a, 303, 304, 307, 336, 544a, and 549.

Section Number and Title:

15.202 Certified operating frequency range.

Brief Description: Section 15.231(a)(5) allows remote control devices to be operated with transmission durations greater than five seconds but less than ten seconds during equipment setup.

Need: There is a need, in some cases, to allow installers of complex security systems to initiate transmissions for greater than the five seconds duration otherwise permitted under Section 15.231. To minimize the likelihood of interference to authorized users of the spectrum the rule limits setup transmissions to no more than ten seconds. This allows manufacturers flexibility in the design of complex security systems while limiting the increase in interference potential of those systems.

Legal Basis: 47 U.S.C. 154, 302a, 303(e), 303, 304, 307, 336, 544a, and 549.

Section Number and Title:

15.231 Periodic operation in the band 40.66–40.70 MHz and above 70 MHz.

PART 20—COMMERCIAL MOBILE SERVICES

Brief Description: Part 20 rules set forth the Commission's requirements and conditions for commercial mobile radio service providers under the Communications Act of 1934, as amended.

Need: These rules are needed on an ongoing basis to implement the Commission's interconnection regulations between local exchange carriers and commercial mobile radio service providers, including compensation and arbitration obligations.

Legal Basis: 47 U.S.C. 151, 152(a), 154(i), 157, 160, 201, 214, 222, 251(e), 301, 302, 303, 303(b), 303(r), 307(a), 309(j)(3), 316(a), 332, 610, 615, 615a, 615b and 615c.

Section Number and Titles:

20.11(d), (e) Interconnection to facilities of local exchange carriers.

Brief Description: Section 20.19 requires providers of covered mobile services and the manufacturers of handsets used with these services to offer a selection of hearing aid-compatible handsets. Providers and manufacturers must ensure that a certain minimum percentage or number of the handsets that they offer meet a specified rating for compatibility with hearing aids in acoustic coupling mode (coupling via the hearing aid microphone) and inductive coupling mode (coupling via a telecoil), as measured under Commission-approved technical standards. In 2005, section 20.19 was amended by adding subsection (b)(4), which directs states that adopt and enforce the Commission's hearing aid compatibility rules on delegated authority to refer to the Commission's Office of Engineering and Technology any questions involving factual determinations of whether particular equipment complies with the Commission-approved technical standards.

Need: Section 20.19 implements, for wireless handsets, the statutory requirement under 47 U.S.C. 610(b) that telephones and devices used for advanced communications services provide internal means for effective use with compatible hearing aids. The rule is also necessary to ensure reasonable access to commercial mobile services by persons with impaired hearing, as required under 47 U.S.C. 610(a).

Legal Basis: 47 U.S.C. 151, 154(i), 157, 160, 201, 202, 208, 214, 301, 302, 303, 308, 309(j), 310, and 610.

Section Number and Title:

20.19(b)(4) Hearing aid-compatible mobile handsets; technical standards.

PART 22—PUBLIC MOBILE SERVICES

Subpart E—Paging and Radiotelephone Service

Brief Description: In 2006, this rule added clarification on reimbursement and relocation expenses when an emerging technologies (ET) services

licensee relocates a paired Paging and Radiotelephone Services (PARS) link under certain conditions.

Need: As part of the effort to transition microwave channels for use by ET services, this provision promotes the transition and accomplishes regulatory parity with a similar provision in Part 27. The need for this rule is ongoing.

Legal Basis: 47 U.S.C. 154, 222, 303, 309 and 332.

Section Number and Title:

22.602(k) Transition of the 2110–2130 and 2160–2180 MHz channels to emerging technologies; Reimbursement and relocation expenses in the 2110–2130 MHz and 2160–2180 MHz bands.

Subpart G—Air-Ground Radiotelephone Service

Brief Description: These rules refined the Commercial Aviation Air-Ground Systems within the Air-Ground Radiotelephone Service. Section 22.853 limits any Air-Ground Radiotelephone Service licensee to the use of no more than 3 MHz of spectrum in the service bands. Section 22.877 defines unacceptable interference to non-cellular Part 90 licensees from this service as equivalent to the definition in Section 22.970 applicable to the Cellular Radiotelephone Service. Section 22.878 outlines the obligations to abate unacceptable interference from commercial aviation ground stations, divided into strict responsibility for single licensees, and joint and several responsibility for multiple licensees. Section 22.879 outlines the interference resolution procedures applicable to licenses for commercial aviation ground stations after a certain date, including notification, interference analysis, and mitigation. Section 22.880 enforces information exchange between this service and public safety/critical infrastructure industry licensees, requiring notification upon request of activation or modification of a ground station site. Section 22.881 defines the service to be subject to competitive bidding, according to the procedures set forth in Part 1, Subpart Q of the same Chapter. Finally, Section 22.882 establishes bidding credits for eligible designated entities to reduce the cost of winning bids for commercial Air-Ground Radiotelephone Service licenses.

Need: In refining the statutory requirements for the Commercial Aviation Air-Ground Radiotelephone Service, which remains in operation today, these rules contain various provisions that advance the interests of small businesses, including those providing for access to the spectrum and those imposing interference limitations, abatement and resolution procedures, including information exchange and notification, to provide small business licensees with further leverage to receive protection from interference. Finally, the rules establish bidding credits for eligible designated entities to encourage participation in the Air-Ground Radiotelephone Services for small and very small businesses as defined. The need for these rules is ongoing.

Legal Basis: 47 U.S.C. 154, 222, 303, 309 and 332.

Section Number and Titles:

22.853 Eligibility to hold interest in licenses limited to 3 MHz of spectrum.
22.877 Unacceptable interference to part 90 non-cellular 800 MHz licensees from commercial aviation air-ground systems.
22.878 Obligation to abate unacceptable interference.
22.879 Interference resolution procedures.
22.880 Information exchange.
22.881 Air-Ground Radiotelephone Service subject to competitive bidding.
22.882 Designated entities.

PART 25—SATELLITE COMMUNICATIONS

Subpart A—General

Brief Description: Part 25 contains the Commission's rules governing the licensing and operation of space stations and earth stations. It includes application requirements, technical requirements, operational requirements, and coordination requirements for various satellite services. The rules also define the Commission's processing of applications.

Need: The Part 25 rules are needed to ensure that satellite services may be provided without harmful interference and consistent with the public interest.

Legal Basis: 47 U.S.C. 154, 301, 302, 303, 307, 309, 310, 319, 332, 605, 721.

Section Number and Titles:

25.103 Definitions.
25.109(c) Cross reference.

Subpart B—Applications and Licenses

25.110 Filing of applications, fees, and number of copies.
25.111(b), (c) Additional information, ITU filings, and ITU cost recovery.
25.112(a)(3), (b) introductory text Dismissal and return of applications.
25.113 Heading and (a) [formerly partially in 25.136, 25.143(i), (j), (k)], (g), (h) Station licenses and launch authority.
25.114 Applications for space station authorizations.
25.115(a)(1), (2)(iii), (c)(1), (2), (e), (f) [formerly primarily in 25.134] Applications for earth station authorizations.
25.116(b)(5), (c) introductory text, (d), (e) Amendments to applications.
25.117(a), (c), (d)(1), (2), (3), (g) Modification of station license.
25.118(b), (e) Modifications not requiring prior authorization.
25.119(a), (c), (d), (g) Assignment or transfer of control of station authorization.
25.120(b) Application for special temporary authorization.
25.121 License term and renewals.
25.129 Equipment authorization for portable earth-station transceivers.
25.130(a), (f) Filing requirements for transmitting earth stations.
25.131(a), (b), (h), (i), (j) Filing requirements and registration for receive-only earth stations.
25.132(a) Verification of earth station antenna performance.
25.133(a), (b) Period of construction; certification of commencement of operation.
25.135(c), (d) Licensing provisions for earth station networks in the non-voice, non-geostationary Mobile-Satellite Service.
25.287 [formerly partially in 25.136] Requirements pertaining to operation of mobile stations in the NVNG, 1.5/1.6 GHz, 1.6/2.4 GHz, and 2 GHz Mobile-Satellite Service bands.
25.137 Requests for U.S. market access through non-U.S.-licensed space stations.
25.138(a) introductory text, (a)(6), (f) Licensing requirements for GSO FSS earth stations in the conventional Ka-band.
25.139 NGSO FSS coordination and information sharing between MVDDS licensees in the 12.2 GHz to 12.7 GHz band.
25.140(a) [formerly generally in 25.140(b)] Further requirements for license applications for GSO space station operation in the FSS and the 17/24 GHz BSS.
25.142(a)(1) Licensing provisions for the non-voice, non-geostationary Mobile-Satellite Service.
25.285 [formerly generally in 25.143(i), (j), (k)] Operation of MSS and ATC transmitters or transceivers on board civil aircraft.
25.143(b)(1) Licensing provisions for the 1.6/2.4 GHz mobile-satellite service and 2 GHz mobile-satellite service.

25.144(b) Licensing provisions for the 2.3 GHz satellite digital audio radio service.
25.145 Licensing provisions for the FSS in the 18.3–20.2 GHz and 28.35–30.0 GHz bands.
25.146 Licensing and operating rules for the NGSO FSS in the 10.7–14.5 GHz bands.
25.148 Licensing provisions for the Direct Broadcast Satellite Service.
25.149 (a)(1) note added Application requirements for ancillary terrestrial components in Mobile-Satellite Service networks operating in the 1.5/1.6 GHz and 1.6/2.4 GHz Mobile-Satellite Service.
25.151(c)(2), (d), (e) Public notice.
25.154(a)(3), (c), (d), (e) Opposition to applications and other pleadings.
25.155 Mutually exclusive applications.
25.156(d) Consideration of applications.
25.157 Consideration of applications for NGSO-like satellite operation.
25.158 Consideration of applications for GSO-like satellite operation.
25.159 Limits on pending applications and unbuilt satellite systems.
25.161(a) Automatic termination of station authorization.
25.164 Milestones.
25.165 Surety bonds.

Subpart C—Technical Standards

25.202(a)(1), (3), (4), (5), (6), (7), (8) Frequencies, frequency tolerance, and emission limits.
25.203(a), (b), (c), (d), (i) introductory text, (k) Choice of sites and frequencies.
25.204(a), (b), (h), (i) Power limits for earth stations.
25.205 Minimum antenna elevation angle.
25.208(a), (c), (d), (l), (m), (o), (p)–(v) Power flux density limits.
25.209(f) Earth station antenna performance standards.
25.210(c) [formerly in 25.215], (f), (j) Technical requirements for space stations.
25.211 heading, (d), (e) Analog video transmissions in the Fixed-Satellite Services.
25.212 heading, (c), (d), (e) Narrowband analog transmissions, digital transmissions and video transmissions in the GSO Fixed-Satellite Service.
25.213(b) Inter-Service coordination requirements for the 1.6/2.4 GHz mobile-satellite service.
25.216 Limits on emissions from mobile earth stations for protection of aeronautical radionavigation-satellite service.
25.217 Default service rules.
25.220 Non-routine transmit/receive earth station operations.
25.221 Blanket licensing provisions for earth stations on vessels (ESVs) receiving in the 3700–4200 MHz (Earth-to-space) frequency band and transmitting in the 5925–6426 MHz (space-to-Earth) frequency band, operating with Geostationary Satellites in the Fixed-Satellite Service.
25.222 Blanket Licensing provisions for Earth Stations on Vessels (ESVs) receiving in the 10.95–11.2 GHz (space-to-Earth), 11.45–11.7 GHz (space-to-Earth), 11.7–12.2 GHz (space-to-Earth) frequency bands and transmitting in the 14.0–14.5 GHz (Earth-to-space) frequency band, operating with Geostationary Satellites in the Fixed-Satellite Service.
25.253 Special requirements for ancillary terrestrial components operating in the 1626.5–1660.5 MHz/1525–1559 MHz bands.
25.254 Special requirements for ancillary terrestrial components operating in the 1610–1626.5 MHz/2483.5–2500 MHz bands.
25.255 Procedures for resolving harmful interference related to operation of ancillary terrestrial components operating in the 1.5/1.6 GHz and 1.6/2.4 GHz bands.
25.256 Special Requirements for operations in the 3.65–3.7 GHz band.
25.258 Sharing between NGSO MSS feeder-link stations and GSO FSS services in the 29.25–29.5 GHz band.
25.261 Procedures for avoidance of in-line interference events for Non Geostationary Satellite Orbit (NGSO) Satellite Network Operations in the Fixed-Satellite Service (FSS) Bands.

Subpart D—Technical Operations

25.271(b), (c) introductory text, (c)(5), (e), (f) Control of transmitting stations.
25.274(e), (f) [redesignated as new (g)], new (f) Procedures to be followed in the event of harmful interference.
25.277(b), (c), (d), (f) Temporary fixed earth station operations.
25.280 Inclined orbit operations.
25.282 Orbit raising maneuvers.
25.283 End-of-life disposal.
25.284 Emergency Call Center Service.

Subpart F—Competitive Bidding Procedures for DARS

25.401 Satellite DARS applications subject to competitive bidding.
25.404 Submission of down payment and filing of long-form applications.

Subpart I—Equal Employment Opportunities

25.601 Equal employment opportunities.

Subpart J—Public Interest Obligations

25.701 Other DBS Public interest obligations.

PART 27—MISCELLANEOUS WIRELESS COMMUNICATIONS SERVICE

Subpart A—General Information

Brief Description: Part 27 contains service and licensing rules for Miscellaneous Wireless Communications Services. Subpart A contains general information.

Need: The revised rules specify that the part 27 rules apply to the Broadband Radio (BRS) and Educational Broadband (EBS) service frequencies in the 2495–2690 MHz. They also add a reference to part 74, the rule part applicable to experimental radio, auxiliary, special broadcast and other program distributional services, as also being applicable to Wireless Communications Service. The need for these rules is ongoing.

Legal Basis: 47 U.S.C. 154, 301, 302, 303, 307, 309, 332, 336, 337, 1403, 1404 and 1451.

Section Number and Titles:

27.1(b)(9) Basis and purpose.
27.3(o) Other applicable rule parts.

Subpart C—Technical Standards

Brief Description: Part 27 contains service and licensing rules for Miscellaneous Wireless Communications Services. Subpart C contains technical standards applicable to a number of services and frequency bands.

Need: The additional rules add power limits for particular types of services that may be offered as BRS or EBS, as well as the measurement procedures and an alternative out of band emissions limit for BRS. The need for these rules is ongoing.

Legal Basis: 47 U.S.C. 154, 301, 302, 303, 307, 309, 332, 336, 337, 1403, 1404 and 1451.

Section Number and Titles:

27.50(h)(3), (4) Power limits and duty cycle.
27.53(m)(6), (7) Emission limits.

Subpart L—1695–1710 MHz, 1710–1755 MHz, 1755–1780 MHz, 2110–2155 MHz, 2155–2180 MHz, 2180–2200 MHz Bands

Brief Description: Part 27 contains service and licensing rules for Miscellaneous Wireless Communications Services. Subpart L contains rules that are applicable to AWS–1 (Advanced Wireless Service) stations operating in the 1710–1755/2110–2155 MHz band and rules applicable to AWS–3 stations operating in the 1695–1710 and 1755–1780/2155–2180 MHz bands and to AWS–4 stations operating in the 2000–2020/2180–2200 MHz bands.

Need: The revised rules establish the relocation and cost sharing rules for relocation of incumbent microwave stations and BRS stations out of the spectrum reallocated to create the AWS bands. The need for these rules is ongoing.

Legal Basis: 47 U.S.C. 154, 301, 302, 303, 307, 309, 332, 336, 337, 1403, 1404 and 1451.

Section Number and Titles:

Cost-Sharing Policies Governing Microwave Relocation from the 2110–2150 MHz and 2160–2200 MHz Bands

27.1160 Cost-sharing requirements for AWS.
27.1162 Administration of the Cost-Sharing Plan.
27.1164 The cost-sharing formula.
27.1166 Reimbursement under the Cost-Sharing Plan.
27.1168 Triggering a reimbursement obligation.
27.1170 Payment issues.
27.1172 Dispute resolution under the Cost-Sharing Plan.
27.1174 Termination of cost-sharing obligations.

Cost-Sharing Policies Governing Broadband Radio Service Relocation From the 2150–2160/62 MHz Band

27.1176 Cost-sharing requirements for AWS in the 2150–2160/62 MHz band.
27.1178 Administration of the Cost-Sharing Plan.
27.1180 The cost-sharing formula.
27.1182 Reimbursement under the Cost-Sharing Plan.
27.1184 Triggering a reimbursement obligation.
27.1186 Payment issues.
27.1188 Dispute resolution under the Cost-Sharing Plan.
27.1190 Termination of cost-sharing obligations.

Subpart M—Broadband Radio Service and Educational Broadband Service

Brief Description: Part 27 contains service and licensing rules for Miscellaneous Wireless Communications Services. Subpart M contains specific rules applicable to the Broadband Radio (BRS) and Educational Broadband (EBS) services that operate in the 2500–2690 MHz band.

Need: The rules specified in 47 CFR 27.1201–27.1221 provide grandfather rights for certain commercial EBS licenses and licensees holding channel E and F licenses, and establish maximum terms for leases of EBS frequencies. The rules in 47 CFR 27.1250–27.1255 establish procedures for relocating Broadband Radio Service licensees from the 2150–2160/62 MHz band to accommodate deployment of Advanced Wireless Service. The need for these rules is ongoing.

Legal Basis: 47 U.S.C. 154, 301, 302, 303, 307, 309, 332, 336, 337, 1403, 1404 and 1451.

Section Number and Titles:

27.1201(d) EBS eligibility.
27.1214(e) EBS spectrum leasing arrangements and grandfathered leases.
27.1216 Grandfathered E and F group EBS licenses.

Technical Standards

27.1221(c), (d) and (e) Interference protection.

Brief Description: Part 27 contains service and licensing rules for Miscellaneous Wireless Communications Services. Subpart M contains specific rules applicable to the Broadband Radio (BRS) and Educational Broadband (EBS) services that operate in the 2500–2690 MHz band.

Need: The rules in 47 CFR 27.1230–27.1239, including the specific provisions below, establish procedures governing the transition of the 2500–2690 MHz band from use by the Multipoint Distribution Service (MDS), the Multichannel Multipoint Distribution Service (MMDS) and the Instructional Television Fixed Service (ITFS) to use by the Broadband Radio Service (BRS) and the Educational Broadband Service (EBS). Since this transition has been completed, these rules are no longer needed.

Legal Basis: 47 U.S.C. 154, 301, 302, 303, 307, 309, 332, 336, 337, 1403, 1404 and 1451.

Section Number and Titles:

Policies Governing the Transition of the 2500–2690 MHz Band BRS and EBS

27.1232(d)(3), (4) Planning the transition.
27.1235(d) Post-transition notification.
27.1236 Self-transitions.
27.1237 Pro rata allocation of transition costs.
27.1238 Eligible costs.
27.1239 Reimbursement obligation.

Relocation Procedures for 2150–2160/62 MHz

27.1250 Transition of the 2150–2160/62 MHz band from the Broadband Radio Service to the Advanced Wireless Service.
27.1251 Mandatory negotiations.
27.1252 Involuntary relocation procedures.
27.1253 Sunset provisions.
27.1254 Eligibility.
27.1255 Relocation criteria for Broadband Radio Service licensees in the 2150–2160/62 MHz band.

PART 43—REPORTS OF COMMUNICATION COMMON CARRIERS AND CERTAIN AFFILIATES

Brief Description: Section 43.51 imposes on U.S. telecommunications carriers identified in section 43.51(b) a general obligation to file with the Commission, within 30 days of execution thereof, a copy of all contracts, agreements, concessions, licenses, authorizations, operating agreements, or other arrangements (including amendments) to which it is a party with respect to exchange of services, the interchange or routing of traffic, and matters concerning rates, accounting rates, divisions of tolls, or the basis of settlement of traffic balances. Section 43.51(b)(1) provides that the general filing rule applies to domestic dominant carriers. Section 43.51(b)(2) provides that the filing rule applies to U.S. international carriers that have been classified as dominant on any route included in the contract (other than those so classified because of a foreign-carrier affiliation under Section 63.10). Section 43.51(c) provides that contracts for domestic-only service do not need to be filed with the Commission but need to be made available upon reasonable request. Section 43.51(d) states that any U.S. carrier, other than a provider of commercial radio services, that is engaged in foreign communications, and enters into an agreement with a foreign carrier, is subject to the Commission's authority to require the U.S. carrier providing service on any U.S.-international routes to file, on an as-needed basis, a copy of each agreement to which it is a party.

Need: The general rule in section 43.51 that carriers must file copies of their contracts and operating agreements is needed to require domestic dominant carriers to file their contracts and to address issues on the U.S.-Cuba route and more generally allow the Commission to obtain contracts for routes on which there is, or has been an

allegation of, anticompetitive conduct. *ISP Reform Order,* 19 FCC Rcd 5709, 5736 (2009).

Legal Basis: 47 U.S.C. 154, 211, 219 and 220.

Section Number and Title:

43.51 Contracts and concessions.

PART 54—UNIVERSAL SERVICE

Subpart A—General Information

Brief Description: Part 54 rules implement section 254 of the Communications Act of 1934, as amended, concerning the Federal universal service program. This rule adopts a new definition of ''rural area'' for the rural health care program.

Need: This rule establishes a definition that accurately defines the rural areas eligible for support under the rural health care program.

Legal Basis: 47 U.S.C. 151, 154(i), 154(j), 201–205, 214, 254, and 403.

Section Number and Title:

54.5 Terms and definitions (when adopted; now 54.600(b)(1) Terms and conditions).

Subpart C—Carriers Eligible for Universal Service Support

Brief Description: Subpart C sets forth the eligibility requirements to receive universal service support. These rules address the requirements for a telecommunications carrier to be designated as an ''eligible telecommunications carrier,'' and thus eligible to receive federal universal service support. Specifically, these rules comprise additional mandatory requirements for ETC designation proceedings in which the Commission acts pursuant to section 214(e)(6) of the Communications Act of 1934, as amended (the Act).[3]

Need: Application of these requirements allows for a more predictable ETC designation process and improve the long-term sustainability of the universal service fund.

Legal Basis: 47 U.S.C. 151, 154(i), 154(j), 155, 201–205, 214, 219, 254 303(r) and 403, and 1302.

Section Number and Title:

54.202(a)(2) and (3), (c) and (d) (when adopted; now 54.202(a)(2) and (3), (b) and (c)) Additional requirements for Commission designation of eligible telecommunications carriers.

Brief Description: These rules originally require each ETC over which the Commission has jurisdiction to submit annually certain information regarding its network and its use of universal service funds. In their current form, the rules apply to ETCs that are recipients of high cost support.

Need: These rules ensure that ETCs continue to comply with the conditions of the ETC designation and that universal service funds are used for their intended purposes.

Legal Basis: 47 U.S.C. 151, 154(i), 154(j), 201–205, 214, 254, and 403.

Section Number and Title:

54.209 (a)(1)–(6) Annual reporting requirements for designated eligible telecommunications carriers (when adopted; now 54.313(a)(1)–(6); Annual reporting requirements for high cost recipients).

Subpart D—Universal Support for High Cost Areas

Brief Description: Subpart D sets forth the regulations to provide universal service in high cost areas. These rules provide that section 54.305—concerning sales or transfers of exchanges—does not apply to transfers of exchanges between non-rural carriers after the phase down of interim hold harmless support, and that rural carriers may receive safety-valve support for investment made in the first year of operating acquired exchanges.

Need: Section 54.305(a) establishes a rule provision to reflect the fact that, after the complete phasedown of interim hold-harmless support, there is no need for section 54.305 with regard to transfers between non-rural carriers. Sections 54.305(d)(1) and (2) provide incentives for carriers not to delay first year investment in order to provide more safety valve support in later years.

Legal Basis: 47 U.S.C. 151, 154(i), 154(j), 214, 218–220, 254 and 405.

Section Number and Title:

54.305(a), (d)(1) and (2) Sale or transfer of exchanges.

Brief Description: These rules condition newly designated ETCs' eligibility for support upon the filing by the ETC of line-count data within 60 days of the carrier's ETC designation. Thereafter, the rules require the filing of data on a quarterly basis.

Need: These requirements enable customers of newly designated ETCs to begin to receive the benefits of universal service support as of the ETC's designation date and ensure that ETCs continue to comply with the conditions of the ETC designation and that universal service funds are used for their intended purposes. This rule is needed on an ongoing basis to provide a deadline for a newly designated competitive eligible telecommunications carrier to submit data required to receive universal service support. Other subsections of Section 54.307 require such a carrier to file the necessary data on a quarterly basis thereafter.

Legal Basis: 47 U.S.C. 151, 154(i), 154(j), 155, 201–205, 214, 219, 220, 254, 303(r), 403, and 1302.

Section Number and Title:

54.307(d) Support to a competitive eligible telecommunications carrier.

Subpart F—Universal Support for Schools and Libraries

Brief Description: These rules establish the matters to which applicants to the Universal Service E-rate program must certify in FCC Form 471 in order to have their applications considered and the certifications that service providers must make in FCC form 473 as a condition of support.

Need: These rules create certainty as to the criteria to which applicants must certify when completing Form 471 and serve to emphasize to potential service providers that practices that thwart the competitive bidding process will not be tolerated.

Legal Basis: 47 U.S.C. 151, 154(i), 154(j), 201–205, 214, 254, and 403.

Section Number and Title:

54.504(c)(1)(i)–(iii), (vi)–(xi) (now 54.504(a)(1)(i)–(ix); 54.504(h) (when adopted; now 54.504(f)) Requests for services.

Subpart G—Universal Support for Health Care Providers

Brief Description: Subpart G sets forth the regulations for eligible health care providers to receive universal service support. This rule allows mobile rural health care providers to receive discounts for satellite services calculated by comparing the rate for the satellite service to the rate for an urban wireline serviced with a similar bandwidth.

Need: This rule provides the support necessary to make mobile telemedicine economical for rural health care providers to provide high-quality health care to rural and remote areas. This rule is needed on an ongoing basis to calculate the support amount for mobile rural health care providers under the universal service support rules.

Legal Basis: 47 U.S.C. 151, 154(i), 154(j), 155, 201–205, 214, 219, 220, 254, 303(r), 403, and 1302.

Section Number and Title:

54.609(e) Calculating support.

Brief Description: This rule requires providers of mobile health services to

[3] 47 U.S.C. 214(e)(6). Section 214(e)(6) of the Act directs the Commission to designate carriers when those carriers are not subject to the jurisdiction of a state commission.

maintain records for their purchases of supported services for at least five years sufficient to document their compliance with all Commission requirements.

Need: These rules further the Commission's efforts to improve its oversight of the operation of the rural health care program to ensure that the statutory goals of section 254 of the Telecommunications Act of 1996 are met.

Legal Basis: 47 U.S.C. 151, 154(i), 154(j), 201–205, 214, 254, and 403.

Section Number and Title:

54.619(a)(1) and (2) Audits and recordkeeping.

Subpart H—Administration

Brief Description: Subpart H sets forth the regulations, functions, and responsibilities for the Administrator of the universal support mechanisms. These rules require interconnected voice over internet Protocol (VoIP) providers to contribute to the universal service fund.

Need: These rules help ensure the stability and sustainability of the Universal Service Fund. This rule is needed on an ongoing basis to determine which entities are considered telecommunications carriers providing interstate telecommunications service and therefore are required to contribute to the universal service support mechanisms.

Legal Basis: 47 U.S.C. 151, 154(i), 154(j), 155, 201–205, 214, 219, 220, 254, 303(r), 403, and 1302.

Section Number and Title:

54.706(a)(18), (19) Contributions.

PART 63—EXTENSION OF LINES, NEW LINES, AND DISCONTINUANCE, REDUCTION, OUTAGE AND IMPAIRMENT OF SERVICE BY COMMON CARRIERS; AND GRANTS OF RECOGNIZED PRIVATE OPERATING AGENCY STATUS

Brief Description: The Part 63 rules set forth definitions, requirements, and conditions applicable to international Section 214 applications and authorizations to provide global facilities-based and global resale services, as well as provisions regarding requests for designation as a recognized private operating agency. The rules pertain to the regulatory classification of U.S. international carriers; notification and prior approval requirements for U.S. international carriers that are or propose to become affiliated with a foreign carrier; procedures for processing international Section 214 applications; special provisions for U.S. international common carriers; contents of applications for international common carriers; special procedures for discontinuances of international services; special provisions relating to temporary or emergency service by international carriers; and related issues. The rules also require carriers to file all notifications and other filings electronically through the International Bureau Filing System (IBFS).

Need: These rules are needed to provide the framework applicable to international Section 214 authorizations and establish the general applications, procedures, conditions and restrictions to ensure that carriers and affiliates providing services on international routes meet statutory requirements for designated global facilities-based and resale telecommunications services.

Legal Basis: 47 U.S.C. 151, 154(i), 154(j), 160, 201–205, 214, 218, 403, and 571, unless otherwise noted.

Section Number and Title:

63.09, Note 2 Definitions applicable to international Section 214 authorizations.

63.10(d), (e) Regulatory classification of U.S. international carriers.

63.11(d), (g)–(j) Notification by and prior approval for U.S. international carriers that are or propose to become affiliated with a foreign carrier.

63.12(c)(3) Processing of international Section 214 applications.

63.14(c) Prohibition on agreeing to accept special concessions.

63.17(b) introductory text, (b)(1)–(2), (b)(4) Special provisions for U.S. international common carriers.

63.18 introductory text, (e)(3), (g), Note to paragraph (h), (q) Contents of applications for international common carriers.

63.19, (d) Special procedures for discontinuances of international services.

63.20(a) Electronic filing, copies required; fees; and filing periods for international service providers.

63.21(a), (h)–(j) Conditions applicable to all international Section 214 authorizations.

63.22(a)–(c), (e)–(f) Facilities-based international common carriers.

63.23(a)–(b), (d) Resale-based international common carriers.

63.24, (e)(4), (f)(2)–(3), (h) Assignments and transfers of control.

63.25(b), (c) introductory text, (d)(2), (e) Special provisions relating to temporary or emergency service by international carriers.

63.51, (c) Additional information.

63.53(a)(1)–(2), (b)–(c) Form.

63.60(d) (currently (g)) Definitions.

63.701 introductory text, (j) Contents of application.

PART 64—MISCELLANEOUS RULES RELATING TO COMMON CARRIERS

Subpart F—Telecommunications Relay Services and Related Customer Premises Equipment for Persons with Disabilities

Brief Description: Part 64, Subpart F implements section 225 of the Communications Act of 1934, as amended. Section 225 codifies Title IV of the Americans with Disabilities Act of 1990 (ADA) which requires that the Commission ensure that telecommunications relay services (TRS) are available, ''to the extent possible and in the most efficient manner,'' to individuals with hearing or speech disabilities in the United States. Section 225 defines TRS as telephone transmission services that provide the ability for an individual who is deaf, hard of hearing, deaf-blind, or who has a speech disability to engage in communication by wire or radio with one or more individuals, in a manner functionally equivalent to the ability of a hearing individual who does not have a speech disability to communicate using voice communication services by wire or radio. The rules provide minimum functional, operational, and technical standards for TRS programs. The rules give states a significant role in ensuring the availability of TRS by treating carriers as compliant with their statutory obligations if they operate in a state that has a relay program certified as compliant by the Commission. The rules also establish a cost recovery and a carrier contribution mechanism (TRS Fund) for the provision of interstate TRS and require states to establish cost recovery mechanisms for the provision of intrastate TRS. In 2005, the rules were amended by adding subsection (b)(2)(iii) to section 64.604, requiring Video Relay Service (VRS) providers to comply with speed of answer requirements to be eligible for compensation from the TRS Fund. Section 64.604 also was amended by adding subsection (c)(5)(iii)(F)(4) (which has been redesignated as 64.604(c)(5)(iii)(F)(2)), requiring internet-based TRS providers (*e.g.,* VRS and internet Protocol (IP) Relay providers) to be certified by the Commission pursuant to section 64.605 (which has been redesignated as 64.606) to be eligible for compensation from the TRS Fund.

Need: The rules are intended to facilitate communication by persons with hearing or speech disabilities by

ensuring that interstate and intrastate TRS are available throughout the country, and by ensuring uniform minimum functional, operational, and technical standards for TRS programs. The rules ensure that individuals with hearing or speech disabilities receive the same quality of service as hearing individuals when they make TRS calls, regardless of where their calls originate or terminate.

Legal Basis: 47 U.S.C. 151, 152, and 225.

Section Number and Titles:

64.604(b)(2)(iii) Technical standards, Speed of answer, Speed of answer requirements for VRS providers.

64.604(c)(5)(iii)(F)(2) Functional standards, Jurisdictional separation of costs, Telecommunications Relay Services Fund, Eligibility for payment from the TRS Fund.

Subpart L—Restrictions on Telemarketing, Telephone Solicitation, and Facsimile Advertising

Brief Description: The Telephone Consumer Protection Act (TCPA) was enacted to address certain telemarketing practices, including calls to wireless telephone numbers, which Congress found to be an invasion of consumer privacy and even a risk to public safety. In the TCPA, Congress created a balance between individual privacy rights and legitimate telemarketing practices. The Commission crafted rules in 1992 to achieve this balance. Subsequently, the Commission has revised and amended the rules that it adopted in 1992 pursuant to the TCPA, including the establishment of a national do-not-call list to carry out Congress' TCPA directives. In 2004, section 64.1200(a)(1) was amended to add subsection (iv), establishing a limited safe harbor period from the prohibition on autodialed or prerecorded or artificial voice calls to wireless numbers when such calls are made to numbers that have been ported from wireline service to wireless service within the previous 15 days and are voice calls, provided the numbers are not already on the national do-not-call registry or the caller's company-specific do-not-call list.

Need: Section 64.1200(a)(1)(iv) strikes an appropriate balance between maximizing consumer privacy protections and avoiding the imposition of undue burdens on telemarketers and other callers by providing a limited time period necessary for persons, including small businesses, to identify numbers that have been ported from wireline to wireless service and, therefore, allow callers to comply with the TCPA.

Legal Basis: 47 U.S.C. 151–154, 227, and 303(r).

Section Number and Title:

64.1200(a)(1)(iv) Delivery restrictions.

Subpart X—Subscriber List Information

Brief Description: These rules allow carriers to redact portions of requested contracts that are wholly unrelated to the carrier's provision of subscriber list information and allow carriers to subject their disclosure of subscriber list information contracts to confidentiality agreements that limit access to and use of the information to the purpose of determining the rates, terms and conditions under which a carrier provides subscriber list information to its own directory publishing operations.

Need: These rules ensure that any disclosure of subscriber list information contracts will not unfairly disadvantage carriers or their directory publishing operations.

Legal Basis: 47 U.S.C. 154, 254(k); secs. 403(b)(2)(B), (c), Public Law 104–104, 110 Stat. 56. Interpret or apply 47 U.S.C. 201, 218, 222, 225, 226, 228, and 254(k).

Section Number and Title:

64.2341(d) and (e) Recordkeeping.

Subpart CC—Customer Account Record Exchange Requirements

Brief Description: The rules in Part 64, Subpart CC were issued pursuant to the Communications Act of 1934, as amended, to facilitate the exchange of customer account information between local exchange carriers (LECs) and interexchange carriers (IXCs) and to establish carriers' responsibilities with respect to such exchanges.

Need: The rules help to ensure that consumers' phone service bills are accurate and that their carrier selection requests are honored and executed without undue delay. These requirements also recognize a carrier's right to be compensated for the services it provides by ensuring that providers of long distance phone services receive proper notification when customers are placed on their networks.

Legal Basis: 47 U.S.C. 154, 201, 202, 222, and 258.

Section Number and Titles:

64.4000 Basis and purpose.

64.4001 Definitions.

64.4002 Notification obligations of LECs.

64.4003 Notification obligations of IXCs.

64.4004 Timeliness of required notifications.

64.4005 Unreasonable terms or conditions on the provision of customer account information.

64.4006 Limitations on use of customer account information.

Subpart DD—Prepaid Calling Card Providers

Brief Description: These rules establish definitions for ''prepaid calling card'' and ''prepaid card providers'' and reporting and certification requirements for prepaid calling card providers. The rules include prepaid calling card providers among the entities required to contribute to the universal service fund, and create an exemption for revenues derived from prepaid calling cards sold by, to, or pursuant to contract with the Department of Defense or a DoD entity.

Need: These rules provide regulatory certainty and ensure compliance with the Commission's access charge and USF contribution requirements.

Legal Basis: 47 U.S.C. 154, 254(k); secs. 403(b)(2)(B), (c), Public Law 104–104, 110 Stat. 56. Interpret or apply 47 U.S.C. 201, 218, 222, 225, 226, 228, and 254(k).

Section Number and Titles:

64.5000 Definitions.

64.5001 Reporting and certification requirements.

PART 73—RADIO BROADCAST SERVICES

Subpart E—Television Broadcast Stations

Brief Description: This rule provides guidance on how the Commission will determine whether TV broadcast stations are in compliance with the Children's Television Act. They were adopted collectively by the Commission to modernize its rules implementing the Act in light of the Digital TV Transition (*Children's Television Obligations of Digital Television Broadcasters,* Report and Order and Further Notice of Proposed Rulemaking, FCC 04–221).

Need: These rules are necessary because they provide licensees of analog and digital stations with explicit guidance on meeting their obligations under the Children's Television Act.

Legal Basis: 47 U.S.C. 154, 303, 309, 310, 334, 336, and 339.

Section Number and Titles:

73.671(c)(7), (d), (e) (73.671(f)—removed) Educational and informational programming for children.

Brief Description: This rule provides an exception for satellite carriers from certain verification requirements. It was adopted by the Commission as part of

implementing the Satellite Home Viewer Extension and Reauthorization Act of 2004 (*Implementation of the Satellite Home Viewer Extension and Reauthorization Act of 2004, Implementation of Section 340 of the Communications Act,* Order, FCC 05–81).

Need: This rule is necessary because it provides regulatory relief for certain satellite carriers.

Legal Basis: 47 U.S.C. 154, 303, 309, 310, 334, 336, and 339.

Section Number and Title:

73.683(f) Field strength contours and presumptive determination of field strength at individual locations.

Subpart F—International Broadcast Stations

Brief Description: These rules provide frequency assignments and technical standards for certain international broadcasting stations. They were collectively adopted by the Commission to implement decisions from the World Radiocommunication Conference held in 2003 (*Amendment of Parts 2, 25, and 73 of the Commission's Rules to Implement Decisions from the World Radiocommunication Conference (Geneva, 2003) (WRC–03) Concerning Frequency Bands Between 5900 khz and 27.5 ghz and to Otherwise Update The Rules in this Frequency Range,* Report and Order, FCC 05–70).

Need: These rules are necessary for the operation of international broadcast stations and compliance with international agreements.

Legal Basis: 47 U.S.C. 154, 303, 309, 310, 334, 336, and 339.

Section Number and Titles:

73.702(g), (h) Assignment and use of frequencies. (73.702(g)—reserved, not in use)

73.702(f), (g)–(k) redesignated as (i)–(m); new (h) Assignment and use of frequencies.

73.757 System specifications for single-sideband (SSB) modulated emissions in the HF broadcasting service.

73.758 System specifications for digitally modulated emissions in the HF broadcasting service.

Subpart J—Class A Television Broadcast Stations

Brief Description: These rules provide technical standards and interference protection requirements for Class A TV stations. They were collectively adopted when the Commission established digital LPTV and digital translator stations as part of the Digital TV Transition (*Amendment of Part 73 and Part 74 of the Commission's Rules to Establish Rules for Digital Low Power Television, Television Translator, and Television Booster Stations to Amend Rules for Digital Class A Television Stations,* Report and Order, FCC 04–220).

Need: These rules are necessary to maintain localism and implement other Class A TV station rules.

Legal Basis: 47 U.S.C. 154, 303, 309, 310, 334, 336, and 339.

Section Number and Titles:

73.6000(2) Definitions.

73.6024(d) Transmission standards and system requirements.

73.6027 Class A TV notifications concerning interference to radio astronomy, research and receiving installations.

PART 74—EXPERIMENTAL RADIO, AUXILIARY, SPECIAL BROADCAST AND OTHER PROGRAM DISTRIBUTIONAL SERVICES

Subpart G—Low Power TV, TV Translator, and TV Booster Stations

Brief Description: These rules provide legal requirements and technical standards for digital low power TV (LPTV) stations, digital translator TV stations, and digital Class A TV stations. They were collectively adopted when the Commission established digital LPTV and digital translator stations as part of the Digital TV Transition (*Amendment of Part 73 and Part 74 of the Commission's Rules to Establish Rules for Digital Low Power Television, Television Translator, and Television Booster Stations to Amend Rules for Digital Class A Television Stations,* Report and Order, FCC 04–220).

Need: These rules are necessary for the licensing and operation of digital LPTV and digital translator stations, to protect the integrity of these stations, and to ensure that these stations do not cause harmful interference to other authorized services.

Legal Basis: 47 U.S.C. 154, 302a, 303, 307, 336 and 554.

Section Number and Titles:

74.701(j)–(p) Definitions.

74.703(f), (g) Interference.

74.710 Digital low power TV and TV translator station protection.

74.786 Digital channel assignments.

74.787 Digital licensing.

74.788 Digital construction period.

74.789 Broadcast regulations applicable to digital low power television and television translator stations.

74.790 Permissible service of digital TV translator and LPTV stations.

74.791 Digital call signs.

74.792 Digital low power TV and TV translator station protected contour.

74.793 Digital low power TV and TV translator station protection of broadcast stations.

74.794 Digital emissions.

74.795 Digital low power TV and TV translator transmission system facilities.

74.796 Modification of digital transmission systems and analog transmission systems for digital operation.

PART 76—MULTICHANNEL VIDEO AND CABLE TELEVISION SERVICE

Subpart D—Carriage of Television Broadcast Signals

Brief Description: These rules address obligations of and restrictions on satellite carriers retransmitting certain television broadcast signals, and provide guidance for television broadcast stations choosing between retransmission consent and mandatory carriage of significantly viewed signals. They were collectively adopted by the Commission as part of implementing the Satellite Home Viewer Extension and Reauthorization Act of 2004 (*Implementation of the Satellite Home Viewer Extension and Reauthorization Act of 2004, Implementation of Section 340 of the Communications Act,* Order, FCC 05–81; Report and Order, FCC 05–187).

Need: These rules are necessary for carrying out the Congressional mandate of the Satellite Home Viewer Extension and Reauthorization Act of 2004.

Legal Basis: 47 U.S.C. 151, 152, 153, 154, 301, 302, 302a, 303, 303a, 307, 308, 309, 312, 315, 317, 325, 338, 339, 340, 341, 503, 521, 522, 531, 532, 534, 535, 536, 537, 543, 544, 544a, 545, 548, 549, 552, 554, 556, 558, 560, 561, 571, 572, 573.

Section Number and Titles:

76.5(gg) Definitions.

76.54(e)–(k) Significantly viewed signals; method to be followed for special showings.

76.66(d)(5) Satellite broadcast signal carriage.

76.66(d)(2)(iii) Satellite broadcast signal carriage.

Subpart G—Cablecasting

Brief Description: These rules modernize rules concerning children's programming to include restrictions on displaying internet website addresses. They were adopted collectively by the Commission to modernize its rules implementing the Act in light of the Digital TV Transition (*Children's Television Obligations of Digital*

Television Broadcasters, Report and Order and Further Notice of Proposed Rulemaking, FCC 04–221).

Need: These rules are necessary to ensure that the Commission's rules continue to respond the Congressional mandate in the Children's Television Act by protecting children from advertising directing them to internet sites.

Legal Basis: 47 U.S.C. 151, 152, 153, 154, 301, 302, 302a, 303, 303a, 307, 308, 309, 312, 315, 317, 325, 338, 339, 340, 341, 503, 521, 522, 531, 532, 534, 535, 536, 537, 543, 544, 544a, 545, 548, 549, 552, 554, 556, 558, 560, 561, 571, 572, 573.

Section Number and Title:

76.225(c)–(d) Commercial limits in children's programs.

PART 80—STATIONS IN THE MARITIME SERVICES

Subpart H—Frequencies

Brief Description: The Part 80 rules set forth the conditions under which portions of the radio spectrum are made available and licensed for stations in the maritime services. Subpart H describes the carrier frequencies and general uses of radiotelegraphy for distress, urgency, safety, call and reply, digital selective calling, narrow-band direct printing, and facsimile for stations within the maritime services.

Need: This rule designates VHF maritime Channels 87B (161.975 MHz) and 88B (162.025 MHz) for Automatic Identification Systems (AIS). The designation of Channels 87B and 88B for AIS in the United States is consistent with the establishment of a seamless global AIS framework, and facilitates the broad, efficient and effective implementation of AIS in U.S. territorial waters. The intended effect is to maximize the benefits of AIS for United States homeland security and maritime safety. The need for this rule is ongoing.

Legal Basis: 47 U.S.C. 154, 303, 307, 309 and 332.

Section Number and Title:

80.393 Frequencies for AIS stations. (Revised 2009)

PART 87—AVIATION SERVICES

Subpart D—Technical Requirements

Brief Description: The Part 87 rules set forth the conditions under which radio stations may be licensed and used in the aviation services. Subpart D rules provide the technical requirements for such radio stations.

Need: The technical requirements are needed on an ongoing basis to protect the safety of life and property in air navigation and must be periodically updated to reflect technological advancements in the aviation industry and maximize spectral efficiency while important safeguards against interference.

Legal Basis: 7 U.S.C. 154, 303 and 307(e), unless otherwise noted.

Section Number and Titles:

87.139(l) Emission limitations.

87.141(k) Modulation requirements.

Subpart F—Aircraft Stations

Brief Description: Part 87 contains the Commission rules governing aviation services. Subpart F sets forth the rules governing assignment of frequencies in those services.

Need: This rule authorizes Universal Access Transceiver data transmission on 978 MHz. The need for this rule is ongoing.

Legal Basis: 47 U.S.C. 154, 303 and 307(e).

Section Number and Title:

87.187(ff) Frequencies.

Subpart L—Aeronautical Utility Mobile Stations

Brief Description: Part 87 contains the Commission rules governing aviation services. Subpart L sets forth the rules governing aeronautical utility mobile stations.

Need: Rules 87.345(f) and 87.349(e) authorize transmissions for Universal Access Transceiver service. The need for these rules is ongoing.

Legal Basis: 47 U.S.C. 154, 303 and 307(e), unless otherwise noted.

Section Number and Titles:

87.345(f) Scope of service.

87.349(e) Frequencies.

Subpart Q—Stations in the Radiodetermination Service

Brief Description: Part 87 contains the Commission rules governing aviation services. Subpart Q sets forth the rules governing station in the Radiodetermination Service.

Need: This rule assigns the frequencies for airborne electronic aids to air navigations and associated land stations. The need for this rule is ongoing.

Legal Basis: 47 U.S.C. 154, 303 and 307(e).

Section Number and Title:

87.475(b)(9) Frequencies.

PART 90—PRIVATE LAND MOBILE RADIO SERVICES

Subpart C—Industrial/Business Radio Pool

Brief Description: Section 90.35(c)(90) set dates for FCC cessation of certain licenses in specific bands.

Need: This rule provision was enacted to transition Private Land Mobile Radio Services below 800 MHz to reflect changes in the international allocations, including consolidation of the services that distribute assignments between low-use and high-use groups more evenly, facilitates advanced technologies, and provides more efficiency and flexibility in spectrum use. The need for this rule is ongoing, insofar as it is a limitation on the 2000–25,000 kHz band in the I/B Frequency Pool in 90.35(b)(3).

Legal Basis: 47 U.S.C. 154, 302, 303 and 332.

Section Number and Title:

90.35 Industrial/Business Pool.

Subpart H—Policies Governing the Assignment of Frequencies

Brief Description: The addition of Section 90.175 clarified frequency coordinator requirements for applications for a new frequency assignment, a change in existing facilities, or operation at temporary locations, while excluding a certain number of categories from the requirements. In general, the rule requires applicants to provide all appropriate technical information, system requirements, and justification for requested station parameters, and clarifies that applicants bear the burden of proceeding and the burden of proof when requesting that the Commission overturn a coordinator's recommendation.

Need: This rule provision retained the frequency coordination requirement for incumbent licensees operating on 800 MHz General Category frequencies, and for site-based 800 MHz General Category applications filed after 800 MHz rebanding. The rule is part of a streamlining and harmonization of licensing provisions in the wireless radio services (WRS). The need for this rule is ongoing.

Legal Basis: 47 U.S.C. 154(i), 161, 303(g), 303(r) and 332(c)(7).

Section Number and Title:

90.175 Frequency coordinator requirements.

Subpart I—General Technical Standards

Brief Description: Part 90 contains service and licensing rules used in the Private Land Mobile Radio Services. Subpart I sets forth the general technical requirements for use of frequencies and equipment in the radio services governed by Part 90.

Need: The revised rules establish the general technical rules for Part 90 licensees. The need for these rules is ongoing.

Legal Basis: 47 U.S.C. 154(i), 161, 303(g), 303(r), and 332(c)(7).

Section Number and Titles:

90.203(o) Certification required.
90.210(m) Emission masks.
90.217(e) Exemption from technical standards.

Subpart K—Standards for Special Frequencies or Frequency Bands

Brief Description: Section 90.265 made additional frequencies available to a combination of Public Safety Pool and Industrial/Business Pool licenses in the bands allocated for Federal use, including forest firefighting and conservation activities, Medical Radiocommunication Systems, and other public safety activities. It also added interference complaint procedures involving the Hydro Committee referenced in the rule part concerning hydrological or meteorological data.

Need: The rule additions generally expanded the availability of frequencies while clarifying the interference complaint procedures to protect them. The need for this rule is ongoing.

Legal Basis: 47 U.S.C. 154(i), 161, 303(g), 303(r), 332(c)(7).

Section Number and Title:

90.265(a)(5–9), (c), (d), (e) Assignment and use of frequencies in the bands allocated for Federal use.

Subpart S—Regulations Governing Licensing and Use of Frequencies in the 806–824, 851–869, 896–901, and 935–940 MHz Bands

Brief Description: Part 90 states the conditions under which radiocommunications systems may be licensed and used in the Public Safety, Industrial/Business Radio Pool, Radiolocations Radio Services, and Commercial Mobile Radio Services. Subpart S sets forth the rules governing the licensing and use of frequencies in the 806–824 MHz, 851–869 MHz, 896–901 MHz, and 935–940 MHz Bands.

Need: This rule requires Economic Areas (EA) licensees operating on certain channels to construct an Enhanced Specialized Mobile Radio (ESMR) system by the license expiration date to promote efficient use of spectrum. This is an ongoing need.

Legal Basis: 47 U.S.C. 154(i), 161, 303(g), 303(r) and 332(c)(7).

Section Number and Title:

90.685(e) Authorization, construction and implementation of EA licenses.

Subpart Z—Wireless Broadband Services in the 3650–3700 MHz Band

Brief Description: Part 90 contains service and licensing rules used in the Public Safety, Industrial/Business Radio Pool, and Radiolocation Radio Services. Subpart Z contains rules that govern broadband operations in the 3650–3700 MHz.

Need: The revised rules establish the service and licensing rules for broadband operations in the 3650–3700 MHz band. The need for these rules is ongoing.

Legal Basis: 47 U.S.C. 310.

Section Number and Titles:

90.1301 Scope.
90.1303 Eligibility.
90.1305 Permissible operations.
90.1307 Licensing.
90.1309 Regulatory status.
90.1311 License term.
90.1312 Assignment and transfer.
90.1319 Policies governing the use of the 3650–3700 MHz band.
90.1321 Power and antenna limits.
90.1323 Emission limits.
90.1331 Restrictions on the operation of base and fixed stations.
90.1333 Restrictions on the operation of mobile and portable stations.
90.1335 RF safety.
90.1337 Operation near Canadian and Mexican borders.

PART 97—AMATEUR RADIO SERVICE

Subpart B—Station Operations Standards

Brief Description: Part 97 contains the Commission rules relating to amateur radio services. Subpart B sets forth station operation standards for amateur radio services.

Need: 97.111(a)(2) is needed on an ongoing basis to ensure that reliable communications are available during emergencies. 97.115(c) is needed to permit transmission of data on behalf of a third party.

Legal Basis: 47 U.S.C. 154, 303. 47 U.S.C. 151–155 and 301–609.

Section Number and Titles:

97.111(a)(2) Authorized transmissions.
97.115(c) Third party communications.

Subpart D—Technical Standards

Brief Description: The Part 97 rules set forth the conditions under which portions of the radio spectrum are made available and licensed for amateur radio service. Subpart D outlines technical standards for the frequency bands available to amateur stations.

Need: 97.303(t) is a restatement of old 97.303(p) to clarify that amateur operations must protect Federal and foreign operations in the 23 mm band. The need for this rule is ongoing.

Legal Basis: 47 U.S.C. 154 and 303.

Section Number and Title:

97.303(t) Frequency sharing requirements. (Revised 2010)

PART 101—FIXED MICROWAVE SERVICES

Subpart B—Applications and Licenses

Brief Description: Part 101 prescribes the manner in which portions of the radio spectrum may be made available for private operational, common carrier, 24 GHz Service, Local Multipoint Distribution Service, and fixed, microwave operations that require transmitting facilities on land or in specified offshore coastal areas within the continental shelf. Subpart B governs application, licensing and transition of microwave licenses under Part 101.

Need: The revised rules are related to requirements for constructing or relocating certain microwave stations (except Multichannel Video Distribution and Data Service, Local Multipoint Distribution Service, and the 24 GHz Service) under Part 101. Section 101.63(g) provides a streamlined process for MVPDs converting from analog to digital modulation to minimize duplicative costs associated with the coordination and licensing process, which is an ongoing requirement. Though section 101.69(g) is no longer needed for relocating the 1850–1990 and 2110–2150 bands, it governs the relocation of fixed microwave services in the 2160–2200 MHz band, which is an ongoing requirement for AWS–3 and AWS–4 licensees. The need for these rules is ongoing.

Legal Basis: 47 U.S.C. 154 and 303.

Section Number and Titles:

101.63(g) Period of construction; certification of completion of construction.
101.69(g) Transition of the 1850–1990 MHz, 2110–2150 MHz and 2160–2200 MHz band from the fixed microwave services to personal communications services and emerging technologies.

Subpart C—Technical Standards

Brief Description: Part 101 prescribes the manner in which portions of the radio spectrum may be made available for private operational, common carrier, 24 GHz Service, Local Multipoint Distribution Service, and fixed, microwave operations that require transmitting facilities on land or in specified offshore coastal areas within the continental shelf. Subpart C sets forth technical standards for applications and licenses in the Fixed Microwave Services.

Need: The revised rules provide the interference protection criteria for fixed stations subject to part 101 and requires that transmitters used in the private operational fixed and common carrier fixed point-to-point microwave and point-to-multipoint services under this part must be a type that has been verified for compliance. The need for these rules is ongoing.

Legal Basis: 47 U.S.C. 154, and 303.

Section Number and Titles:

101.105(a)(5) and (6) Interference protection criteria.

101.139(h) and (i) Authorization of transmitters.

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DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Part 192

[Docket ID: PHMSA–2017–0151]

RIN 2137–AF29

Pipeline Safety: Class Location Change Requirements

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Advance notice of proposed rulemaking (ANPRM).

SUMMARY: PHMSA is seeking public comment on its existing class location requirements for natural gas transmission pipelines as they pertain to actions operators are required to take following class location changes due to population growth near the pipeline. Operators have suggested that performing integrity management measures on pipelines where class locations have changed due to population increases would be an equally safe but less costly alternative to the current requirements of either reducing pressure, pressure testing, or replacing pipe. This request for public comment continues a line of discussion from a Notice of Inquiry published in 2013 and a report to Congress in 2016 regarding whether expanding integrity management requirements would mitigate the need for class location requirements.

DATES: Persons interested in submitting written comments on this ANPRM must do so by October 1, 2018.

ADDRESSES: You may submit comments identified by the Docket: PHMSA–2017–0151 by any of the following methods:

E-Gov website: https://www.regulations.gov. This site allows the public to enter comments on any **Federal Register** notice issued by any agency. Follow the online instructions for submitting comments.

Fax: 1–202–493–2251.

Mail: Hand Delivery: U.S. DOT Docket Management System, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001 between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays.

Instructions: Identify the Docket ID at the beginning of your comments. If you submit your comments by mail, submit two copies. If you wish to receive confirmation that PHMSA has received your comments, include a self-addressed stamped postcard. Internet users may submit comments at *https://www.regulations.gov/.*

Note: Comments are posted without changes or edits to *https://www.regulations.gov,* including any personal information provided. There is a privacy statement published on *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT:

Technical questions: Steve Nanney, Project Manager, by telephone at 713–272–2855 or by email at *steve.nanney@dot.gov.*

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SUPPLEMENTARY INFORMATION:

Outline of This Document

Background

I. Class Location History and Purpose

The class location concept pre-dates Federal regulation of gas transmission pipelines [1] and was an early method of differentiating areas and risks along natural gas pipelines based on the potential consequences of a hypothetical pipeline failure. Class location designations were previously included in the American Standards Association B31.8–1968 version of the ''Gas Transmission and Distribution Pipeline Systems'' standard, which eventually became the American Society of Mechanical Engineers (ASME) International Standard, ASME B31.8 ''Gas Transmission and Distribution Pipeline Systems.'' The class location definitions incorporated into title 49, Code of Federal Regulations (CFR) § 192.5 were initially derived from the designations in this standard and were first codified on April 19, 1970.[2] These definitions were like the original ASME B31.8 definitions for Class 1 through 3 locations but added an additional Class 4 definition and, with some modifications, still apply today.

Gas transmission pipelines are divided into classes from 1 (rural areas) to 4 (densely populated, high-rise areas) that are based on the number of buildings or dwellings for human occupancy in the area. This concept is to provide safety to people from the effects of a high-pressure natural gas pipeline leak or rupture that could explode or catch on fire. PHMSA uses class locations in 49 CFR part 192 to implement a graded approach in many areas that provides more conservative safety margins and more stringent safety standards commensurate with the potential consequences based on population density near the pipeline. When crafting the natural gas

[1] The Department of Transportation first proposed class location regulations on March 24, 1970 (35 FR 5012). The proposal was part of a series of NPRMs published in response to the Natural Gas Pipeline Safety Act of 1968 (Pub. L. 90–481). The NPRMs were directed at developing a comprehensive system of Federal safety standards for gas pipeline facilities and for the transportation of gas through such pipelines. The class location rulemaking was finalized on August 19, 1970, as part of a consolidated rulemaking establishing the first minimum Federal safety standards for the transportation of natural gas by pipelines (35 FR 13248).

[2] 35 FR 13248.

regulations, DOT's Office of Pipeline Safety (OPS) determined that these more stringent standards were necessary because a greater number of people in proximity to the pipeline substantially increases the probabilities of personal injury and property damage in the event of an accident. At the same time, the external stresses, the potential for damage from third-parties, and other factors that contribute to accidents increase along with the population; consequently, additional protective measures are often needed in areas with greater concentrations of population.

The most basic and earliest use of the class location concept focused on the design (safety) margin for the pipeline. As pipelines are designed based, in part, on the population along their pipeline route and therefore the class location of the area, it is important to decrease pipe stresses in areas where there is the potential for higher consequences or where higher pipe stresses could affect the safe operation of a pipeline in larger-populated areas. Pipeline design factors are derating factors that ensure pipelines are operated below 100 percent of the maximum pipe yield strength. From an engineering standpoint, they were developed based on risk to the public [3] and for piping that may face additional operational stresses.[4] Pipeline design factors vary, ranging from 0.72 in a Class 1 location to 0.40 in a Class 4 location. They are used in the pipeline design formula (§ 192.105) to determine the design pressure for steel pipe, and are generally reflected in the maximum allowable operating pressure (MAOP) based upon a percentage of the specified minimum yield strength (SMYS) at which the pipeline can be operated.[5] [6] Design factors are used along with pipe characteristics in engineering calculations (Barlow's Formula) to calculate the design pressure and MAOP of a steel pipeline. More specifically, the formula at § 192.105 is $P = (2St/D) \times F \times E \times T$, where P is the design pressure, S is the pipe's yield strength, t is the wall thickness of the pipe, D is the diameter of the pipe, F is the design factor per the class location, E is the longitudinal joint factor,[7] and T is the temperature derating factor.[8] The formula in § 192.105 can be used to calculate the MAOP of a 1000 psig pipeline with the same operating parameters (diameter, wall thickness, yield strength, seam type, and temperature) but in different class locations (and therefore different design factors), and the MAOP of that pipeline in the different class locations would be as follows:

- No class location—design factor = 1.0 (none); MAOP = 1000 psig
- Class 1—design factor = 0.72; MAOP = 720 psig
- Class 2—design factor = 0.60; MAOP = 600 psig
- Class 3—design factor = 0.50; MAOP = 500 psig
- Class 4—design factor = 0.40; MAOP = 400 psig

As therefore evidenced, pipelines at higher class locations will have lower operating pressures and maximum allowable operating pressures due to more stringent design factors to protect people near the pipeline.

As natural gas pipeline standards and regulations evolved, the class location concept was incorporated into many other regulatory requirements, including test pressures, mainline block valve spacing, pipeline design and construction, and operations and maintenance (O&M) requirements, to provide additional safety to populated areas. In total, class location concepts affect 12 of 16 subparts of part 192 and a total of 28 individual sections.[9]

A. Class Location Determinations

Pipeline class locations for onshore gas pipelines are determined as specified in § 192.5(a) by using a ''sliding mile.'' The ''sliding mile'' is a unit that is 1 mile in length, extends 220 yards on either side of the centerline of a pipeline, and moves along the pipeline. The number of buildings [10] within this sliding mile at any point during the mile's movement determines the class location for the entire mile of pipeline contained within the sliding mile. Class locations are not determined at any given point of a pipeline by counting the number of dwellings in static mile-long pipeline segments stacked end-to-end.

When higher dwelling concentrations are encountered during the continuous sliding of this mile-long unit, the class location of the pipeline rises commensurately. As it pertains to structure counts, a Class 1 location is a class location unit along a continuous mile containing 10 or fewer buildings intended for human occupancy, a Class 2 location is a class location unit along a continuous mile containing 11 to 45 buildings intended for human occupancy, and a Class 3 location is a class location unit along a continuous mile containing 46 or more buildings intended for human occupancy.[11] Class 4 locations exist where buildings with four or more stories above ground are prevalent. Whenever there is a change in class location that will cause an apparent overlapping of class locations, the higher-numbered class location applies.

B. Class Location—''Cluster Rule'' Adjustments

After proposing the initial natural gas safety regulations in 1970, OPS received several comments stating that the proposed class location definitions could create 2-mile stretches of higher class locations for the sole protection of small clusters of buildings at crossroads or road crossings. Because part 192 regulations become more stringent as class locations increase from Class 1 to 4 locations, pipelines in higher class location areas such as these can result in increased expenditures to the pipeline operator in areas where there is no population. When finalizing the class location definitions as a part of establishing part 192 on August 19, 1970 (35 FR 13248), OPS added a new paragraph to allow operators to adjust the boundaries of Class 2, 3, and 4

[3] For instance, the number of human dwellings near the pipeline or the type of dwelling (hospital, school, playground, nursing care facility, etc.).

[4] This can include piping at compressor stations, metering stations, fabrications, and road or railroad crossings.

[5] Design factors for steel pipe are listed in § 192.111. Class 1 locations have a 0.72 design factor, Class 2 locations have a 0.60 factor, Class 3 locations have a 0.50 factor, and Class 4 locations have a 0.40 design factor.

[6] SMYS is an indication of the minimum stress a pipe may experience that will cause plastic, or permanent, deformation of the steel pipe.

[7] The seam type of a pipeline, per this formula, has a limiting effect on the MAOP of the pipeline. While it is typically ''1.00'' and does not affect the calculation, certain types of furnace butt-welded pipe or pipe not manufactured to certain industry standards will have factors of 0.60 or 0.80, which will necessitate a reduction in design pressure.

[8] The temperature derating factor ranges from 1.000 to 0.867 depending on the operating temperature of the pipeline. Pipelines designed to operate at 250 degrees Fahrenheit and lower have a factor of 1.000, which does not affect the design pressure calculation. Pipelines designed to operate at higher temperatures, including up to 450 degrees Fahrenheit, will have derating factors that will lower the design pressure of the pipeline.

[9] §§ 192.5, 192.8, 192.9, 192.65, 192.105, 192.111, 192.123, 192.150, 192.175, 192.179, 192.243, 192.327, 192.485, 192.503, 192.505, 192.609, 192.611, 192.613, 192.619, 192.620, 192.625, 192.705, 192.706, 192.707, 192.713, 192.903, 192.933, and 192.935.

[10] Per the regulations, a ''building'' is a structure intended for human occupancy, whether it is used as a residence, for business, or for another purpose. For the purposes of this rulemaking, a ''building'' may be interchangeably referred to as a ''home,'' a ''house,'' or a ''dwelling.''

[11] Under § 192.5, Class 1 locations also include offshore areas, and Class 3 locations contain areas where the pipeline lies within 100 yards of a building or a small, well-defined outside area (including playgrounds, recreation areas, and outdoor theaters) that is occupied by 20 or more persons at least 5 days a week for 10 weeks in any 12-month period. The days and weeks need not be consecutive.

locations. Under this provision, operators can choose to end Class 4 location boundaries 220 yards from the furthest edges of a group of 4-story buildings, and operators can choose to end Class 2 and 3 boundaries up to 220 yards upstream and downstream from the furthest edges of a group or ''cluster'' of buildings.[12] ''Clustering,'' therefore, is a means of reducing the length of a Class 2, 3, or 4 location in a sliding mile unit that requires a Class 2, 3, or 4 location; in other words, it allows operators to cluster or reduce the amount of pipe that is subject to the requirements of a higher class location.[13]

It is important to note that while clustering allows for the adjustment of the length of class locations in certain areas, it does not change the length of class location units themselves nor the method by which class location units are determined. Further, clustering does not exclude ''buildings for human occupancy'' in a class location unit/sliding mile, so all buildings within a specified class location unit must be protected by the maximum class location level that was determined for the entire class location unit. This concept becomes especially important when other buildings for human occupancy are built within a class location unit/sliding mile where a cluster exists and an operator has adjusted the class location length to exclude certain lengths of pipe outside of the cluster area.

For instance, assume there is a class location unit/sliding mile containing 47 homes close to one another. The class location unit would be a Class 3 location per the definition provided at § 192.5(b). An operator can consider these homes a ''cluster'' and appropriately apply the adjustment at § 192.5(c) so that the boundaries of the Class 3 location are 220 yards upstream and downstream from the furthest edges of the clustered homes (buildings for human occupancy). Therefore, while the entirety of the pipeline is in a Class 3 class location unit, the only pipe subject to Class 3 requirements is the length of the cluster plus 220 yards on both sides of the cluster. The remaining pipe in the class location unit/sliding mile, the pipe that is outside of this clustered area, could therefore be operated at Class 1 requirements rather than at the otherwise-required Class 3 requirements.

However, what would happen if new buildings were built within that sliding mile but away from that single cluster? If, per the example above, there is a cluster of 47 homes at one end of a class location unit/sliding mile, and 3 homes are built at the other end of the class location unit, the operator must count and treat those 3 homes as a second cluster, with the length of the cluster plus 220 yards on both sides of the cluster subject to Class 3 requirements. The pipeline between these two clusters would still be in a Class 3 location per its class location unit, as there would be 50 homes within the sliding mile, but the pipeline between the clusters could be operated under Class 1 location requirements. If the 220-yard extensions of any two or more clusters intercept or overlap, the separate clusters must be considered a single cluster for purposes of applying the adjustment.

An operator must use the clustering method consistently to ensure that all buildings for human occupancy within a class location unit are covered by the appropriately determined class location requirements. Any new buildings for human occupancy built in a class location unit where clustering has been used must also be clustered, whether they form a new, independent cluster or are added to the existing cluster. Note that even a single house could form the basis of a second cluster under this requirement, as all buildings within a specified class location unit must be protected by the maximum class location level that was determined for the entire class location unit.

PHMSA's interpretation to Air Products and Chemicals, Inc., issued on March 11, 2015,[14] explains and diagrams this concept further.

II. Changes in Class Location Due to Population Growth

Class locations can change as the population living or working near a pipeline grows and, as outlined earlier, are specifically determined based on the density of dwellings within the 440-yard-wide (quarter-mile-wide) sliding mile down the pipeline centerline. Class locations are used to determine a pipeline's design factor, which is a component of the design formula equation at § 192.105 and ultimately factors into the pressure at which the pipeline is operated. As population around a pipeline increases and the pipeline's class location increases, the numeric value of the design factor decreases, which translates, via the formula at § 192.105, into a lower MAOP for the pipeline. To illustrate this, a Class 4 location containing a prevalence of 4-or-more-story buildings has a safety factor of 0.4, whereas a Class 2 location containing 11 to 45 dwellings has a safety factor of 0.6. If a Class 2 location is very quickly developed to a point where there is a prevalence of 4-or-more story buildings, the corresponding difference in safety factor when the class location changes, from a 0.6 to a 0.4, equates to a 33% reduction in MAOP per the design formula equation.

A change in class location requires operators to confirm safety factors and to recalculate the MAOP of a pipeline. If the MAOP per the newly determined class location is not commensurate with the present class location, current regulations require that pipeline operators (1) reduce the pipe's MAOP to reduce stress levels in the pipe; (2) replace the existing pipe with pipe that has thicker walls or higher yield strength to yield a lower operating stress at the same MAOP; or (3) pressure test at a higher test pressure if the pipeline segment has not previously been tested at the higher pressure and for a minimum of 8 hours.[15] Depending on the pipeline's test pressure and whether it meets the requirements in §§ 192.609 and 192.611 (''Change in class location: Required study,'' and ''Change in class location: Confirmation or revision of maximum allowable operating pressure,'' respectively), an operator can base the pipeline's MAOP on a certain safety factor times the test pressure for the new class location as long as the corresponding hoop stress of the pipeline does not exceed certain percentages of the specified minimum yield strength (SMYS) of the pipe.[16]

[12] See § 192.5(c)(1) & (2).

[13] For example, if all buildings for human occupancy in a sliding mile containing enough buildings to require a Class 3 location were clustered in the middle of that sliding mile, the Class 3 area would end 220 yards from the nearest building (on either side of the cluster through which the pipeline passes) rather than at the end of the 1-mile class location unit that would otherwise be the basis for classification. Thus, if the cluster were 200 yards in length, the total length of the Class 3 area would be 640 yards (220 + 200 + 220).

[14] PHMSA Interpretation #PI–14–0017, available at *https://www.phmsa.dot.gov/sites/phmsa.dot.gov/files/legacy/interpretations/Interpretation%20Files/Pipeline/2015/Air_Products_PI_14_0017_10_01_2014_Part_192.5.pdf.*

[15] See § 192.611 as appropriate to one-class changes (*e.g.,* Class 1 to 2 or Class 2 to 3 or Class 3 to 4). As an example, for a Class 1 to Class 2 location change, the pipeline segment would require a pressure test to 1.25 times the MAOP for 8 hours. Following a successful pressure test, the pipeline segment would not need to be replaced with new pipe, but the existing design factor of 0.72 for a Class 1 location would be acceptable for a Class 2 location.

[16] See § 192.611. Specifically, if the applicable segment has been hydrostatically tested for a period of longer than 8 hours, the MAOP is 0.8 times the test pressure in Class 2 locations, 0.667 times the test pressure in Class 3 locations, or 0.555 times the test pressure in Class 4 locations. The corresponding hoop stress may not exceed 72% of

Continued

This is often referred to as a ''one-class bump,'' as an operator can use this method when class locations change from a Class 1 to 2, a Class 2 to a 3, or a Class 3 to a 4.

The §§ 192.5 and 192.611 requirements to change-out pipe, re-pressure test, or de-rate pipe to a lower MAOP when population growth occurs and requires a class location change are the most significant reasons that operators request that class locations be revised or eliminated. Throughout the process of considering class location changes,[17] comments PHMSA received from the trade associations state that reducing a pipeline's operating pressure below that at which the pipeline historically operated may unacceptably restrict deliveries to natural gas customers. These same commenters suggest that pressure testing pipelines may be practicable in select cases, but the test pressure required for higher class locations may exceed what a pipeline is designed to accommodate. Operators also contend that they should not have to change out pipe when a class location change occurs if the operator can prove that the pipe segment is fit for service through integrity assessments.[18]

III. Class Location Change Special Permits

As population growth occurs around pipelines that were formerly in rural areas, some operators have applied for special permits to prevent the need for pipe replacement or pressure reduction when the class location changes. A special permit is an order issued under § 190.341 that waives or modifies compliance with regulatory requirements if the pipeline operator requesting it demonstrates a need and PHMSA determines that granting the special permit would be consistent with pipeline safety. PHMSA performs extensive technical analysis on special permit applications and typically grants special permits on the condition that operators will perform alternative measures to provide an equal or greater level of public safety. PHMSA publishes a notice and request for comment in the **Federal Register** for each special permit application received and tracks issued, denied, and expired special permits on its website.

Since 2004, PHMSA has approved over 15 class location special permits based on operators adopting additional conditions, including certain operating safety criteria and periodic integrity evaluations.[19] [20] Generally, the additional conditions PHMSA requires are designed to identify and mitigate integrity issues that could threaten the pipeline segment and cause failure, especially given the fact that the majority of class location special permits it receives and reviews are for older pipelines that may have manufacturing, construction, or ongoing maintenance issues, such as seam or pipe body cracking, poor external coating, insufficient soil cover, lack of material records, dents, or repairs not made to class location design safety factors.

Typically, PHMSA requires operators to incorporate the affected segments into the company's O&M procedures and integrity management plan, perform additional assessments for threats to the pipeline segments identified during an operator's risk assessment, perform additional cathodic protection [21] and corrosion control measures, and repair any discovered anomalies to a specified schedule. Therefore, the additional monitoring and maintenance requirements PHMSA prescribes through this process help to ensure the integrity of the pipe and protection of the population living near the pipeline segment at a comparable margin of safety and environmental protection throughout the life of the pipe compared to the regulations as written. The class location change special permits that PHMSA has granted have allowed operators to continue operating the pipeline segments identified under the special permits at the current MAOP based on the previous class locations. PHMSA notes that it developed its class location special permit process by adapting Integrity Management (IM) concepts and published the typical considerations for class location change special permit requests in the **Federal Register** in 2004.[22] Based on its experiences when renewing some of the earliest class location change special permits, PHMSA has extended the expiration date of its class location change special permits from 5 years to 10 years. This extension should provide additional regulatory certainty to operators that apply for these permits. Further, throughout the renewal process of existing special permits, PHMSA has not significantly changed the original conditions imposed on individual operators. While PHMSA can make modifications to its special permit conditions when it is in the interest of safety and the public to do so, PHMSA has determined that the present special permit conditions and process are consistent with public safety.

A. Special Permit Conditions

In the special permit conditions and criteria PHMSA published in the **Federal Register** on June 29, 2004, PHMSA outlines several ''threshold conditions'' pipelines must meet to be considered for a special permit when class locations change. For instance, PHMSA does not consider any pipeline segments for a special permit where the class location those segments are in changes to a Class 4 location. Typically, PHMSA receives special permit requests

SMYS of the pipe in Class 2 locations, 60% of SMYS in Class 3 locations, or 50% of SMYS in Class 4 locations.

[17] See Section IV of this document. In the context of this rulemaking, PHMSA has been considering issues related to class location requirements since publishing an ANPRM on the gas transmission regulations in 2011. Following that, PHMSA published a notice of inquiry soliciting comments on expanding gas IM program requirements and mitigating class location requirements (78 FR 46560; August 1, 2013) and held a public meeting on the notice of inquiry topics on April 16, 2014 (both actions under Docket Number PHMSA–2013–0161). PHMSA also received comments on the issues discussed in this rulemaking in the docket titled ''Transportation Infrastructure: Notice of Review of Policy, Guidance, and Regulations Affecting Transportation Infrastructure Projects'' which was noticed in the **Federal Register** on June 8, 2017 (82 FR 26734; Docket Number OST–2017–0057).

[18] Operators did not outline the type of integrity assessments that would be appropriate from their perspective nor the factors that should be considered to determine whether a pipeline segment is fit for service (such as pipe, pipe seam, or coating conditions; O&M history; material properties; pipe depth of cover; non-destructive testing of girth welds; type pipe coatings used and if they shield cathodic protection; seam type; failure or leak history; and pressure testing or acceptance criteria and any re-evaluation intervals).

[19] Special permit conditions are implemented to mitigate the causes of gas transmission incidents and are based on the type of threats pertinent to the pipeline. The conditions are generally more heavily weighted on identifying: Material, coating and cathodic protection issues, pipe wall loss, pipe and weld cracking, depth of pipe cover, third party damage prevention, marking of the pipeline and pipeline right-of-way patrols, pressure tests and documentation, data integration of integrity issues, and reassessment intervals.

[20] Examples of PHMSA's class location special permit conditions can be found at: *https://primis.phmsa.dot.gov/classloc/docs/SpecialPermit_ExampleClassLocSP_Conditions_090112_draft1.pdf,* and more information about PHMSA's special permit process for class location changes can be found at: *https://primis.phmsa.dot.gov/classloc/documents.htm*

[21] Cathodic protection is a technique used to control the corrosion of a metal surface by making it the cathode of an electrochemical cell. This can be achieved with a special coating on the external surface of the pipeline along with an electrical system and anodes buried in the ground or with a ''sacrificial'' or galvanic metal acting as an anode. In these systems, the anode will corrode before the protected metal will.

[22] **Federal Register** (69 FR 38948, June 29, 2004). Additional guidance is provided online at: *http://primis.phmsa.dot.gov/classloc/index.htm.* Public notices were published in **Federal Register**: 69 FR 22115 and 69 FR 38948, dated April 23, 2004 and June 29, 2004: Docket No. RSPA–2004–17401—Pipeline Safety: Development of Class Location Change Waiver (Special Permit).

for pipeline segments where the class location is changing from Class 1 to Class 3. PHMSA also does not consider for class location change special permits any segments that have bare pipe or wrinkle bends. Other manufacturing- and construction-related items PHMSA considers include whether the applicable segments have certain seam types that may be more prone to defects and failures, whether the pipe has certain coating types that provide an adequate level of cathodic protection, and the design strength of the pipe.

There are also operation and maintenance factors that PHMSA considers when evaluating pipeline segments for class location change special permit feasibility. For example, PHMSA doesn't consider for a Class 1 to Class 3 location change special permit any pipe segments that operate above 72 percent SMYS. Operators also need to produce a hydrostatic test record showing the segment was tested to 1.25 times the MAOP. Also, operators are required to have pipe material records to document the pipelines diameter, wall thickness, strength, seam type and coating type. For operators who do not have these records, PHMSA requires they make these records per the special permit conditions. PHMSA often requires operators to operate each applicable segment at or below its existing MAOP as well.

As part of the special permit conditions, operators are required by PHMSA to incorporate the applicable pipeline segments into their IM program and inspect them on a regular basis according to the operator's procedures. As an extension of this requirement, operators must perform in-line inspections on the applicable segments, and the segments must not have any significant anomalies that would indicate any systemic problems. Additionally, PHMSA's published special permit criteria defines a ''waiver inspection area,'' also known as a ''special permit inspection area,'' as up to 25 miles of pipe on either side of the applicable segment. Operators must incorporate these areas into their IM programs as well and inspect and repair them per the operator's IM program procedures. Some of the factors PHMSA uses when deciding the length of special permit inspection areas are based on factors including what class location the surrounding pipe is in and whether class location ''clustering'' has been used. For both the special permit segments and the special permit inspection areas, PHMSA also typically requires operators to perform assessments and surveys to identify pipe that may be susceptible to certain issues, especially seam or cracking issues in the pipe seam or pipe body, based on the coating type, vintage, or manufacturing of the pipe. Pipelines in the special permit segments or in the special permit inspection areas that have had a leak or failure history are also taken into consideration when PHMSA develops an individual special permit's conditions so as to prevent similar issues in the future. Further, PHMSA looks at the enforcement history of an operator applying for a special permit as a benchmark for how the operator has followed the Federal Pipeline Safety Regulations when developing the conditions following a special permit request.

In class location change special permit requests, PHMSA also ensures that integrity threats to pipelines in special permit segments and special permit inspection areas are addressed in operator operations and management plans, including a systematic, ongoing program to review and remediate pipeline safety concerns. Some of the typical integrity and safety threats PHMSA would expect operators to address include pipe coating quality, cathodic protection effectiveness, stress corrosion and seam cracking, and any long-term pipeline system flow reversals. To this end, PHMSA often requires coating condition surveys, the remediation of coating, and cathodic protection systems for pipelines where the operator has requested a class location change special permit. Any data gathered on the special permit area and special permit inspection area would have to be incorporated into the operator's greater IM program.

PHMSA incorporates these conditions into class location change special permit requests to ensure that operators meet or exceed the threshold requirements with equivalent safety to the provisions in the Federal Pipeline Safety Regulations that are being waived and ensure that granting the special permit will not be inconsistent with safety.

IV. Pipeline Safety, Regulatory Certainty, and Job Creation Act of 2011—Section 5

On January 3, 2012, the Pipeline Safety, Regulatory Certainty, and Job Creation Act of 2011 (Pub. L. 112–90) was enacted. Among the many provisions of the Act, Section 5 required PHMSA to evaluate whether IM system requirements, or elements thereof, should be expanded beyond high-consequence areas (HCA) and, with respect to gas transmission pipeline facilities, whether applying IM program requirements, or elements thereof, to additional areas would mitigate the need for class location requirements. PHMSA was required to report the findings of this evaluation to Congress and was authorized to issue regulations pursuant to the findings of the report following a prescribed review period.

A. 2013 Notice of Inquiry: Class Location Requirements

In August 2013, through a Notice of Inquiry, PHMSA solicited comments on whether expanding IM requirements would mitigate the need for class locations in line with the Section 5 mandate of the 2011 Pipeline Safety Act.[23] Several topics were discussed, including whether class locations should be eliminated and a single design factor used, whether design factors should be increased for higher class locations, and whether pipelines without complete material records should be allowed to use a single design factor if class locations were to be eliminated.[24]

There was broad consensus among PHMSA's stakeholders that eliminating class locations entirely would not lead to improvement to pipeline safety. Further, commenters noted that establishing a single design factor in lieu of class location designations might be too complicated to implement. Many commenters noted that any changes in class location requirements would impact not only the classifications of many pipelines but would also possibly create several unintended consequences within part 192, as the class location requirements are referenced or built upon throughout the natural gas regulations.

Several industry trade groups had suggestions for changing the class location regulations, and these suggestions were developed further through subsequent discussions at advisory committee meetings and at public workshops. The Interstate Natural Gas Association of America (INGAA) noted that IM should be extended beyond HCAs with the caveat that PHMSA should examine the effects of such a change on other areas of the pipeline safety regulations. Along with this, it suggested that PHMSA revise certain operations and maintenance requirements that may no longer be necessary given technological advances and IM activities.

[23] **Federal Register** (78 FR 46560, August 1, 2013).

[24] Regarding these questions, PHMSA received 30 comment letters, available at *www.regulations.gov* at docket PHMSA–2013–0161.

B. 2014 Pipeline Advisory Committee Meeting, Class Location Workshop, and Subsequent Comments

On February 25, 2014, PHMSA hosted a joint meeting of the Gas and Liquid Pipeline Advisory Committees.[25] At that meeting, PHMSA updated the committees on its activities regarding the Section 5 mandate of the 2011 Pipeline Safety Act, and committee members and members of the public provided their comments.

INGAA, reinforcing its comments on the 2013 Notice of Inquiry, noted that the original class location definitions in ASME B31.8 were intended to provide an increased margin of safety for locations of higher population density and stated that IM is a much better risk management tool than class locations. INGAA reiterated that it intends for its members to perform elements of IM on pipelines outside of HCAs.

On April 16, 2014, PHMSA sponsored a Class Location Workshop to solicit comments on whether applying the gas pipeline IM program requirements beyond HCAs would mitigate the need for gas pipeline class location requirements. Presentations were made by representatives from PHMSA, the National Energy Board of Canada (NEB), National Association of Pipeline Safety Representatives (NAPSR), pipeline operators, industry groups, and public interest groups.[26]

During the workshop, INGAA representatives noted that the current class location regulations require changes that result in the replacement of ''good pipe,'' and the special permit process for class location changes should be embedded in part 192. Representatives from the American Gas Association (AGA) noted that applying the current class location change requirements can cost more than $1 million per change. AGA claimed the special permit process for class location changes is burdensome, the renewal process is increasingly complex, and the outcome is uncertain.[27] Therefore, AGA suggested eliminating the special permit process for class location changes and incorporating specific requirements for special permits into part 192 as part of the base regulations. AGA recommended two approach methods, one based on IM and the other using the current class location approach.

Public interest groups including Accufacts and the Pipeline Safety Trust (PST) pointed out how deeply the concept of class locations is embedded in part 192, while also noting that IM requirements and class locations overlap in densely populated areas to provide a redundant, but necessary, safety regime. The PST also suggested that, in time, the older class location method potentially could be replaced with an IM method for regulation. However, the PST noted that incidents and data suggest there is room for improvement in the IM regulations, as data shows higher incident rates in HCAs than in non-HCAs, and noted that pipe installed after 2010 has a higher incident rate than pipe installed a decade earlier. Similarly, Accufacts noted that the incident at San Bruno, CA, exposed weaknesses in the operator's IM program and demonstrated that the consequences resulting from the incident spread far beyond the potential radius in which they were expected to occur.[28] Therefore, Accufacts suggested that shifting the class location approach to solely an IM approach might decrease the protection of public safety.

Following the Class Location Workshop, INGAA submitted additional comments to the docket stating that advancements in IM technology and processes have superseded the need for mandatory pipe replacement following a class location change. It noted that, in the past, it was logical to replace a pipeline when class locations changed because of the widespread belief that thicker pipe would take longer to corrode and would withstand greater external forces, such as damage from excavators, before failure. However, given current technology, improvements in pipe quality, and ongoing regulatory processes such as IM, operators can mitigate most threats without the need for pipe replacement. Therefore, INGAA offered an approach to class locations changes to not require pipe replacement for existing pipelines if pipe segments meet certain requirements that are in line with current IM requirements. Specifically, INGAA suggested that pipelines meeting a ''fitness for service'' standard in 18 categories of requirements could address potential safety concerns and preclude the need for pipe replacement.[29] The 18 categories are very similar to the special permit conditions that PHMSA uses for a Class 1 to 3 location special permit as noted in the 2004 **Federal Register** notice.[30]

C. 2016 Class Location Report

The Pipeline Safety, Regulatory Certainty, and Job Creation Act of 2011 required that PHMSA evaluate whether IM should be expanded beyond HCAs and whether such expansion would mitigate the need for class location requirements. In its report titled ''Evaluation of Expanding Pipeline Integrity Management Beyond High-Consequence Areas and Whether Such Expansion Would Mitigate the Need for Gas Pipeline Class Location Requirements,'' [31] which was submitted to Congress in April 2016 concurrently with the publication of the NPRM titled ''Safety of Gas Transmission and Gathering Pipelines'' (81 FR 20722), PHMSA noted that the application of IM program elements, such as assessment and remediation timeframes, beyond HCAs would not warrant the elimination of class locations.

PHMSA notes that class locations affect all gas pipelines and are integral to determining MAOPs; design pressures; pipe wall thickness; valve spacing; HCAs, in certain cases; and O&M inspection, surveillance, and repair intervals. While IM measures are a critical step towards pipeline safety and are important to mitigate risk, the assessment and remediation of defects do not adequately compensate for these other aspects of class locations. Thus, as outlined in the report, PHMSA determined the existing class location

[25] The Pipeline Advisory Committees are statutorily mandated advisory committees that advise PHMSA on proposed safety standards, risk assessments, and safety policies for natural gas and hazardous liquid pipelines (49 U.S.C. 60115). These Committees were established under the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C. app. 1–16) and the Federal Pipeline Safety Statutes (49 U.S.C. chap. 601–603). Each committee consists of 15 members, with membership divided among Federal and State agency representatives, the regulated industry, and the public.

[26] Meeting presentations are available online at: *http://primis.phmsa.dot.gov/meetings/MtgHome.mtg?mtg=95.*

[27] PHMSA notes that the special permit process is outlined in § 190.341 and is no different for the class location regulations than for any other pipeline safety regulation. Of the 18 special permits up for renewal from 2010–2017, 9 of them were for class location changes. When reviewing the class location change permits up for renewal, PHMSA found no safety reason to extensively modify any of the prior permits and made no major revisions to any of the previously imposed safety conditions.

[28] The potential impact radius for the ruptured pipe segment involved in the San Bruno incident was calculated at 414 feet. However, the NTSB, in its accident report (NTSB/PAR–11/01), noted that the subsequent fire damage extended to a radius of about 600 feet from the blast center.

[29] Those 18 categories were as follows: Baseline Engineering and Record Assessments—Girth Weld Assessment, Casing Assessment, Pipe Seam Assessment, Field Coating Assessment, Cathodic Protection, Interference Currents Control, Close Interval Survey, Stress Corrosion Cracking Assessments, In-line Inspection Assessments, Metal Loss Anomaly Management, Dent Anomaly Management, Hard Spots Anomaly Management. Ongoing Requirements—Integrity Management Program, Root Cause Analysis for Failure or Leak, Line Markers, Patrols, Damage Prevention Best Practices, Recordkeeping & Documentation.

[30] See also: *http://primis.phmsa.dot.gov/classloc/index.htm.*

[31] *https://www.regulations.gov/document?D=PHMSA-2011-0023-0153.*

requirements were appropriate for maintaining pipeline safety and should be retained. Therefore, any revisions to the class location requirements would have to be forward-looking (*i.e.,* applying to pipelines constructed after a certain effective date) and would have to comport with the existing regulatory regime to provide commensurate safety if any changes are made to aspects of pipeline safety related to design and construction, which is where key safety benefits of class locations are realized.[32]

As a part of the continuing discussion on class location changes and subsequent pipe replacement, PHMSA summarized at the end of the Class Location Report the concerns operators expressed regarding the cost of replacing pipe in locations that change from a Class 1 to a Class 3 location or a Class 2 to a Class 4 location. As discussed throughout the document, operators submitted that the safe operation of pipelines constructed in Class 1 locations that later change to Class 3 locations can be achieved using current IM practices.

However, over the past decade, PHMSA observed problems with pipe and fitting manufacturing quality, including low-strength material; [33] construction practices; welding; field coating practices; IM assessments and reassessment practices; [34] [35] and record documentation practices.[36] [37] These issues give PHMSA pause in considering approaches allowing a two-class bump (Class 1 to 3 or Class 2 to 4) without requiring pipe replacement, especially for higher-pressure transmission pipelines.

PHMSA stated in the conclusion of its Class Location Report that it would further evaluate the feasibility and the appropriateness of alternatives to address issues pertaining to pipe replacement requirements, continue to reach out to and consider input from all stakeholders, and consider future rulemaking if a cost-effective and safety-focused approach to adjusting specific aspects of class location requirements could be developed to address the issues identified by industry. In doing so, PHMSA would evaluate alternatives in the context of other issues it is addressing related to new construction quality- and safety-management systems and will also consider inspection findings, IM assessment results, and lessons learned from past incidents. Therefore, PHMSA has initiated this rulemaking to gain further information on analyzing the current requirements resulting in pipe replacement and alternatives to that practice.

V. INGAA Submission on Regulatory Reform—Proposal To Perform IM Measures in Lieu of Pipe Replacement When Class Locations Change

On July 24, 2017, INGAA submitted comments to a DOT docket regarding regulatory review actions (Docket No. OST–2017–0057). In its submission, INGAA estimated that gas transmission pipeline operators incur annual costs of $200–$300 million [38] nationwide replacing pipe solely to satisfy the class location change regulations and requested PHMSA consider revising the current class location change regulations to include an alternative beyond pressure reduction, pressure testing, or pipe replacement.

INGAA's proposed alternate approach focuses on recurring IM assessments that would leverage advanced assessment technologies to determine whether the pipe condition warrants pipe replacement in areas where the class location has changed. INGAA states that such an approach would further promote IM processes and principles throughout the nation's gas transmission pipeline network, improve economic efficiency by reducing regulatory burden, and help fulfill the purposes of Section 5 of the 2011 Pipeline Safety Act.

INGAA claims that the current alternatives to pipe replacement following a class location change do not reflect the substantial developments in IM processes, technologies, and regulations over the past 15-plus years. More specifically, in-line inspection (ILI) technologies, such as high-resolution magnetic flux leakage tools, can precisely assess the presence of corrosion and other potential defects, allowing an operator to establish whether a pipeline segment requires remediation or replacement.[39]

INGAA further notes that PHMSA's proposed rulemaking titled ''Safety of Gas Transmission and Gathering Pipelines'' aims to expand IM assessments to newly defined ''Moderate Consequence Areas'' (proposed § 192.710), and such an expansion provides a framework for developing an alternative for managing class location changes. INGAA suggests that the costs saved from avoiding pipe replacement using such an alternative could mitigate, to some degree, part of the costs of the proposed rulemaking. Additionally, INGAA notes that the proposed rulemaking contains several new provisions that will require operators to better manage the integrity of their pipelines by implementing more preventative and mitigative measures to manage the threat of corrosion. INGAA states that the inclusion of such corrosion control measures as a part of a program for managing the integrity of pipeline segments, including ones that have experienced class location changes, would further justify the development of an IM-focused alternative to class location changes.

Based on those statements, INGAA recommends PHMSA develop an alternative approach to § 192.611 that leverages the proposed § 192.710 for areas outside of HCAs and the IM requirements at § 192.921 to require recurring IM assessments and incorporation of those affected pipeline segments into IM programs. Further, INGAA suggests this approach require operators to reconfirm pipeline MAOP in a changed class location for any pipeline segment without traceable, verifiable, and complete records of a hydrostatic pressure test supporting the segment's previous MAOP.

PHMSA acknowledges that the class location change regulations predate the development of modern pipeline inspection technology such as ILI, above-ground surveys, and modern integrity management processes. In fact, it wasn't until the mid-1990s that PHMSA, following models from other industries such as nuclear power, started to explore whether a risk-based approach to regulation could improve public and environmental safety. PHMSA finalized the IM regulations for gas transmission pipelines on December

[32] In its comments following the public workshop on Class Locations in 2014, INGAA noted that, after further analysis, it appears that applying the Potential Impact Radius (PIR) method to existing pipelines may be unworkable.

[33] PHMSA has documented pipe material low-strength issues through an advisory bulletin and the following website link: *http://primis.phmsa.dot.gov/lowstrength/index.htm.*

[34] IM and operational procedures and practices were issues in the Pacific Gas & Electric (PG&E) San Bruno, CA, rupture in September 2010 and the Enbridge Marshall, MI, rupture in July 2010.

[35] PHMSA issued Advisory Bulletins ADB–11–01 and ADB–2012–10 to operators regarding IM meaningful metrics and assessments on January 10, 2011, and December 5, 2012, respectively, which can be reviewed at: *http://phmsa.dot.gov/pipeline/regs/advisory-bulletin.*

[36] PHMSA issued Advisory Bulletin, ADB–12–06, concerning documentation of MAOP on May 7, 2012, which can be reviewed at: *http://phmsa.dot.gov/pipeline/regs/advisory-bulletin.*

[37] Also note PHMSA's Advisory Bulletin titled ''Deactivation of Threats,'' issued March 16, 2017 (82 FR 14106).

[38] PHMSA requests further substantiation of this estimate. In extrapolating the national data, PHMSA estimates this number is the cost incurred for *all* pipe replacement projects on transmission lines, not just those projects triggered in response to class location changes.

[39] PHMSA notes that ILI and in-the-ditch evaluation technologies for crack identification are under development and could further be improved.

15, 2003,[40] in response to tragic incidents on pipelines in Bellingham, WA, in 1999 and near Carlsbad, NM, in 2000, which killed 3 people and 12 people, respectively. The IM regulations designated HCAs where operators would perform periodic assessments of the condition of their pipelines and make necessary repairs within specific timeframes if discovered anomalies met certain criteria. More specifically, the IM regulations outline the risk-based processes that pipeline operators must use to identify, prioritize, assess, evaluate, repair, and validate the integrity of gas transmission pipelines.

For many years, the pipeline industry used internal steel brush devices (''cleaning pigs'') moved by product flow to clean the inside of their pipelines. This pigging concept was later adapted through the application of technology to measure and record irregularities in the pipe and welds that may represent corrosion, cracks, deformations, and other defects. Now operators use ILI technology (''smart pigging or ILI'') as a backbone of the modern IM program. ILI tools are inserted into pipelines at locations, such as near valves or compressor stations, that have special configurations of pipes and valves where the ILI tools can be loaded into launchers, the launchers can be closed and sealed, and the flow of the product the pipeline is carrying can be directed to launch the tool down the pipeline. A similar setup is located downstream where the tool is directed out of the main line into a receiver so that an operator can remove the tool and retrieve the recorded data for analysis and reporting. ILI tools come in several different varieties that have distinct advantages and disadvantages over other methods of pipeline assessment. For instance, while some ILI tools might be able to reliably determine whether a pipeline has internal corrosion, the same tool might not be able to determine whether the pipeline has any crack indications. In selecting the tools most suitable for inline inspections, pipeline operators must know the type of threats that are applicable to the pipeline segment. Threats that ILI tools can identify typically include existing pipe wall thickness, pipe wall changes, pipe wall loss, cracking, and dents.

At the time the class location regulations were promulgated, it was logical to replace a pipeline when population growth resulted in a class location change in order to restore the safety margin appropriate for that location because the industry did not have the technology that is available today to learn the *in situ* material condition of the pipe. Further, since the existing pipe would not achieve a similar safety margin as replaced pipe, operators would need to use applicable inspection technology and pressure testing to ensure pipe has the correct wall thickness; strength; seam condition; toughness; no detrimental cracking or corrosion in the pipe body or seam; and a pipe coating that has not deteriorated or shields cathodic protection currents to allow corrosion or cracking issues such as girth weld cracking, stress corrosion cracking, or selective seam weld corrosion.

Currently, operators are not required to inspect pipelines or otherwise perform IM on those portions of pipelines unless they are within high consequence areas (HCAs) or the operator otherwise voluntarily assesses them and performs remediation measures for threats to the pipeline. As such, while prudent operators may know the characteristics and conditions of their pipelines outside of HCAs and can be confident that they can manage class location change expectations through the performance of IM measures, some operators may not.

PHMSA notes that while class locations and HCAs both provide additional protection to areas with high population concentrations, they were designed for different purposes. Unlike class locations, which provide blanket levels of safety throughout the nation's pipeline network at all locations by driving MAOP and design, construction, testing, and O&M requirements, the purpose of the IM regulations is to provide a structure for operators to focus their resources on improving pipeline integrity in the areas where a failure would have the greatest impact on public safety. Whereas over time the safety margins that class locations provide can be reduced due to corrosion or other types of pipe degradation, IM requirements provide a continuing minimum safety margin for more densely populated areas because operators are required to inspect and repair those applicable pipelines at a minimum of every 7 years and more frequently based upon risk assessments of threats to the segment in the HCA.

PHMSA acknowledges that applying modern IM assessments and processes could potentially be a comparable alternative to pipe change-outs. PHMSA notes that if operators perform integrity assessments on significant portions of non-HCA pipe mileage, PHMSA could further consider operators using such assessments to determine whether pipe in a changed class location is fit for service rather than having to replace it.

PHMSA is concerned, however, that some issues that result in pipeline failures, including poor construction practices[41] and operational maintenance threats, are not always being properly assessed and mitigated by operators, whether due to lack of technology or other causes. Further, as the incident at San Bruno in 2010 showed, operators may not have traceable, verifiable, and complete records of pipe properties, such as pipe material yield strength, pipe wall thickness, pipe seam type, pipe and seam toughness, and coating quality, that are critical and necessary for IM processes and pipeline safety in Class 3 and 4 locations and HCAs where there are higher population densities. PHMSA also points out that there might be instances where a pipeline may be in ''good condition'' from a visual standpoint, but it may not have the initial pipe manufacturing, pipe strength, construction quality, and O&M history requirements that add the extra level of safety required by the regulations for the higher population density area and the MAOP.[42] Section 192.611 already allows a ''one-class location'' bump for pipeline class locations that are in satisfactory physical condition and have the required pressure test.

Because of these factors, PHMSA seeks comment on the potential safety consequences of altering the current class location methodology and moving to an IM-only method in certain areas.

[40] 68 FR 69778; Pipeline Safety: Pipeline Integrity Management in High Consequence Areas (Gas Transmission Pipelines).

[41] PHMSA has met with operators constructing new pipelines on several occasions to discuss issues found during inspection. To reach out to all members of the pipeline industry, PHMSA hosted a public workshop in collaboration with our State partners, the Federal Energy Regulatory Commission (FERC) and Canada's National Energy Board (NEB) in April 2009. The objective of the workshop was to inform the public, alert the industry, review lessons learned from inspections, and to improve new pipeline construction practices prior to the 2009 construction season. This website makes available information discussed at the workshop and provides a forum in which to share additional information about pipeline construction concerns. This workshop focused on transmission pipeline construction. *http://primis.phmsa.dot.gov/construction/index.htm.*

[42] Note that the potential impact radius (PIR) in Integrity Management (IM) does not give any criteria to establish the pipelines operating pressure, anomaly repair criteria, safety surveys for leaks, 3rd party encroachments, etc. When Class locations change (from additional dwellings for human occupancy) from one-level to a higher level there are cut-off levels that may require a different design factor, pressure test, or maintenance criteria. For pipe to be replaced the class location change would have to be from a Class 1 to 3 or Class 2 to 4, which is a large increase in dwellings along the pipeline.

VI. Questions for Consideration

PHMSA is requesting comments and information that will be used to determine if revisions should be made to the Federal Pipeline Safety Regulations regarding the current requirements operators must meet when class locations change. The list of questions below is not exhaustive and represents an effort to help in the formulation of comments. Any additional information that commenters determine would be beneficial to this discussion is also welcomed.

Q1—When the population increases along a pipeline route that requires a class location change as defined at § 192.5, should PHMSA allow pipe integrity upgrades from Class 1 to Class 3 locations by methods other than pipe replacement or special permits? [43] Why or why not?

1a.—Should part 192 continue to require pipe integrity upgrades when class locations change from Class 1 to Class 3 locations or Class 2 to 4 locations? Why or why not?

1b.—Should part 192 continue to require pipe integrity upgrades from Class 1 to Class 3 locations for the ''cluster rule'' (see § 192.5(c)) when 10 or fewer buildings intended for human occupancy have been constructed along the pipeline segment? Why or why not?

1c.—Should part 192 continue to require pipe integrity upgrades for grandfathered pipe (*e.g.,* pipe segments without a pressure test or with an inadequate pressure test, operating pressures above 72% SMYS, or inadequate or missing material records; see § 192.619(c))? Why or why not?

Q2—Should PHMSA give operators the option of performing certain IM measures in lieu of the existing measures (pipe replacement, lower the operating pressure, or pressure test at a higher pressure; see § 192.611) when class locations change from Class 1 to Class 3 due to population growth within the sliding mile? Why or why not?

2a.—If so, what, if any, additional integrity management and maintenance approaches or safety measures should be applied to offset the impact on safety these proposals might create?

Q3—Should PHMSA give operators the option of performing certain IM measures in lieu of the existing measures (pipe replacement with a more conservative design safety factor or a combination of pressure test and lower MAOP) when class locations change due to additional structures being built outside of clustered areas within the sliding mile, if operators are using the cluster adjustment to class locations per § 192.5(c)(2)? Why or why not?

3a.—If so, what, if any, additional integrity management and maintenance approaches or safety measures should be applied to offset the impact on safety these proposals might create?

3b.—At what intervals and in what timeframes should operators be required to assess these pipelines and perform remediation measures?

Q4—If PHMSA allows operators to perform certain IM measures in lieu of pipe replacement when class locations change from Class 1 to Class 3, should some sort of ''fitness for service'' standard determine which pipelines are eligible? Why or why not?

4a.—If so, what factors should make a pipeline eligible or ineligible?

(i) Should grandfathered pipe (lacking records, including pressure test or material records) or pipe operating above 72% SMYS be eligible? Why or why not?

(ii) Should pipe that has experienced an in-service failure, was manufactured with a material or seam welding process during a time or by a manufacturer where there are now known integrity issues or has lower toughness in the pipe and weld seam (Charpy impact value) be eligible? Should pipe with a failure or leak history be eligible? Why or why not?

(iii) Should pipe that contains or is susceptible to cracking, including in the body, seam, or girth weld, or having disbonded coating or CP shielding coatings be eligible? Are there coating types that should disqualify pipe? Should some types of pipe, such as lap-welded, flash-welded, or low-frequency electric resistance welded pipe be ineligible? Should pipe where the seam type is unknown be ineligible? Why or why not?

(iv) Should pipe with significant corrosion (wall loss) be eligible for certain IM measures, or should it be replaced? Why or why not?

(v) Should anomalies be repaired similar to IM, allowed to grow to only a 10-percent safety factor [44] (§ 192.933(d)) before remediation in high population areas such as Class 2, 3 and 4 locations, or should they have an increased safety factor for remediation should these class location factors be eliminated? Why or why not?

(vi) Should pipe that has been damaged (dented) or has lost ground cover due to 3rd party activity (excavation or other) be eligible? Why or why not?

(vii) Should pipe lacking cathodic protection due to disbonded coating be eligible? Why or why not?

(viii) Should pipe with properties such as low frequency electric resistance weld (LF–ERW), lap welded, or other seam types that have a history of seam failure due to poor manufacturing properties or seam types that have a derating factor below 1.0 be eligible? Why or why not?

4b.—Should PHMSA base any proposed requirements off its criteria used for considering class location change waivers (69 FR 38948; June 29, 2004), including the age and manufacturing and construction processes of the pipe, and O&M history? Why or why not?

4c.—In the 2004 **Federal Register** notice (69 FR 38948), PHMSA outlines certain requirements pipelines must meet to be eligible for waiver consideration, including no bare pipe or pipe with wrinkle bends, records of a hydrostatic test to at least 1.25 times MAOP, records of ILI runs with no significant anomalies that would indicate systemic problems, and agreement that up to 25 miles of pipe both upstream and downstream of the waiver location must be included in the operator's IM program and periodically inspected using ILI technology. Further, the criteria provides no waivers for segments changing to Class 4 locations or for pipe changing to a Class 3 location that is operating above 72% SMYS. Should PHMSA require operators and pipelines to meet the threshold conditions outlined earlier in this document (Section 3A; ''Class Location Change Special Permits—Special Permit Conditions) or other thresholds to be eligible for a waiver when class locations change? Why or why not?

Q5—As it is critical for operators to have traceable, verifiable, and complete (TVC) records to perform IM, should operators be required to have TVC records as a prerequisite for performing IM measures on segments instead of replacing pipe when class locations change? Why or why not?

5a.—If so, what records should be necessary and why? Should records include pipe properties, including yield strength, seam type, and wall thickness; coating type; O&M history; leak and failure history; pressure test records; MAOP; class location; depth of cover; and ability to be in-line inspected?

5b.—If operators do not have TVC records for affected segments and TVC records were a prerequisite for performing IM measures on pipeline

[43] Sections involving class location requirements include §§ 192.5, 192.609, 192.611, 192.619 and 192.620.

[44] Section 192.933 has anomaly repair requirements based upon a predicted failure pressure being less than or equal to 1.1 times the MAOP.

segments in lieu of replacing pipe, how should those records be obtained, and when should the deadline for obtaining those records be?

Q6—Should PHMSA incorporate its special permit conditions regarding class location changes into the regulations, and would this incorporation satisfy the need for alternative approaches? Why or why not? (Examples of typical PHMSA class location special permit conditions can be found at *https://primis.phmsa.dot.gov/classloc/documents.htm*.)

6a.—What, if any, special permit conditions could be incorporated into the regulations to provide regulatory certainty and public safety in these high population density areas (Class 2, 3, and 4)?

Q7—For all new and replaced pipelines, to what extent are operators consulting growth and development plans to avoid potentially costly pipe change-outs in the future?

Q8—What is the amount of pipeline mileage per year being replaced due to class location changes for pipelines: (1) Greater than 24 inches in diameter, (2) 16–24 inches in diameter, and (3) less than 16 inches in diameter?

8a.—Of this mileage, how much is being replaced due to class locations changing when additional structures for human occupancy are built near clustered areas, if operators are using the cluster adjustment to class locations per § 192.5(c)(2)?

8b.—At how many distinct locations are pipe replacements occurring due to class location changes and that involve pipe with these diameters?

8c.—What is the average amount of pipe (in miles) being replaced and cost of replacement at the locations described in question 8b. and for these diameter ranges due to class location changes?

Q9—Should any additional pipeline safety equipment, preventative and mitigative measures, or prescribed standard pipeline predicted failure pressures more conservative than in the IM regulations be required if operators do not replace pipe when class locations change due to population growth and perform IM measures instead? Why or why not?

9a.—Should operators be required to install rupture-mitigation valves or equivalent technology? Why or why not?

9b.—Should operators be required to install SCADA systems for impacted pipeline segments? Why or why not?

Q10—Should there be any maximum diameter, pressure, or potential impact radius (PIR) limits that should disallow operators from using IM principles in lieu of the existing requirements when class locations change? For instance, PHMSA has seen construction projects where operators are putting in 42-inch-diameter pipe designed to operate at up to 3,000 psig. The PIR for that pipeline would be over 1,587 feet, which would mean the total blast diameter would be more than 3,174 feet.

VII. Regulatory Notices

A. Executive Order 12866, Executive Order 13563, Executive Order 13771, and DOT Regulatory Policies and Procedures

Executive Orders 12866 and 13563 require agencies to regulate in the ''most cost-effective manner,'' to make a ''reasoned determination that the benefits of the intended regulation justify its costs,'' and to develop regulations that ''impose the least burden on society.'' Executive Order 13771 (''Reducing Regulation and Controlling Regulatory Costs''), issued January 30, 2017, provides that ''it is essential to manage the costs associated with the governmental imposition of private expenditures required to comply with Federal regulations.'' One way to manage the costs of rulemakings is to propose new regulations that are deregulatory in nature, *i.e.* regulations that reduce the cost of regulatory compliance. PHMSA seeks information on whether this rulemaking could result in a deregulatory action under E.O. 13771, meaning that a potential final rule could have ''total costs less than zero.'' [45] We therefore request comments, including specific data if possible, concerning the costs and benefits of revising the pipeline safety regulations to accommodate any of the changes suggested in the advance notice.

B. Executive Order 13132: Federalism

Executive Order 13132 requires agencies to assure meaningful and timely input by State and local officials in the development of regulatory policies that may 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. PHMSA is inviting comments on the effect a possible rulemaking adopting any of the amendments discussed in this document may have on the relationship between national government and the States.

C. Regulatory Flexibility Act

Under the Regulatory Flexibility Act of 1980 (5 U.S.C. 601 *et seq.*), PHMSA must consider whether a proposed rule would have a significant impact on a substantial number of small entities. ''Small entities'' include small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations under 50,000. If your business or organization is a small entity and if adoption of any of the amendments discussed in this ANPRM could have a significant economic impact on your operations, please submit a comment to explain how and to what extent your business or organization could be affected and whether there are alternative approaches to the regulations the agency should consider that would minimize any significant negative impact on small business while still meeting the agency's statutory objectives.

D. National Environmental Policy Act

The National Environmental Policy Act of 1969 requires Federal agencies to consider the consequences of Federal actions and that they prepare a detailed statement analyzing them if the action significantly affects the quality of the human environment. Interested parties are invited to address the potential environmental impacts of this ANPRM, including comments about compliance measures that would provide greater benefit to the human environment or any alternative actions the agency could take that would provide beneficial impacts.

E. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

Executive Order 13175 requires agencies to assure meaningful and timely input from Indian Tribal Government representatives in the development of rules that ''significantly or uniquely affect'' Indian communities and that impose ''substantial and direct compliance costs'' on such communities. We invite Indian Tribal governments to provide comments on any aspect of this ANPRM that may affect Indian communities.

F. Paperwork Reduction Act

Under 5 CFR part 1320, PHMSA analyzes any paperwork burdens if any information collection will be required by a rulemaking. We invite comment on the need for any collection of

[45] See OMB Memorandum M–17–21, ''Guidance Implementing Executive Order 13771, Titled 'Reducing Regulation and Controlling Regulatory Costs,' '' (April 5, 2017).

information and paperwork burdens related to this ANPRM.

G. Privacy Act Statement

Anyone can search the electronic form of comments received in response to any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). DOT's complete Privacy Act Statement was published in the **Federal Register** on April 11, 2000 (65 FR 19477).

Issued in Washington, DC, on July 25, 2018, under authority delegated in 49 CFR 1.97.

Alan K. Mayberry,

Associate Administrator for Pipeline Safety.

[FR Doc. 2018–16376 Filed 7–30–18; 8:45 am]

BILLING CODE 4910–60–P

Notices

Federal Register
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Tuesday, July 31, 2018

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

Submission for OMB Review; Comment Request

July 25, 2018.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding (1) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on 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.

Comments regarding this information collection received by August 30, 2018 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), *OIRA_Submission@omb.eop.gov* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Food and Nutrition Service

Title: Request for Administrative Review.

OMB Control Number: 0584–0520.

Summary of Collection: The Food and Nutrition Service (FNS) of the U.S. Department of Agriculture is the Federal agency responsible for the Supplemental Nutrition Assistance Program (SNAP). The Food and Nutrition Act of 2008 (7 U.S.C. 2011–2036), as codified under 7 CFR parts 278 and 279, requires that the FNS determine the eligibility of retail food stores and certain food service organizations to participate in the SNAP. If a retail or wholesale firm is found to be ineligible by FNS or is otherwise aggrieved by certain FNS actions(s), that firm has the right to file a written request for review of the administrative action with FNS.

Need and Use of the Information: The request for administrative review is a formal letter, provided by the requester, with an original signature. FNS receives the letter requesting an administrative review and maintains it as part of the official review record. The designated reviewer will adjudicate the appeals process and make a final determination regarding the aggrieved action.

Description of Respondents: Business or other for profit; Farms.

Number of Respondents: 1,282.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 262.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2018–16261 Filed 7–30–18; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding (1) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on 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.

Comments regarding this information collection received by August 30, 2018 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725 17th Street NW, Washington, DC 20502. Commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Animal and Plant Health Inspection Service

Title: Pale Cyst Nematode.

OMB Control Number: 0579–0322.

Summary of Collection: Under the Plant Protection Act (7 U.S.C. 7701–7772), the Secretary of Agriculture is authorized to prohibit or restrict the importation, entry, or movement of plants and plant pests to prevent the introduction of plant pests into the United States or their dissemination within the United States. APHIS' ''Domestic Quarantine Notices'' in 7 CFR 301, ''Potato Cyst Nematode'' (§§ 301.86 through 301.86.9) requires quarantining parts of Bingham and Bonneville counties, ID; due to the discovery of the potato cyst nematode (PCN) and establishes restrictions on the

interstate movement of regulated articles from the quarantined area. This action is necessary to prevent the spread of the PCN via potatoes, soil, and other host material to non-infested areas of the United States.

Need and Use of the Information: APHIS will collect information using certificates, limited permits, compliance agreements, self-certification, appeal of withdrawn certificate or limited permit, appeal of withdrawn compliance agreement, and labeling to prevent the spread of PCN and to ensure that regulated articles can be moved safely from the quarantined area without spreading PCN. If APHIS did not collect this information, the spread of PCN in the United States could result in a loss of United States potatoes and other commodities from domestic and/or foreign markets.

Description of Respondents: Farms; Business or other for-profit.

Number of Respondents: 123.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 445.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2018–16180 Filed 7–30–18; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Forest Service

Establishment of Divided Mountain Purchase Unit, Grayson County, Virginia

AGENCY: Forest Service, USDA.

ACTION: Notice.

SUMMARY: On September 26, 2017 the Under Secretary of Natural Resources and the Environment created the Divided Mountain Unit. This purchase unit comprises 112.3 acres within Grayson County, Virginia. A legal description of lands within the purchase unit appears at the end of this notice.

APPLICABLE DATE: The Forest Service established this purchase unit on September 26, 2017.

ADDRESSES: A copy of the map showing the purchase unit is on file and available for public inspection in the Office of the Director, Lands Staff, First Floor-Southeast, Sidney R. Yates Federal Building, Forest Service, USDA, 201 14th Street SW, Washington, DC 20250, between the hours of 8:30 a.m. and 4:30 p.m. on business days. Those wishing to inspect the map are encouraged to call ahead to (202) 205–1248 to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Kevin Heikkila, Acting Director of Lands and Realty Management, by phone at 202–205–2818. Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 twenty-four hours a day, every day of the year, including holidays.

SUPPLEMENTARY INFORMATION: The Divided Mountain Project, legally described below, will provide additional road access into Cherokee National Forest and additional access to Pond Mountain State Game Lands. State game lands allow for recreational opportunities such as hiking, fishing, hunting, and cross country skiing. Acquisition of the Divided Mountain Tract will provide opportunities to extend these activities into the National Forest while conserving high-elevation open space, mitigating wildfire risks, protecting streams and water quality, and protecting the nearby Rogers Ridge Scenic Area viewshed.

All that tract or parcel of land lying and being situated in the Wilson Magisterial District of Grayson County, Virginia, being described as Tax Map No. 60–A–1A, being the same tract conveyed to The Conservation Fund by Warranty Deed signed September 16, 2016, and recorded on September 23, 2016, in Deed Book 599, Pages 589–591 Grayson County, Virginia Circuit Court Clerk Office; this Tract is identified as the portion of United States of America Tract U–1601 situated in Virginia. Bounded on the West by the Tennessee State Line (USA Tract U–1601), on the North by Robert Russell, on the East by Joseph Dalia, and on the South by the North Carolina State Line;

Bearings are oriented to Tennessee State Plane grid north,

Beginning on *Corner 1 of USA Tract U–1601,* the common corner to the States of Tennessee, Virginia and North Carolina, which is also Corner 1 of USA Tract U–137, being monumented by a brass disk in a large rock;

Thence with the Tennessee State Line (USA Tract U–1601), one (1) line;

1. *N 48°16′35″ E, 2766.22 feet* to *Corner 4 of USA Tract U–1601,* a standard Forest Service Monument situated in the Tennessee and Virginia State Line common to the lands of Russell;

Thence with the lands of Robert Russell, one (1) line;

1. *S 72°28′26″ E, 1204.95 feet* to *Corner 5 of USA Tract U–1601,* a standard Forest Service Monument common to the lands of Russell and Dalia;

Thence with the lands of Joseph Dalia, one (1) line;

1. *S 29°24′20″ E, 1962.76 feet* to *Corner 6 of USA Tract U–1601,* a standard Forest Service Monument situated in the Virginia and North Carolina State Line, common to the lands of Dalia;

Thence with the North Carolina State Line, *N 86°49′30″ W, 4183.72 feet* to *Corner 1 of USA Tract U–1601,* the POINT OF BEGINNING, containing 112.304 acres more or less, with the bearings, distances and acres here described being as shown on the plat of survey titled ''PROPERTY OF LOWELL K. HENSLEY AND BERNICE HENSLEY TO BE CONVEYED TO THE CONSERVATION FUND'' as drawn by Addison Surveyors recorded in Deed Book 599, page 591 Grayson County, Virginia Circuit Court Clerk Office.

End of Description

Dated: July 13, 2018.

Gregory C. Smith,

Acting Associate Deputy Chief, National Forest System, U.S. Forest Service.

[FR Doc. 2018–16290 Filed 7–30–18; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

National Institute of Food and Agriculture

Notice of Intent To Extend a Currently Approved Information Collection

AGENCY: National Institute of Food and Agriculture, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 and Office of Management and Budget (OMB) regulations, this notice announces the National Institute of Food and Agriculture (NIFA) intention to request approval for an extension of the currently approved information collection for the NIFA proposal review process.

DATES: Written comments on this notice must be received by October 1, 2018, to be assured of consideration. Comments received after that date will be considered to the extent practicable.

ADDRESSES: Written comments concerning this notice and requests for copies of the information collection may be submitted by any of the following methods: Email: *rmartin.usda.gov;* Fax: 202–720–0857; Mail: Office of Information Technology (OIT), NIFA, USDA, STOP 2216, 1400 Independence

Avenue SW, Washington, DC 20250–2216.

FOR FURTHER INFORMATION CONTACT: Robert Martin, eGovernment Program Leader; Phone Number: 202–445–5388; Email: *rmartin@nifa.usda.gov.*

SUPPLEMENTARY INFORMATION:

Title: NIFA Proposal Review Process.

OMB Number: 0524–0041.

Expiration Date of Current Approval: 10/31/2018.

Type of Request: Extension of a currently approved information collection for three years.

Abstract: The National Institute of Food and Agriculture (NIFA) is responsible for performing a review of proposals submitted to NIFA competitive award programs in accordance with section 103(a) of the Agricultural Research, Extension, and Education Reform Act of 1998, 7 U.S.C. 7613(a). Reviews are undertaken to ensure that projects supported by NIFA are of high quality, and are consistent with the goals and requirements of the funding program.

Proposals submitted to NIFA undergo a programmatic evaluation to determine worthiness of Federal support. The evaluations consist of a peer panel review and may also entail an assessment by Federal employees and electronically submitted (ad-hoc) reviews in the Peer Review System.

Need and Use of the Information: The information collected from the evaluations is used to support NIFA grant programs. NIFA uses the results of the proposal evaluation to determine whether a proposal should be declined or recommended for award. When NIFA has rendered a decision, copies of reviews, excluding the names of the reviewers, and summaries of review panel deliberations, if any, are provided to the submitting Project Director.

Given the highly technical nature of many of these proposals, the quality of the peer review greatly depends on the appropriate matching of the subject matter of the proposal with the technical expertise of the potential reviewer. In order to obtain this information, an electronic questionnaire is used to collect information about potential panel and ad-hoc reviewers. If the reviewer is already in our database, the questionnaire asks potential reviewers to update their basic biographical information including address, contact information, professional expertise, and their availability to review for NIFA in the future. If the reviewer is new, they are prompted to complete the questionnaire. This information has been invaluable in the NIFA review process, which has been recognized by the grantee and grantor community for its quality.

The applications and associated materials made available to reviewers, as well as the discussions that take place during panel review meetings are strictly confidential and are not to be disclosed to or discussed with anyone who has not been officially designated to participate in the review process. While each panelist certifies at the time of preparing a review they do not have a conflict-of-interest with a particular application and will maintain its confidentiality in the Peer Review System, a certification of their intent at the time of the panel review proceedings is collected to emphasize and reinforce confidentiality not only of applications and reviews but also panel discussions. On the Conflict-of-Interest and Confidentiality Certification Form, the panelist affirms they understand the conflict-of-interest guidelines and will not be involved in the review of the application(s) where a conflict exists. The panelist also affirms their intent to maintain the confidentiality of the panel process and not disclose to another individual any information related to the peer review or use any information for personal benefit.

Estimate of Burden: NIFA estimates that anywhere from one hour to twenty hours may be required to review a proposal. It is estimated that approximately five hours are required to review an average proposal. Each proposal receives an average of four reviews, accounting for an annual burden of 20 hours. NIFA estimates it receives 4,600 competitive applications each year. The total annual burden on reviewers is 92,000 hours. NIFA estimates that the potential reviewer questionnaire takes an estimated 10 minutes to complete. The database consists of approximately 50,000 reviewers. The total annual burden of questionnaire is 8,330 hours. NIFA estimates that the potential Conflict-of-Interest and Confidentiality Certification Form takes an estimated 10 minutes to complete. The agency has approximately 1,000 panelists each year. The total annual burden of the certification form is 167 hours. The total annual burden of the component of the entire review process is 100,497 hours.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (b) the accuracy of the Agency's estimate of the burden of the 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 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.

All responses to this notice will be summarized and included in the request to OMB for approval. All comments will become a matter of public record.

Done in Washington, DC, on July 24, 2018.

Thomas Shanower,

Acting Director, National Institute of Food and Agriculture.

[FR Doc. 2018–16326 Filed 7–30–18; 8:45 am]

BILLING CODE 3410–22–P

DEPARTMENT OF COMMERCE

Bureau of the Census

Census Scientific Advisory Committee Public Meeting

AGENCY: Bureau of the Census, Department of Commerce.

ACTION: Notice of public meeting.

SUMMARY: The Bureau of the Census (Census Bureau) is giving notice of a meeting of the Census Scientific Advisory Committee (CSAC). The Committee will address policy, research, and technical issues relating to a full range of Census Bureau programs and activities, including communications, decennial, demographic, economic, field operations, geographic, information technology, and statistics. The CSAC will meet in a plenary session on September 13–14, 2018. Last minute changes to the schedule are possible, which could prevent giving advance public notice of schedule adjustments. Please visit the Census Advisory Committees website for the most current meeting agenda at: *http://www.census.gov/cac/.* The meeting will be available via webcast at: *https://www.census.gov/newsroom/census-live.html.* Topics of discussion will include:

- 2020 Census Program Update
- 2018 End-to-End Test Update
- Administrative Records Update
- Efforts to Modernize Disclosure Limitation Update

DATES: September 13–14, 2018. On Thursday, September 13, the meeting will begin at 8:30 a.m. and end at approximately 5:00 p.m. On Friday, September 14, the meeting will begin at 8:30 a.m. and end at approximately 2:00 p.m.

ADDRESSES: The meeting will be held at the U.S. Census Bureau Auditorium, 4600 Silver Hill Road, Suitland, Maryland 20746.

FOR FURTHER INFORMATION CONTACT: Tara Dunlop Jackson, Branch Chief for Advisory Committees, Customer Liaison and Marketing Services Office, *census.scientific.advisory.committee@census.gov,* Department of Commerce, U.S. Census Bureau, Room 8H177, 4600 Silver Hill Road, Washington, DC 20233, telephone 301–763–5222. For TTY callers, please use the Federal Relay Service 1–800–877–8339.

SUPPLEMENTARY INFORMATION: The CSAC members are appointed by the Director, U.S. Census Bureau. The Committee provides scientific and technical expertise, as appropriate, to address Census Bureau program needs and objectives. The Committee has been established in accordance with the Federal Advisory Committee Act (Title 5, United States Code, Appendix 2, Section 10).

All meetings are open to the public. A brief period will be set aside at the meeting for public comment on September 14. However, individuals with extensive questions or statements must submit them in writing by email *census.scientific.advisory.committee@census.gov* (subject line ''September 2018 CSAC Meeting Public Comment'') or by letter to Tara Dunlop Jackson, Committee Liaison Officer, Department of Commerce, U.S. Census Bureau, Room 8H177, 4600 Silver Hill Road, Washington, DC 20233.

If you plan to attend the meeting, please register by Monday, September 10, 2018. You may access the online registration from the following link: *https://www.regonline.com/csac_meeting_sep2018.* Seating is available to the public on a first-come, first-served basis.

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should also be directed to the Committee Liaison Officer as soon as known, and preferably two weeks prior to the meeting.

Please call 301–763–9906 upon arrival at the Census Bureau on the day of the meeting. A photo ID must be presented in order to receive your visitor's badge. Visitors are not allowed beyond the first floor.

Dated: July 24, 2018.

Ron S. Jarmin,

Associate Director for Economic Programs, Performing the Non-Exclusive Functions and Duties of the Director, Bureau of the Census.

[FR Doc. 2018–16321 Filed 7–30–18; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–549–822]

Certain Frozen Warmwater Shrimp From Thailand: Rescission of Antidumping Duty Administrative Review; 2017–2018

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 certain frozen warmwater shrimp (shrimp) from Thailand for the period February 1, 2017, through January 31, 2018, based on the timely withdrawal of all requests for review.

DATES: Applicable July 31, 2018.

FOR FURTHER INFORMATION CONTACT: Alice Maldonado, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4682.

SUPPLEMENTARY INFORMATION:

Background

On February 1, 2018, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the antidumping duty order on shrimp from Thailand for the period February 1, 2017, through January 31, 2018.[1] In February 2018, Commerce received timely requests, in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act), to conduct an administrative review of this antidumping duty order from the Ad Hoc Shrimp Trade Action Committee (the petitioner), the American Shrimp Processors Association (ASPA), and certain individual companies.[2] Based upon these requests, on April 16, 2017, in accordance with section 751(a) of the Act, Commerce published in the **Federal Register** a notice of initiation listing 160 companies for which Commerce received timely requests for review.[3]

In July 2018, all parties timely withdrew their requests for an administrative review.[4]

Rescission of Review

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if a party who requested the review withdraws the request within 90 days of the date of publication of notice of initiation of the requested review. As noted above, all parties withdrew their requests for review by the 90-day deadline. Accordingly, we are rescinding the administrative review of the antidumping duty order on frozen warmwater shrimp from Thailand covering the period February 1, 2017, through January 31, 2018.

Assessment

Commerce will instruct U.S. Customs and Border Protection (CBP) to assess antidumping duties on all appropriate entries. 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 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.

Notification Regarding Administrative Protective Orders

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or

[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 83 FR 4639 (February 1, 2018).

[2] *See* Good Luck Product Co., Ltd.'s (Good Luck's) February 22, 2018, Request for Administrative Review; Petitioner's February 26, 2018, Request for Administrative Review; and May Ao Foods Co., Ltd./A Foods 1991 Co., Ltd.'s (collectively, Mayao's), Thai Royal Frozen Food Co., Ltd.'s (Thai Royal's), Thai Union Group Public Co., Ltd. (also known as Thai Union Frozen Products Public Co. Ltd.)/Thai Union Seafood Co., Ltd./Pakfood Public Company Limited/Okeanos Food Co. Ltd.'s (collectively, Thai Union/Pakfood's), and ASPA's February 27, 2017, Requests for Administrative Review.

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 83 FR 16298 (April 16, 2018).

[4] *See* Petitioner's, ASPA's, Mayao's, Thai Union/Pakfood's, and Thai Royal's, June 28, 2018, Withdrawals of Administrative Review Request, and Good Luck's June 29, 2018, Withdrawal of Administrative Review Request.

destruction 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) and 777(i)(1) of the Act and 19 CFR 351.213(d)(4).

Dated: July 25, 2018.

James Maeder,

Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations performing the duties of Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2018–16341 Filed 7–30–18; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–552–823]

Laminated Woven Sacks From the Socialist Republic of Vietnam: Postponement of Preliminary Determination in the Less-Than-Fair-Value Investigation

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

DATES: Applicable July 31, 2018.

FOR FURTHER INFORMATION CONTACT: Drew Jackson or Celeste Chen, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4406 or (202) 482–0890, respectively.

SUPPLEMENTARY INFORMATION:

Background

On March 27, 2018, the Department of Commerce (Commerce) initiated a less-than-fair-value (LTFV) investigation of imports of laminated woven sacks (LWS) from the Socialist Republic of Vietnam (Vietnam).[1] Currently, the preliminary determination is due no later than August 14, 2018.

Postponement of Preliminary Determination

Section 733(b)(1)(A) of the Tariff Act of 1930, as amended (the Act), requires Commerce to issue the preliminary determination in a LTFV investigation within 140 days after the date on which Commerce initiated the investigation. However, section 733(c)(1)(A)(b)(1) of the Act permits Commerce to postpone the preliminary determination until no later than 190 days after the date on which Commerce initiated the investigation if: (A) The petitioner makes a timely request for a postponement; or (B) Commerce concludes that the parties concerned are cooperating, that the investigation is extraordinarily complicated, and that additional time is necessary to make a preliminary determination. Under 19 CFR 351.205(e), the petitioner must submit a request for postponement 25 days or more before the scheduled date of the preliminary determination and must state the reasons for the request. Commerce will grant the request unless it finds compelling reasons to deny the request.

On July 17, 2018, the petitioners [2] submitted a timely request that Commerce postpone the preliminary determination in the LTFV investigation.[3] The petitioners stated that they request postponement ''because the initial questionnaire responses submitted by the respondents in this investigation are substantially deficient, and it may not be possible for {Commerce} to obtain usable corrected responses within the current schedule.'' [4]

For the reasons stated above, and because there are no compelling reasons to deny the request, Commerce, in accordance with section 733(c)(1)(A) of the Act, is postponing the deadline for the preliminary determination by 50 days (*i.e.,* 190 days after the date on which this investigations was initiated). As a result, Commerce will issue its preliminary determination no later than October 3, 2018. In accordance with section 735(a)(1) of the Act and 19 CFR 351.210(b)(1), the deadline for the final determination of this investigation will continue to be 75 days after the date of the preliminary determination, unless postponed at a later date.

This notice is issued and published pursuant to section 733(c)(2) of the Act and 19 CFR 351.205(f)(1).

Dated: July 25, 2018.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2018–16334 Filed 7–30–18; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–552–801]

Certain Frozen Fish Fillets From the Socialist Republic of Vietnam: Notice of Court Decisions Not in Harmony With Final Results of Administrative Review and Notice of Amended Final Results of Antidumping Duty Administrative Review

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

SUMMARY: On May 24, 2018, the United States Court of International Trade (Court) issued final judgments in *Vinh Hoan Corporation et al.* v. *United States,* Consol. Court No. 13–00156, sustaining the Department of Commerce's (Commerce) remand results for the eighth administrative review of the antidumping duty order on certain frozen fish fillets from the Socialist Republic of Vietnam (Vietnam) covering the period of review (POR) August 1, 2010, through July 31, 2011. Commerce is notifying the public that the Court's final judgment is not in harmony with Commerce's final results of the administrative review, and that Commerce is amending the final results with respect to certain exporters.

DATES: Applicable June 3, 2018.

FOR FURTHER INFORMATION CONTACT: Javier Barrientos, 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) 482–2243.

SUPPLEMENTARY INFORMATION:

Background

On March 21, 2013, Commerce issued its *AR8 Final Results.*[1] On May 20, 2013, Commerce issued its *AR8 Amended Final Results.*[2] Vinh Hoan *et*

[1] *See Laminated Woven Sacks From the Socialist Republic of Vietnam: Initiation of Less-Than-Fair-Value Investigation,* 83 FR 14257 (April 3, 2018) (*Initiation Notice*).

[2] The petitioners are the Laminated Woven Sacks Fair Trade Coalition and its individual members, Polytex Fibers Corporation and ProAmpac Holdings Inc.

[3] *See* Petitioners' Letter, ''Investigation of Laminated Woven Sacks From the Socialist Republic of Vietnam: Petitioners' Request For Postponement Of The Preliminary Determination,'' dated July 17, 2018.

[4] *Id.*

[1] *See Certain Frozen Fish Fillets from the Socialist Republic of Vietnam: Final Results of Antidumping Duty Administrative Review and New Shipper Reviews; 2010–2011,* 78 FR 17350 (March 21, 2013) (*AR8 Final Results*).

[2] *See Certain Frozen Fish Fillets from the Socialist Republic of Vietnam: Amended Final Results of Antidumping Duty Administrative Review;* 2010–

al.[3] and the petitioners [4] timely filed complaints with the Court and challenged certain aspects of the *AR8 Amended Final Results.* On February 19, 2015, the Court remanded Commerce's *AR8 Amended Final Results.*[5]

In the first remand, in accordance with the Court's instructions, Commerce reconsidered its selection of the surrogate country, and the selection of certain surrogate values (SVs), *i.e.,* whole live *pangasius* fish, surrogate financial statements, various by-products and several other SVs, as they relate to the selection of the surrogate country.[6] Additionally, and in accordance with the Court's instructions, Commerce made changes to Vinh Hoan Corporation's [7] (Vinh Hoan) margin calculation, specifically, by adjusting the denominators for Vinh Hoan's factors of production (FOPs) to exclude water weight, and adjusting the consignment expense for certain sales. Commerce made changes to the margin calculations of Vinh Hoan, Anvifish Joint Stock Company (Anvifish) and the separate rate respondents' margins to account for a small change in the whole live fish SV. Also, at Commerce's request, the Court granted Commerce a voluntary remand to reconsider the calculation of the cap applied to Vinh Hoan's fish oil by-product offset.

On May 26, 2016, the Court remanded Commerce's First Remand Results.[8] In the second remand, in accordance with the Court's instructions, Commerce reconsidered its selection of the sawdust and rice husk SVs, provided further explanation concerning the cap to the fish oil by-product offset, and discussed the use of the absolute value of by-products in the margin calculation.[9] The Court upheld our findings on these issues, except one, the fish oil by-product offset.[10]

On July 10, 2017, the Court remanded Commerce's Second Remand Results.[11] In the third remand, in accordance with the Court's instructions, Commerce provided further explanation with respect to the calculated fish oil by-product offset and its superiority with respect to the other fish oil SVs on the record.[12] On September 22, 2017, Commerce filed the Third Remand Results with the Court. On May 24, 2018, the Court upheld the Third Remand Results.

As a result of the AR8 Remand Results,[13] there are calculation changes. After accounting for all such changes and issues in the AR8 Remand Results, the resulting antidumping margin for Vinh Hoan is $0.13 per kilogram and $2.39 per kilogram for Anvifish. Because Vinh Hoan's and Anvifish's margins changed, their weighted average also becomes the margin ($1.28 per kilogram) for those companies not individually examined but receiving a separate rate. On May 24, 2018, the Court sustained the AR8 Remand Results.[14]

Consistent with the decision of the United States Court of Appeals for the Federal Circuit (CAFC) in *Timken Co.* v. *United States,* 893 F.2d 337 (Fed. Cir. 1990) (*Timken*), as clarified by *Diamond Sawblades Mfrs. Coalition* v. *United States,* 626 F.3d 1374 (Fed. Cir. 2010) (*Diamond Sawblades*), Commerce is notifying the public that the final judgment in this case is not in harmony with Commerce's final results of the antidumping duty administrative review of the antidumping duty order on fish fillets from Vietnam covering the POR. Thus, Commerce is amending the *AR8 Amended Final Results* with respect to the weighted-average dumping margins for Vinh Hoan, Anvifish and the separate rate respondents.[15]

Timken Notice

In its decision in *Timken,* 893 F.2d at 341, as clarified by *Diamond Sawblades,* the CAFC held that, pursuant to section 516A(e) of the Tariff Act of 1930, as amended (Act), Commerce must publish a notice of a court decision that is not ''in harmony'' with a Commerce determination and must suspend liquidation of entries pending a ''conclusive'' court decision. The Court's May 24, 2018, judgment sustaining the AR8 Remand constitutes a final decision of the Court that is not in harmony with Commerce's *AR8 Amended Final Results.* This notice is published in fulfillment of the publication requirement of *Timken.*

Amended Final Results

Because there is now a final court decision, Commerce is amending the *AR8 Amended Final Results* with respect to Vinh Hoan, Anvifish and the separate rate respondents. The revised weighted-average dumping margins for these exporters during the period August 1, 2010, through July 31, 2011, are as follows:

2011, 78 FR 29323 (May 20, 2013) (*AR8 Amended Final Results*) and accompanying Ministerial Error Memorandum.

[3] These include Vinh Hoan, the Vietnam Association of Seafood Exporters and Producers, Binh An Seafood Joint Stock Company (Binh An), Anvifish and Vinh Quang Fisheries Corporation (Vinh Quang).

[4] Catfish Farmers of America and the following individual U.S. catfish processors: America's Catch, Consolidated Catfish Companies, LLC dba Country Select Catfish, Delta Pride Catfish, Inc., Harvest Select Catfish, Inc., Heartland Catfish Company, Pride of the Pond, and Simmons Farm Raised Catfish, Inc. (collectively, the petitioners).

[5] *See Vinh Hoan Corporation et al.* v. *United States,* Court No. 13–00156, Slip Op. 15–16 (CIT February 19, 2015).

[6] *See* Final Results of Redetermination Pursuant to *Vinh Hoan Corporation et al.* v. *United States,* Consol. Court No. 13–00156, and Slip Op. 15–16, dated August 3, 2015 (First Remand Results).

[7] Vinh Hoan was one of two mandatory respondents selected by Commerce. Vinh Hoan includes Vinh Hoan Corporation and its affiliates Van Duc Food Export Joint Company and Van Duc Tien Giang (VDTG).

[8] *See Vinh Hoan Corporation et al.* v. *United States,* Court No. 13–00156, Slip Op. 16–53 (CIT May 26, 2016).

[9] *See* Final Results of Redetermination Pursuant to *Vinh Hoan Corporation et al.* v. *United States,* Consol. Court No. 13–00156, Slip Op. 16–00053, dated May 26, 2016 (Second Remand Results).

[10] *See Vinh Hoan Corporation et al.* v. *United States,* Consol. Court No. 13–00156, Slip Op. 17–00081 (July 10, 2017) (*Vinh Hoan*).

[11] *See Vinh Hoan Corporation et al.* v. *United States,* Court No. 13–00156, Slip Op. 17–81 (CIT July 10, 2017).

[12] *See* Final Results of Redetermination Pursuant To Court Remand, Consol. Court No. 13–00156, Slip Op. 15–16 (CIT February 19, 2015), dated September 22, 2017, (Third Remand Results).

[13] *See* First Remand Results, Second Remand Results, and Third Remand Results (collectively AR8 Remand Results).

[14] *See Vinh Hoan Corporation et a.* v. *United States,* Court No. 13–00156, Slip Op. 18–59 (CIT May 24, 2018).

[15] These include: An Giang Agriculture and Food Import-Export Joint Stock Company; Asia Commerce Fisheries Joint Stock Company; Binh An Seafood Joint Stock Company; Cadovimex II Seafood Import-Export and Processing Joint Stock Company; Hiep Thanh Seafood Joint Stock Company; Hung Vuong Corporation; Nam Viet Corporation; NTSF Seafoods Joint Stock Company; QVD Food Company Ltd.; Saigon Mekong Fishery Co., Ltd.; Southern Fisheries Industries Company Ltd.; and Vinh Quang Fisheries Corporation (collectively, separate rate respondents).

Exporter	Weighted-average dumping margin (dollars per kilogram)
Vinh Hoan Corporation [16]	0.13
Anvifish Joint Stock Company [17]	2.39
An Giang Agriculture and Food Import-Export Joint Stock Company	1.28
Asia Commerce Fisheries Joint Stock Company	1.28
Binh An Seafood Joint Stock Company	1.28
Cadovimex II Seafood Import-Export and Processing Joint Stock Company	1.28
Hiep Thanh Seafood Joint Stock Company	1.28
Hung Vuong Corporation	1.28
Nam Viet Corporation	1.28
NTSF Seafoods Joint Stock Company	1.28
QVD Food Company Ltd [18]	1.28
Saigon Mekong Fishery Co., Ltd	1.28
Southern Fisheries Industries Company Ltd	1.28
Vinh Quang Fisheries Corporation	1.28

Accordingly, Commerce will continue the suspension of liquidation of the subject merchandise pending the expiration of the period of appeal or, if appealed, pending a final and conclusive court decision. In the event the Court's ruling is not appealed or, if appealed, upheld by the CAFC, Commerce will instruct U.S. Customs and Border Protection to assess antidumping duties on unliquidated entries of subject merchandise exported by the companies mentioned above using the assessment rate calculated by Commerce in the AR8 Remand Results and listed above.

Cash Deposit Requirements

Unless the applicable cash deposit rates have been superseded by cash deposit rates calculated in an intervening administrative review of the AD order on frozen fish fillets from Vietnam, Commerce will instruct U.S. Customs and Border Protection to require a cash deposit for estimated AD duties at the rate noted above for each specified exporter and producer combination, for entries of subject merchandise, entered or withdrawn from warehouse, for consumption, on or after June 3, 2018.

[16] This rate is applicable to the Vinh Hoan Group which includes: Vinh Hoan, Van Duc, and VDTG.

[17] Includes the trade name Anvifish Co., Ltd.

[18] This rate is also applicable to QVD Dong Thap Food Co., Ltd. (Dong Thap) and Thuan Hung Co., Ltd. (THUFICO). In the second review of this order, Commerce found QVD, Dong Thap and THUFICO to be a single entity, and because there has been no evidence submitted on the record of this review that calls this determination into question, we continue to find these companies to be part of a single entity. Therefore, we will assign this rate to the companies in the single entity. *See Certain Frozen Fish Fillets from the Socialist Republic of Vietnam: Preliminary Results of Antidumping Duty Administrative Review,* 71 FR 53387 (September 11, 2006).

Notification to Interested Parties

This notice is issued and published in accordance with sections 516A(e), 751(a)(1), and 777(i)(1) of the Act.

Dated: July 20, 2018.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2018–16338 Filed 7–30–18; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–836]

Glycine From the People's Republic of China: Rescission of Antidumping Duty Administrative Review; 2017–2018

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 glycine from the People's Republic of China (China) for the period March 1, 2017, through February 28, 2018, based on the timely withdrawal of the request for review.

DATES: Applicable July 31, 2018.

FOR FURTHER INFORMATION CONTACT: Edythe Artman 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) 482–3931 or (202) 482–0195, respectively.

SUPPLEMENTARY INFORMATION:

Background

On March 5, 2018, Commerce published a notice of opportunity to request an administrative review of the antidumping duty order on glycine from China in the **Federal Register.** The period of review covers March 1, 2017, through February 28, 2018.[1] On March 30, 2018, in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.213(b), Commerce received a timely request from GEO Specialty Chemicals, Inc. (GEO), a domestic producer of glycine, to conduct an administrative review of the order with respect to entries of subject merchandise made by Kumar Industries, Rudraa International, Salvi Chemical Industries, Avid Organics Pvt. Ltd., and Baoding Mantong Fine Chemistry Co., Ltd.[2] On May 2, 2018, pursuant to this request, in accordance with section 751(a) of the Act and 19 CFR 351.221(c)(1)(i), we initiated a review of those companies.[3] On May 30, 2018, GEO filed a timely withdrawal of its request of review for each of the five companies.[4] No other party requested an administrative review of this order.

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

[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 83 FR 9284 (March 5, 2018).

[2] See GEO's Request for Review, dated March 30, 2018.

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 83 FR 19215 (May 2, 2018).

[4] *See* Withdrawal of Request for Administrative Review, dated May 30, 2018.

request within 90 days of the date of publication of the notice of initiation of the requested review. As noted above, GEO withdrew its request for review by the 90-day deadline and no other party requested an administrative review of the antidumping duty order. Accordingly, we are rescinding the administrative review of the antidumping duty order on glycine from China for the period

March 1, 2017, through February 28, 2018, in its entirety, in accordance with 19 CFR 351.213(d)(1).

Assessment

Commerce will instruct U.S. Customs and Border Protection (CBP) to assess antidumping duties on all appropriate entries of glycine 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.

Notification Regarding Administrative Protective Orders

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305. 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: July 23, 2018.

James Maeder,

Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the duties of Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2018–16336 Filed 7–30–18; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–552–801]

Certain Frozen Fish Fillets From the Socialist Republic of Vietnam: Notice of Court Decisions Not in Harmony With Final Results of Administrative Review and Notice of Amended Final Results of Antidumping Duty Administrative Review

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

SUMMARY: On May 24, 2018, the United States Court of International Trade (Court) issued final judgments in *An Giang Fisheries Import and Export Joint Stock Company et al.* v. *United States,* Consol. Court No. 14–00109, sustaining the Department of Commerce's (Commerce) remand results for the ninth administrative review of the antidumping duty order on certain frozen fish fillets from the Socialist Republic of Vietnam (Vietnam) covering the period of review (POR) August 1, 2011, through July 31, 2012. Commerce is notifying the public that the Court's final judgment is not in harmony with Commerce's final results of the administrative review, and that Commerce is amending the final results with respect to certain exporters.

DATES: Applicable June 3, 2018.

FOR FURTHER INFORMATION CONTACT: Javier Barrientos, 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) 482–2243.

SUPPLEMENTARY INFORMATION:

Background

On April 7, 2014, Commerce issued its *AR9 Final Results*.[1] On July 2, 2014, Commerce issued its *AR9 Amended Final Results*.[2] Agifish et al.[3] and the petitioners[4] timely filed complaints with the Court and challenged certain aspects of the *AR9 Amended Final Results*. On June 7, 2015, the Court remanded Commerce's *AR9 Amended Final Results*.[5]

In the first remand, in accordance with the Court's instructions, Commerce reconsidered its selection of the surrogate value (SV) for rice husk and provided further explanation concerning the cap to the fish oil by-product offset in Vinh Hoan Corporation's[6] margin calculation.[7] Additionally, and in accordance with the Court's instructions, Commerce made changes to Vinh Hoan's margin calculation, specifically, by adjusting the denominators for Vinh Hoan's factors of production (FOPs) to exclude water weight, and subsequently recalculating Vinh Hoan's net U.S. price of sales for subject merchandise on a net weight basis exclusive of water weight.[8] The Court upheld our findings on all but one of these issues, *i.e.,* the fish oil by-product offset.[9]

On July 10, 2017, the Court remanded Commerce's First Remand Results.[10] In the second remand, in accordance with the Court's instructions, Commerce provided further explanation with respect to the calculated fish oil by-

[1] *See Certain Frozen Fish Fillets from the Socialist Republic of Vietnam: Final Results of Antidumping Duty Administrative Review and New Shipper Review; 2011–2012,* 79 FR 19053 (April 7, 2014) (*AR9 Final Results*).

[2] *See Amended Final Results of Antidumping Duty Administrative Review; 2010–2011,* 79 FR 37714 (July 2, 2014) (*AR9 Amended Final Results*) and accompanying Ministerial Error Memorandum.

[3] These include An Giang Fisheries Import and Export Joint Stock Company, Asia Commerce Fisheries Joint Stock Company, Cuu Long Fish Joint Stock Company, Hiep Thanh Seafood Joint Stock Company, International Development and Investment Corporation, NTSF Seafoods Joint Stock Company, QVD Food Company Ltd., Southern Fishery Industries Company, Ltd., and Vinh Hoan Corporation (collectively Agifish et al.).

[4] Catfish Farmers of America and the following individual U.S. catfish processors: America's Catch, Consolidated Catfish Companies, LLC dba Country Select Catfish, Delta Pride Catfish, Inc., Harvest Select Catfish, Inc., Heartland Catfish Company, Pride of the Pond, and Simmons Farm Raised Catfish, Inc. (collectively, the petitioners).

[5] *See An Giang Fisheries Import and Export Joint Stock Company et al.* v. *United States,* Court No. 14–00109, Slip Op. 16–55 (CIT June 7, 2016).

[6] Vinh Hoan was one of two mandatory respondents selected by Commerce. (Vinh Hoan) includes Vinh Hoan Corporation and its affiliates Van Duc Food Export Joint Company and Van Duc Tien Giang (VDTG).

[7] *See* Final Results of Redetermination Pursuant to *An Giang Fisheries Import and Export Joint Stock Company et al.* v. *United States,* Consol. Court No. 14–00109, and Slip Op. 16–55, dated February 9, 2017 (First Remand Results).

[8] *Id.*

[9] *See An Giang Fisheries Import and Export Joint Stock Company et al.* v. *United States,* Consol. Court No. 14–00109, Slip Op. 17–00082 (July 10, 2017) (*An Giang Fisheries*).

[10] *See Vinh Hoan Corporation et al.* v. *United States,* Court No. 14–00109, Slip Op. 17–82 (CIT July 10, 2017).

product offset and its superiority as compared to the other fish oil SVs on the record.[11] On September 22, 2017, Commerce filed the Second Remand Results with the Court.

As a result of the AR9 Remand Results,[12] there are calculation changes. After accounting for all such changes and issues in the AR9 Remand Results, the resulting antidumping duty margin for Vinh Hoan is *de minimis.* Because Vinh Hoan's margin is now *de minimis,* Agifish's margin (unchanged) becomes the margin ($1.20 per kilogram) for those companies not individually examined but receiving a separate rate. On May 24, 2018, the Court sustained the AR9 Remand Results.[13]

Consistent with the decision of the United States Court of Appeals for the Federal Circuit (CAFC) in *Timken Co.* v. *United States,* 893 F.2d 337 (Fed. Cir. 1990) (*Timken*), as clarified by *Diamond Sawblades Mfrs. Coalition* v. *United States,* 626 F.3d 1374 (Fed. Cir. 2010) (*Diamond Sawblades*), Commerce is notifying the public that the final judgment in this cases is not in harmony with Commerce's final results of the antidumping duty administrative review of the antidumping duty order on fish fillets from Vietnam covering the POR. Thus, Commerce is amending the *AR9 Amended Final Results* with respect to the weighted-average dumping margins for Vinh Hoan, and the separate rate respondents.[14]

Timken Notice

In its decision in *Timken,* 893 F.2d at 341, as clarified by *Diamond Sawblades,* the CAFC held that, pursuant to section 516A(e) of the Tariff Act of 1930, as amended (Act), Commerce must publish a notice of a court decision that is not ''in harmony'' with a Commerce determination and must suspend liquidation of entries pending a ''conclusive'' court decision. The Court's May 24, 2018, judgment sustaining the AR9 Remand constitutes a final decision of the Court that is not in harmony with Commerce's *AR9 Amended Final Results.* This notice is published in fulfillment of the publication requirement of *Timken.*

Amended Final Results

Because there is now a final court decision, Commerce is amending the *AR9 Amended Final Results* with respect to Vinh Hoan, and the separate rate respondents. The revised weighted-average dumping margins for these exporters during the period August 1, 2011, through July 31, 2012, are as follows:

Exporter name	Weighted-average dumping margin (dollars per kilogram)
Vinh Hoan Corporation[15]	0.00
Hung Vuong Group[16]	1.20
An My Fish Joint Stock Company	1.20
Anvifish Joint Stock Company[17]	1.20
Asia Commerce Fisheries Joint Stock Company	1.20
Binh An Seafood Joint Stock Company	1.20
Cadovimex II Seafood Import-Export and Processing Joint Stock Company	1.20
Cantho Import-Export Seafood Joint Stock Company	1.20
Cuu Long Fish Import-Export Corporation[18]	
Cuu Long Fish Joint Stock Company	1.20
East Sea Seafoods Limited Liability Company[19]	1.20
Green Farms Seafood Joint Stock Company	1.20
Hiep Thanh Seafood Joint Stock Company	1.20
Hoa Phat Seafood Import-Export and Processing JSC	1.20
International Development & Investment Corporation	1.20
NTSF Seafoods Joint Stock Company	1.20
QVD Food Company Ltd.[20]	1.20
Saigon Mekong Fishery Co., Ltd	1.20
Seafood Joint Stock Company No.4 Branch Dongtam Fisheries Processing Company	1.20
Southern Fisheries Industries Company Ltd	1.20
Sunrise Corporation	1.20
Thien Ma Seafood Co., Ltd	1.20
To Chau Joint Stock Company	1.20
Viet Phu Food & Fish Corporation	1.20
Vinh Quang Fisheries Corporation	1.20

[11] *See* Final Results of Redetermination Pursuant To Court Remand, Consol. Court No. 14–00109, Slip Op. 17–00082 (CIT July 10, 2017), dated September 22, 2017, (Second Remand Results).

[12] *See* First Remand Results and Second Remand Results (collectively, AR9 Remand Results).

[13] *See An Giang Fisheries Import and Export Joint Stock Company et al.* v. *United States,* Consol. Court No. 14–109, Slip Op. 18–60 (CIT May 24, 2018).

[14] These include: An My Fish Joint Stock Company; Anvifish Joint Stock Company; Asia Commerce Fisheries Joint Stock Company; Binh An Seafood Joint Stock Company; Cadovimex II Seafood Import-Export and Processing Joint Stock Company; Cantho Import-Export Seafood Joint Stock Company; Cuu Long Fish Import-Export Corporation; Cuu Long Fish Joint Stock Company; East Sea Seafoods Limited Liability Company; Green Farms Seafood Joint Stock Company; Hiep Thanh Seafood Joint Stock Company; Hoa Phat Seafood Import-Export and Processing JSC; International Development & Investment Corporation; NTSF Seafoods Joint Stock Company; QVD Food Company Ltd.; Saigon Mekong Fishery Co., Ltd.; Seafood Joint Stock Company No.4 Branch Dongtam Fisheries Processing Company; Southern Fisheries Industries Company Ltd.; Sunrise Corporation; Thien Ma Seafood Co., Ltd.; To Chau Joint Stock Company; Viet Phu Food & Fish Corporation; and Vinh Quang Fisheries Corporation (collectively, separate rate respondents).

[15] This rate is applicable to the Vinh Hoan Group which includes: Vinh Hoan, Van Duc, and VDTG.

[16] This rate is applicable to the Hung Vuong Group, which includes: An Giang Fisheries Import and Export Joint Stock Company, Asia Pangasius Company Limited, Europe Joint Stock Company, Hung Vuong Joint Stock Company, Hung Vuong Mascato Company Limited, Hung Vuong—Vinh Long Co., Ltd., and Hung Vuong—Sa Dec Co., Ltd.

[17] Includes the trade name Anvifish Co., Ltd., and Anvifish JSC.

[18] Includes the trade name CL Panga Fish.

[19] Includes the trade names East Sea Seafoods LLC and ESS.

[20] This rate is also applicable to QVD Dong Thap Food Co., Ltd. (Dong Thap) and Thuan Hung Co., Ltd. (THUFICO). In the second review of this order, Commerce found QVD, Dong Thap and THUFICO to be a single entity, and because there has been no evidence submitted on the record of this review that calls this determination into question, we continue to find these companies to be part of a single entity. Therefore, we will assign this rate to the companies in the single entity. *See Certain Frozen Fish Fillets from the Socialist Republic of Vietnam: Preliminary Results of Antidumping Duty Administrative Review,* 71 FR 53387 (September 11, 2006).

Accordingly, Commerce will continue the suspension of liquidation of the subject merchandise pending the expiration of the period of appeal or, if appealed, pending a final and conclusive court decision. In the event the Court's ruling is not appealed or, if appealed, upheld by the CAFC, Commerce will instruct U.S. Customs and Border Protection to assess antidumping duties on unliquidated entries of subject merchandise exported by the companies identified above using the assessment rate calculated by Commerce in the AR9 Remand Results and listed above.

Cash Deposit Requirements

Unless the applicable cash deposit rates have been superseded by cash deposit rates calculated in an intervening administrative review of the AD order on frozen fish fillets from Vietnam, Commerce will instruct U.S. Customs and Border Protection to require a cash deposit for estimated AD duties at the rate noted above for each specified exporter and producer combination, for entries of subject merchandise, entered or withdrawn from warehouse, for consumption, on or after June 3, 2018.

Notification to Interested Parties

This notice is issued and published in accordance with sections 516A(e), 751(a)(1), and 777(i)(1) of the Act.

Dated: July 25, 2018.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2018–16333 Filed 7–30–18; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG377

Gulf of Mexico Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The Gulf of Mexico Fishery Management Council (Council) will hold a four-day meeting to consider actions affecting the Gulf of Mexico fisheries in the exclusive economic zone (EEZ).

DATES: The meeting will be held on Monday, August 20 through Thursday, August 23, 2018.

ADDRESSES: The meeting will take place at the Omni Corpus Christi hotel located at 900 N. Shoreline Boulevard, Corpus Christi, TX 78401; telephone: (361) 887–1600.

Council address: Gulf of Mexico Fishery Management Council, 4107 W. Spruce Street, Suite 200, Tampa, FL 33607; telephone: (813) 348–1630.

FOR FURTHER INFORMATION CONTACT: Dr. Carrie Simmons, Executive Director, Gulf of Mexico Fishery Management Council; telephone: (813) 348–1630.

SUPPLEMENTARY INFORMATION:

Agenda

Monday, August 20, 2018; 8:30 a.m.–5:15 p.m.

The Coral Committee will receive an update on the Flower Garden Banks National Marine Sanctuary Expansion; discuss Final Action: Abbreviated Framework Action—Clarification of Fishing in Habitat Area Particular Concerns (HAPCs); and, receive an update on the Coral Reef Conservation Program Grant. The Sustainable Fisheries Committee will review a Draft Abbreviated Framework Action: Conversion of Historical Captain Endorsements to Federal For-Hire Permits; and, review of Senate Bill S. 3138—A Bill to Establish a Regulatory System for Marine Aquaculture in the United States Exclusive Economic Zone (EEZ).

After lunch, the Mackerel Committee will convene to discuss the Coastal Migratory Pelagics (CMP) Landings Update; receive an update on Cobia catch per unit effort (CPUE) Indices and Scientific and Statistic Committee (SSC) recommendations; and, review Options: CMP Framework Amendment 7—Modifications to Gulf Cobia Size and Possession Limits. The Gulf SEDAR Committee will receive an overview of the revised SEDAR process; and review and finalize the 2020 and 2021 Gulf SEDAR Schedule. The Shrimp Committee will receive an update on Council request regarding shrimp effort threshold reduction in the area monitored for juvenile red snapper bycatch and SSC recommendations. The Spiny Lobster Committee will review and discuss the Spiny Lobster Landings and review Final Action: Spiny Lobster Amendment 13—Modifications to the Spiny Lobster Gear Requirements and Cooperative Management Procedures.

Tuesday, August 21, 2018; 8:30 a.m.–5:30 p.m.

The Reef Fish Management Committee will convene and review the Reef Fish Landings; review Final Action: Framework Action to Modify Red Snapper Acceptable Catch Limits (ACL) and Acceptable Catch Targets (ACT) and Gulf Hogfish ACLs. The committee will also review Draft Amendment 36B—Modifications to Commercial Individual Fishing Quota (IFQ) Programs and Final Action: Modification to the Recreational Red Snapper ACT Buffers. After lunch, the committee will discuss the Gulf of Mexico Allocation Review Triggers; compare the Council's Allocation Policy with National Marine Fisheries Service (NMFS) Allocation Review Policy; review Scoping Document: Reallocation of the Red Snapper ACL and the revised Draft Amendment 50: State Management Program for Recreational Red Snapper and Individual State Amendments.

Wednesday, August 22, 2018; 8:30 a.m.–5 p.m.

The Reef Fish Committee will receive a presentation on the Great Red Snapper Count; and review the Scientific and Statistical Committee (SSC) Summary Report. The Data Committee will review the Gulf of Mexico 2017 Headboat Summary Report; and receive an update on Southeast For-Hire Electronic Reporting Programs (SEFHIER) Implementation Plan.

Mid-morning (approximately 10:45 a.m.), the Full Council will convene with a Call to Order, Announcements, and Introductions. The Council will hold the induction of new Council Members, followed by the Adoption of Agenda and Approval of Minutes. The Council will receive presentations on Highly Migratory Species (HMS) Amendment 11 regarding Shortfin Mako Sharks; and from Texas Law Enforcement. The Council will receive open public testimony from 1:30 p.m. until 5 p.m. on the following items: Final Action: Abbreviated Framework Action—Clarification of Fishing in HAPCs; Final Action: Framework Action to Modify Red Snapper ACLs and ACTs, and Gulf Hogfish ACLs; Final Action: Modification to the Recreational Red Snapper Annual Catch Target Buffers; Final Action: Spiny Lobster Amendment 13—Modifications to the Spiny Lobster Gear Requirements and Cooperative Management Procedures; and, on any other fishery issues or concerns. Anyone wishing to speak during public comment should sign in at the registration station located at the entrance to the meeting room.

Thursday, August 23, 2018; 8:30 a.m.–3:30 p.m.

The Council will receive reports from the following committees: Coral, Mackerel, Spiny Lobster, Sustainable Fisheries, Gulf SEDAR, Data Collection, Shrimp, and Reef Fish Management Committees. After lunch, the Council will receive updates from the following supporting agencies: South Atlantic Fishery Management Council; NOAA Office of Law Enforcement (OLE), Gulf States Marine Fisheries Commission; U.S. Coast Guard; U.S. Fish and Wildlife Service; and, the Department of State.

The Council will discuss any Other Business items. Lastly, the Council will hold an election for Chair and Vice-Chair.

—Meeting Adjourns

The meeting will be broadcast via webinar. You may register for the webinar by visiting *www.gulfcouncil.org* and clicking on the Council meeting on the calendar. *https://attendee.gotowebinar.com/register/3383291116212545537-*. The timing and order in which agenda items are addressed may change as required to effectively address the issue, and the latest version along with other meeting materials will be posted on *www.gulfcouncil.org* as they become available.

Although other non-emergency issues not contained in this agenda may come before this Council for discussion, those issues may not be the subjects of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided that the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kathy Pereira (see **ADDRESSES**) at least 5 days prior to the meeting date.

Dated: July 26, 2018.

Tracey L. Thompson,

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

[FR Doc. 2018–16311 Filed 7–30–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

U.S. Integrated Ocean Observing System (IOOS®) Advisory Committee

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

ACTION: Notice of open meeting.

SUMMARY: Notice is hereby given of a meeting of the U.S. Integrated Ocean Observing System (IOOS®) Advisory Committee (Committee) in Juneau, Alaska.

DATES AND TIMES: The meeting will be held on Tuesday, August 28, 2018, from 9:00 a.m. to 5:30 p.m., and Wednesday, August 29, 2018 from 9:00 a.m.–3:00 p.m. These times and the agenda topics described below are subject to change. Refer to the web page listed below for the most up-to-date agenda.

ADDRESSES: On Tuesday, August 28th from 9:00 a.m. to 12:00 p.m. the meeting will be held at the Elizabeth Peratrovich Hall Conference Center, 320 W Willoughby Ave, Juneau, AK. This will be a half-day joint meeting with NOAA's Hydrographic Services Review Panel on topics of joint interest such as water level partnerships. From 2:00 to 5:30 p.m., the IOOS Advisory Committee meeting will be held at the Westmark Baranof Hotel, 127 N Franklin Street, Juneau, AK. On Wednesday, August 29th, the meeting will be held from 9:00 a.m. to 3:00 p.m. at the NOAA Fisheries Auke Bay Lab, 17109 Point Lena Loop Road, Juneau, AK. Venues may be subject to change. Refer to the web page listed below for the most up-to-date information.

FOR FURTHER INFORMATION CONTACT: Jessica Snowden, Designated Federal Official, U.S. IOOS Advisory Committee, U.S. IOOS Program, 1315 East-West Highway, Station 2612, Silver Spring, MD 20910; Phone 240–533–9466; Fax 301–713–3281; Email *jessica.snowden@noaa.gov* or visit the U.S. IOOS Advisory Committee website at *http://ioos.noaa.gov/community/u-s-ioos-advisory-committee/.*

SUPPLEMENTARY INFORMATION: The Committee was established by the NOAA Administrator as directed by Section 12304 of the Integrated Coastal and Ocean Observation System Act, part of the Omnibus Public Land Management Act of 2009 (Pub. L. 111–11). The Committee advises the NOAA Administrator and the Interagency Ocean Observation Committee (IOOC) on matters related to the responsibilities and authorities set forth in section 12302 of the Integrated Coastal and Ocean Observation System Act of 2009 and other appropriate matters as the Under Secretary refers to the Committee for review and advice.

The Committee will provide advice on:

(a) Administration, operation, management, and maintenance of the System;

(b) expansion and periodic modernization and upgrade of technology components of the System;

(c) identification of end-user communities, their needs for information provided by the System, and the System's effectiveness in dissemination information to end-user communities and to the general public; and

(d) any other purpose identified by the Under Secretary of Commerce for Oceans and Atmosphere or the Interagency Ocean Observation Committee.

The meeting will be open to public participation with a 15-minute public comment period on August 28, 2018, from 5:00 p.m. to 5:15 p.m., and on August 29, 2018, from 2:45 p.m. to 3:00 p.m. (check agenda on website to confirm time.) The Committee expects that public statements presented at its meetings will not be repetitive of previously submitted verbal or written statements. In general, each individual or group making a verbal presentation will be limited to a total time of three (3) minutes. Written comments should be received by the Designated Federal Official by August 21, 2018 to provide sufficient time for Committee review. Written comments received after August 21st will be distributed to the Committee, but may not be reviewed prior to the meeting date. Seats will be available on a first-come, first-served basis. A webinar will be provided. Sign-up information for the webinar will be posted on the website.

Matters To Be Considered: The meeting will focus on ongoing committee priorities, including discussions of stakeholder needs specific to the Alaska and Arctic regions and developing the next set of recommendations. The latest version of the agenda will be posted at *http://ioos.noaa.gov/community/u-s-ioos-advisory-committee/.*

Special Accomodations: These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Jessica Snowden, Designated Federal

Official at 240–533–9466 by August 20, 2018.

Dated: July 17, 2018.

Carl C. Gouldman,

Director, U.S. IOOS Program, National Ocean Service.

[FR Doc. 2018–16286 Filed 7–30–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Notice of 30-Day Public Comment Period on the Injury Assessment Plan for the Lower Duwamish River (''Lower Duwamish River Natural Resource Damage Assessment: Injury Assessment Plan'')

AGENCY: National Ocean Service, National Oceanic and Atmospheric Administration, U.S. Department of Commerce.

ACTION: Notice of public comment period.

SUMMARY: NOAA, on behalf of its co-members of the Elliott Bay Trustee Council (Trustee Council), announce the release of the Lower Duwamish River Injury Assessment Plan, which sets forward the Trustee Council's approach for assessing natural resource damages at the Lower Duwamish River. The Injury Assessment Plan is one of the first steps in the natural resources damages assessment process, and is being released to the public in accordance with the applicable regulations.

Through today's notice, NOAA is announcing: (1) The Trustees' plan to begin the assessment of natural resource damages for lost ecological and human use services resulting from releases of hazardous substances and oil to the Lower Duwamish River in Seattle, Washington; and (2) a provision of a 30-day period for public comment on the plan.

ADDRESSES: Comments are sought on the draft injury assessment plan and should be emailed to *Rebecca.Hoff@noaa.gov* with the subject line: ''Comments on Lower Duwamish River Natural Resource Damage Assessment: Injury Assessment Plan.'' Comments may also be mailed to: Rebecca Hoff of NOAA Western Region Center, 7600 Sand Point Way Building 1, Seattle, WA 98118.

SUPPLEMENTARY INFORMATION: The increasingly industrial uses of the Lower Duwamish River led to contamination of natural resources through multiple pathways from releases of hazardous substances upland and adjacent to the river. As a result of this contamination, EPA designated Harbor Island, Lockheed West Seattle, and the Lower Duwamish Waterway (collectively, the Site) as Superfund sites on the National Priority List. Examples of contaminants of concern released to the Lower Duwamish River include polychlorinated biphenyls (PCBs), metals, and polycyclic aromatic hydrocarbons (PAHs). Natural resources such as benthic invertebrates, migratory fish (such as juvenile Chinook salmon), resident fish (such as sculpin and English sole), birds, and fish eating mammals exposed to these compounds can potentially be harmed as a result. In addition, hazardous substances released to the Lower Duwamish River have potentially reduced the human use services (*e.g.,* recreational fishing, recreational boating, tribal uses) provided by the River. In addition, fish consumption advisories related to hazardous substances have been issued to the public warning of the risks associated with consumption of various fish species commonly targeted by anglers. The Injury Assessment Plan sets forth the approach the Trustee Council will apply to completing the damage assessment process to resolve natural resource damages liability with non-settling parties.

The Elliott Bay Trustee Council is comprised of Federal, state and tribal natural resource trustees. Members of the Trustee Council include the U.S. Department of the Interior; the U.S. Department of Commerce, acting through NOAA; the State of Washington; the Suquamish Tribe; and the Muckleshoot Indian Tribe. The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), 42 U.S.C. §§ 9601 *et seq.;* the Oil Pollution Act (OPA) of 1990, 33 U.S.C. §§ 2701 *et seq.;* the Clean Water Act (CWA), 33 U.S.C. § 1251; the National Oil and Hazardous Substances Pollution Contingency Plan [National Contingency Plan (NCP)], 40 CFR 300, Subpart G; Executive Orders 12580 and 12777; and other applicable federal and state laws and regulations, provide a legal framework for the Trustee Council's actions.

Under the federal regulations, the Trustee Council can elect to perform a Type A or Type B injury assessment. Type A assessment procedures use simplified model assumptions to address injuries that result from a single event or short-term exposure. Releases of hazardous substances from the Site have occurred from multiple sources over many decades, resulting in complex exposure conditions impacting aquatic and upland media and associated complex food webs. Therefore, the Elliott Bay Trustee Council previously elected to perform a Type B assessment, the procedures for which require ''more extensive field observation than the Type A procedures.'' 43 CFR § 11.33(b). This assessment method includes injury determination, quantification, and damage determination. Because substantial Site-specific data already exist to support the assessment, a Type B assessment can be conducted for the Site at a reasonable cost. The federal regulations for a Type B assessment outline methods for determining (1) pathways through which hazardous substances released by potentially responsible parties expose natural resources, (2) injuries to natural resources, (3) the extent of those injuries and resultant public losses, (4) baseline conditions and time required for the resources to recover to baseline, and (5) the cost or value of restoring injured resources. These methods facilitate calculation of natural resource damages. 43 CFR §§ 11.60–11.84.

Dated: July 19, 2018.

David Westerholm,

Director, Office of Response and Restoration.

[FR Doc. 2018–16287 Filed 7–30–18; 8:45 am]

BILLING CODE 3510–JE–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Evaluation of State Coastal Management Programs

AGENCY: Office for Coastal Management (OCM), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice of public meeting.

SUMMARY: The National Oceanic and Atmospheric Administration (NOAA), Office for Coastal Management will hold a public meeting to solicit comments on the performance evaluation of the Mississippi Coastal Management Program.

DATES: *Mississippi Coastal Management Program Evaluation:* The public meeting will be held on September 25, 2018, and written comments must be received on or before October 5, 2018.

For specific dates, times, and locations of the public meetings, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: You may submit comments on the program or reserve NOAA intends to evaluate by any of the following methods:

Public Meeting and Oral Comments: A public meeting will be held in Biloxi, Mississippi. For the specific location, see **SUPPLEMENTARY INFORMATION.**

Written Comments: Please direct written comments to Dr. Maria Honeycutt, Program Evaluator, NOAA Office for Coastal Management, 1305 East-West Highway N/OCM1, Silver Spring, Maryland 20910, or via email to *Maria.Honeycutt@noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Maria Honeycutt, Ph.D., CFM, NOAA Office for Coastal Management, 1305 East-West Highway N/OCM1, Silver Spring, Maryland 20910, by phone at (240) 533–0726, or via email to *Maria.Honeycutt@noaa.gov.* Copies of the previous evaluation findings and 2016–2020 Assessment and Strategy may be viewed and downloaded on the internet at *http://coast.noaa.gov/czm/evaluations.* A copy of the evaluation notification letter and most recent progress report may be obtained upon request by contacting the person identified under **FOR FURTHER INFORMATION CONTACT**.

SUPPLEMENTARY INFORMATION: Section 312 of the Coastal Zone Management Act (CZMA) requires NOAA to conduct periodic evaluations of federally approved state and territorial coastal programs. The process includes one or more public meetings, consideration of written public comments, and consultations with interested Federal, state, and local agencies and members of the public. During the evaluation, NOAA will consider the extent to which the state has met the national objectives, adhered to the management program approved by the Secretary of Commerce, and adhered to the terms of financial assistance under the CZMA. When the evaluation is completed, NOAA's Office for Coastal Management will place a notice in the **Federal Register** announcing the availability of the Final Evaluation Findings.

You may participate or submit oral comments at the public meeting scheduled as follows:

Date: September 25, 2018

Time: 6:00 p.m., local time

Location: Bolton State Building, Public Meeting Room, 1141 Bayview Avenue, Biloxi, Mississippi 39530

Written public comments must be received on or before October 5, 2018.

(Federal Domestic Assistance Catalog 11.419. Coastal Zone Management Program Administration.)

Dated: July 17, 2018.

Keelin Kuipers,

Acting Deputy Director, Office for Coastal Management, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2018–16284 Filed 7–30–18; 8:45 am]

BILLING CODE 3510–08–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Hydrographic Services Review Panel Meeting

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

ACTION: Notice of open public meeting.

SUMMARY: The Hydrographic Services Review Panel (HSRP) will hold a meeting that will be open to the public and public comments are requested in advance and/or during the meeting. Information about the HSRP meeting, agenda, presentations, webinar registration, and other background documents will be posted online at: *https://www.nauticalcharts.noaa.gov/hsrp/hsrp.htm.*

DATES: The meeting is planned for two and a half days during August 28–30, 2018. The dates, agenda, and times are subject to change. For updates, please check online at: *https://www.nauticalcharts.noaa.gov/hsrp/hsrp.htm.*

Location: Juneau, Alaska. The meeting venue will be announced online at: *https://www.nauticalcharts.noaa.gov/hsrp/hsrp.htm.*

FOR FURTHER INFORMATION CONTACT: Lynne Mersfelder-Lewis, HSRP program manager, National Ocean Service, Office of Coast Survey, NOAA (N/NSD), 1315 East-West Highway, SSMC3 #6305, Silver Spring, Maryland 20910; telephone: 301–533–0064; email: *Lynne.Mersfelder@noaa.gov.*

SUPPLEMENTARY INFORMATION: The meeting is open to the public, seating will be available on a first-come, first-served basis, and public comment is encouraged. There are public comment periods scheduled each day and noted in the agenda. Each individual or group making verbal comments will be limited to a total time of five (5) minutes and will be recorded. For those not onsite, comments can be submitted via the webinar chat function or via email in writing. Individuals who would like to submit written statements in advance, during or after the meeting should email their comments to *Lynne.Mersfelder@noaa.gov.* The HSRP will provide webinar capability. Pre-registration is required to access the webinar: *https://attendee.gotowebinar.com/register/3898703691780313857.*

The Hydrographic Services Review Panel (HSRP) is a Federal Advisory Committee established to advise the Under Secretary of Commerce for Oceans and Atmosphere, the NOAA Administrator, on matters related to the responsibilities and authorities set forth in section 303 of the Hydrographic Services Improvement Act of 1998, as amended, and such other appropriate matters that the Under Secretary refers to the Panel for review and advice. The charter and other information are located online at: *https://www.nauticalcharts.noaa.gov/hsrp/CharterBylawsHSIAStatute.htm.*

Past recommendations and issue papers are at: *https://www.nauticalcharts.noaa.gov/hsrp/recommendations.htm.*

Past HSRP public meeting summary reports, agendas, presentations, transcripts, webinars, and other information is available online at: *https://www.nauticalcharts.noaa.gov/hsrp/meetings.htm.*

Matters To Be Considered: The panel is convening to hear federal, state, regional and local partners and stakeholders on issues relevant to NOAA's navigation services, focusing on Alaska and the U.S. Arctic region as well as national issues. The HSRP will have a joint session with NOAA's Integrated Ocean Observation System Advisory Committee on water level partnerships. Navigation services include the data, products, and services provided by the NOAA programs and activities that undertake geodetic observations, gravity modeling, shoreline mapping, bathymetric mapping, hydrographic surveying, nautical charting, tide and water level observations, current observations, and marine modeling. This suite of NOAA products and services support safe and efficient navigation, resilient coasts and communities, and the nationwide positioning information infrastructure to support America's commerce. The Panel will hear from state and federal agencies, non-federal organizations, stakeholders and partners about their missions and use of NOAA's navigation services, the value these services bring, and what improvements could be made. Other administrative matters may be considered. The agenda and speakers are subject to change.

Special Accommodations: This meeting is physically accessible to people with disabilities. Please direct requests for sign language interpretation

or other auxiliary aids to *Lynne.Mersfelder@noaa.gov* by August 8, 2018.

Dated: July 13, 2018.

Kathryn Ries,

Deputy Director, Office of Coast Survey, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2018–16285 Filed 7–30–18; 8:45 am]

BILLING CODE 3510–JE–P

DEPARTMENT OF DEFENSE

Department of the Army

Inland Waterways Users Board; Request for Nominations

AGENCY: Department of the Army, U.S. Army Corps of Engineers, DOD.

ACTION: Notice of request for nominations.

SUMMARY: The Department of the Army is publishing this notice to request nominations to serve as representatives on the Inland Waterways Users Board, sponsored by the U.S. Army Corps of Engineers. Section 302 of Public Law 99–662 established the Inland Waterways Users Board. The Board is an independent Federal advisory committee. The Secretary of the Army appoints its 11 (eleven) representative organizations. This notice is to solicit nominations for seven (7) appointments for terms that will begin by May 28, 2019. For additional information about the Board, please visit the committee's website at *http://www.iwr.usace.army.mil/Missions/Navigation/InlandWaterwaysUsersBoard.aspx.*

ADDRESSES: Institute for Water Resources, U.S. Army Corps of Engineers, ATTN: Mr. Mark R. Pointon, Designated Federal Officer (DFO) for the Inland Waterways Users Board, CEIWR–GM, 7701 Telegraph Road, Casey Building, Alexandria, VA 22315–3868; by telephone at 703–428–6438; and by email at *Mark.Pointon@usace.army.mil.*

FOR FURTHER INFORMATION CONTACT: Alternatively, contact Mr. Kenneth E. Lichtman, the Alternate Designated Federal Officer (ADFO), in writing at the Institute for Water Resources, U.S. Army Corps of Engineers, ATTN: CEIWR–GW, 7701 Telegraph Road, Casey Building, Alexandria, VA 22315–3868; by telephone at 703–428–8083; and by email at *Kenneth.E.Lichtman@usace.army.mil.*

SUPPLEMENTARY INFORMATION: The selection, service, and appointment of representative organizations to the Board are covered by provisions of Section 302 of Public Law 99–662. The substance of those provisions is as follows:

a. Selection. Representative organizations are to be selected from the spectrum of commercial carriers and shippers using the inland and intracoastal waterways, to represent geographical regions, and to be representative of waterborne commerce as determined by commodity ton-miles and tonnage statistics.

b. Service. The Board is required to meet at least semi-annually to develop and make recommendations to the Secretary of the Army on waterways construction and major rehabilitation priorities and spending levels for commercial navigation improvements, and report its recommendations annually to the Secretary and Congress.

c. Appointment. The operation of the Board and appointment of representative organizations are subject to the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended) and departmental implementing regulations. Representative organizations serve without compensation but their expenses due to Board activities are reimbursable. The considerations specified in Section 302 for the selection of representative organizations to the Board, and certain terms used therein, have been interpreted, supplemented, or otherwise clarified as follows:

(1) Carriers and Shippers. The law uses the terms ''primary users and shippers.'' Primary users have been interpreted to mean the providers of transportation services on inland waterways such as barge or towboat operators. Shippers have been interpreted to mean the purchasers of such services for the movement of commodities they own or control. Representative companies are appointed to the Board, and they must be either a carrier or shipper or both. For that purpose a trade or regional association is neither a shipper nor primary user.

(2) Geographical Representation. The law specifies ''various'' regions. For the purposes of the Board, the waterways subjected to fuel taxes and described in Public Law 95–502, as amended, have been aggregated into six regions. They are (1) the Upper Mississippi River and its tributaries above the mouth of the Ohio; (2) the Lower Mississippi River and its tributaries below the mouth of the Ohio and above Baton Rouge; (3) the Ohio River and its tributaries; (4) the Gulf Intracoastal Waterway in Louisiana and Texas; (5) the Gulf Intracoastal Waterway east of New Orleans and associated fuel-taxed waterways including the Tennessee-Tombigbee, plus the Atlantic Intracoastal Waterway below Norfolk; and (6) the Columbia-Snake Rivers System and Upper Willamette. The intent is that each region shall be represented by at least one representative organization, with that representation determined by the regional concentration of the firm's traffic on the waterways.

(3) Commodity Representation. Waterway commerce has been aggregated into six commodity categories based on ''inland'' ton-miles shown in Waterborne Commerce of the United States. These categories are (1) Farm and Food Products; (2) Coal and Coke; (3) Petroleum, Crude and Products; (4) Minerals, Ores, and Primary Metals and Mineral Products; (5) Chemicals and Allied Products; and (6) All Other. A consideration in the selection of representative organizations to the Board will be that the commodities carried or shipped by those firms will be reasonably representative of the above commodity categories.

d. Nomination. Reflecting preceding selection criteria, the current representation by the seven (7) organizations whose terms expire includes Regions 1, 2, 4, 5 and 6, five carrier and two shipper representation and all commodity representation.

Individuals, firms or associations may nominate representative organizations to serve on the Board. Nominations will:

(1) Include the commercial operations of the carrier and/or shipper representative organization being nominated. This commercial operations information will show the actual or estimated ton-miles of each commodity carried or shipped on the inland waterways system in a recent year (or years), using the waterway regions and commodity categories previously listed.

(2) State the region(s) to be represented.

(3) State whether the nominated representative organization is a carrier, shipper or both.

(4) Provide the name of an individual to be the principle person representing the organization and information pertaining to their personal qualifications, to include a current biography or resume.

Previous nominations received in response to notices published in the **Federal Register** in prior years will not be retained for consideration. Renomination of representative organizations is required.

e. *Deadline for Nominations.* All nominations must be received at the

address shown above no later than September 15, 2018.

Brenda S. Bowen,

Army Federal Register Liaison Officer.

[FR Doc. 2018–16329 Filed 7–30–18; 8:45 am]

BILLING CODE 3720–58–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DOD–2018–OS–0048]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness, DoD.

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Office of the Under Secretary of Defense for Personnel and Readiness 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 October 1, 2018.

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 OUSD (Personnel and Readiness) Office of Total Force Planning & Requirements, ATTN: Mr. Thomas Hessel, 4000 Pentagon, Washington, DC 20301, or call (703) 697–3402.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: DoD Enterprise-Wide Contractor Manpower Reporting Application (ECMRA); OMB Control Number 0704–0491.

Needs and Uses: This information collection is necessary to achieve the collection of direct labor hours and associated costs in order to meet the requirements set for the DoD by section 2330a of Title 10, United States Code. Furthermore, ECMRA collections enable DoD organizations to understand the extent of contracted support, the associated level of effort in achieving mission, the reliance on contracted services necessary to facilitate their workforce planning processes, and to support statutory requirements set forth in sections 115a, 129a, 235, 2461, and 2463 of Title 10, United States Code.

Affected Public: Businesses or Other For-Profit.

Annual Burden Hours: 583.33 hours.

Number of Respondents: 7,000.

Responses per Respondent: 1.

Annual Responses: 7,000.

Average Burden per Response: 5 minutes.

Frequency: Annually.

Dated: July 26, 2018.

Shelly E. Finke,

Alternate OSD Federal Register, Liaison Officer, Department of Defense.

[FR Doc. 2018–16303 Filed 7–30–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 18–0A]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Arms sales notice.

SUMMARY: The Department of Defense is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: DSCA at *dsca.ncr.lmo.mbx.info@mail.mil* or (703) 697–9709.

SUPPLEMENTARY INFORMATION: This 36(b)(5)(C) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 18–0A.

Dated: July 26, 2018.

Shelly E. Finke,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

The Honorable Paul D. Ryan
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

10 JUL 2018

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(5)(C) of the Arms Export Control Act (AECA), as amended, we are forwarding Transmittal No. 18-0A. This report relates to enhancements or upgrades from the level of sensitivity of technology or capability described in the Section 36(b)(1) AECA certification 11-05 of 1 February 2011.

Sincerely,

Charles W. Hooper
Lieutenant General, USA
Director

Enclosures:
1. Transmittal

BILLING CODE 5001–06–C

Transmittal No. 18–0A

REPORT OF ENHANCEMENT OR UPGRADE OF SENSITIVITY OF TECHNOLOGY OR CAPABILITY (SEC. 36(B)(5)(C), AECA)

(i) *Purchaser:* Australia

(ii) *Sec. 36(b)(1), AECA Transmittal No.:* 11–05

Date: February 1, 2011

Military Department: Navy

(iii) *Description:* On February 1, 2011, Congress was notified by Congressional certification transmittal number 11–05 of the Government of Australia's request for ten year Through-Life-Support (TLS) for Australia's fleet of twenty-four (24) MH–60R helicopters. The sustainment effort includes spare and repair parts provisioning, support and test equipment, publications and technical documentation, U.S. Government and contractor engineering, technical and logistics support services, and other related elements of logistics support. The estimated cost was $1.6 billion, with no Major Defense Equipment (MDE).

This transmittal includes the extension of the sustainment support through June 2028 as requested by Australia and includes additional spare parts. There is no increase in MDE cost. The case value will increase from $1.6 billion to $2.8 billion.

(iv) *Significance:* The proposed sale will allow Australia to effectively maintain its current force projection capability that enhances interoperability with U.S. forces well into the future.

(v) *Justification:* This sale will contribute to the foreign policy and national security of the United States by helping to improve the security of an important major non-NATO ally and partner who contributes significantly to peacekeeping, humanitarian, and combat operations around the world.

(vi) *Date Report Delivered to Congress:* July 10, 2018.

[FR Doc. 2018–16307 Filed 7–30–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 18–26]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Arms sales notice.

SUMMARY: The Department of Defense is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: DSCA at *dsca.ncr.lmo.mbx.info@mail.mil* or (703) 697–9709.

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 18–26 with attached Policy Justification and Sensitivity of Technology.

Dated: July 26, 2018.

Shelly E. Finke,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

JUN 2 6 2018

The Honorable Paul D. Ryan
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 18-26, concerning the Navy's proposed Letter(s) of Offer and Acceptance to the Commonwealth of Australia for defense articles and services estimated to cost $185 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

for Charles W. Hooper
Lieutenant General, USA
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology

BILLING CODE 5001–06–C

Transmittal No. 18–26

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Commonwealth of Australia

(ii) *Total Estimated Value:*

Major Defense Equipment *	$ 0.0 million
Other	$185.0 million
TOTAL	$185.0 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:* Australia has requested the possible sale of long lead items, engineering and development activities, establishment of engineering development sites, and commencement of development activities associated with the integration of the CEAFAR 2 Phased Array Radar System with the AEGIS Combat System.

Major Defense Equipment (MDE): None

Non-MDE: AEGIS Weapon System Technical Equivalent Components including Command Display System (CDS) Consoles (including 2 consoles in Gun Weapon System configuration); Multi-Mission Display (MMD) systems, including projectors, sensors and cameras; Tactical Equivalent Core Computing System (CCS) Cabinets; Tactical Equivalent AEGIS LAN Interconnect System (ALIS) Cabinets; Tactical Equivalent AEGIS Conversion Equipment Group Input/Output (ACEG I/0) Cabinets; Tactical Equivalent Advanced Storage Area Network (ASAN) Cabinets; Global Command and Control System—Maritime (GCCS–M); Cooperative Engagement Capability (CEC) sites systems, to include processing rack, simulation equipment and workstation; AN/SPQ–15 Converter/Receiver and/signal data converter equipment; Defense Visual Information Distribution Service (DIVDS) cabinet; AN/SQQ–89 Sonobouy Processing Core Computing System racks, with console and laptop; AEGIS simulator racks and workstations; AEGIS Training System; and various ancillary equipment and support products, including desktop computers, displays, test units and compilations servers, printers, workstations, spares, cabling and software licenses. Also included are spare and repair parts, support and test equipment, engineering and technical services to support sites equipment, U.S. Government and contractor engineering, technical and support services, engineering technical assistance, other technical assistance, and other related elements of program and logistics support.

(iv) *Military Department:* Navy

(v) *Prior Related Cases, if any:* AT–P–LCQ, Implemented 31 Oct 05; AT–P–GTG, Implemented 31 Mar 14; AT–P–GSU, Implemented 26 Nov 15; AT–P–GSB, Implemented 2 Feb 16

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Attached Annex

(viii) *Date Report Delivered to Congress:* June 26, 2018

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Australia—AEGIS Combat System Equipment for Australia Surface Combatants

The Government of Australia has requested to buy long lead items, engineering and development activities, establishment of engineering development sites, and commencement of development activities associated with the integration of the CEAFAR 2 Phased Array Radar System with the AEGIS Combat System. Included are AEGIS Weapon System Technical Equivalent Components including Command Display System (CDS) Consoles (including 2 consoles in Gun Weapon System configuration); Multi-Mission Display (MMD) systems, including projectors, sensors and cameras; Tactical Equivalent Core Computing System (CCS) Cabinets; Tactical Equivalent AEGIS LAN Interconnect System (ALIS) Cabinets; Tactical Equivalent AEGIS Conversion Equipment Group Input/Output (ACEG I/0) Cabinets; Tactical Equivalent Advanced Storage Area Network (ASAN) Cabinets; Global Command and Control System—Maritime (GCCS–M); Cooperative Engagement Capability (CEC) sites systems, to include processing rack, simulation equipment and workstation; AN/SPQ–15 Converter/Receiver and/signal data converter equipment; Defense Visual Information Distribution Service (DIVDS) cabinet; AN/SQQ–89 Sonobouy Processing Core Computing System racks, with console and laptop; AEGIS simulator racks and workstations; AEGIS Training System; and various ancillary equipment and support products, including desktop computers, displays, test units and compilations servers, printers, workstations, spares, cabling and software licenses. Also included are spare and repair parts, support and test equipment, engineering and technical services to support sites equipment, U.S. Government and contractor engineering, technical and support services, engineering technical assistance, other technical assistance, and other related elements of program and logistics support. The total estimated program cost is $185 million.

This sale will support the foreign policy and national security of the United States by helping to improve the security of a major ally that is an important force for political stability and economic progress in the Western Pacific. It is vital to the U.S. national interest to assist our ally in developing and maintaining a strong and ready self-defense capability.

The proposed sale will enhance Australia's Surface Combatant capability by adding nine AEGIS capable Future Frigates over the next 20 years and by upgrading their existing three AEGIS capable Hobart Class destroyers with the latest technology and capability. This sale enhances Australia's self-defense capability, while significantly improving interoperability with U.S. Navy AEGIS combatants in the region. By deploying a surface combatant fleet that will incorporate Cooperative Engagement Capability (CEC), Australia will significantly improve network-centric warfare capability for U.S. forces operating in the region. Australia will have no difficulty absorbing this equipment into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The prime contractor will be Lockheed Martin, Rotary and Mission Systems, Moorestown, NJ. There are a significant number of companies under contract with the U.S. Navy that will provide components and systems as well as engineering services during the execution of this effort. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will require travel of U.S. Government and/or contractor representatives to Australia on a temporary basis for program support and management oversight, consistent with the current level of effort.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 18–26

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. The AEGIS Weapon System is a multi-mission combat system providing Integrated Air and Missile Defense (IAMD) capability for surface ship combatants. This sale involves the procurement of development site equipment to support the Australian Surface Combatant Program. The equipment will be installed in U.S.-based development and testing site locations to support the continued development of the AEGIS Combat System for the Australia Surface Combatant Programs. A subsequent LOR is anticipated for procurement of combat system equipment to be exported to Australia for installation on their future surface combatants.

2. AEGIS Weapon System simulation software, documentation, training and study material will be provided a classification levels up to and including SECRET.

3. No delivery of restricted information will be provided under this LOR. Delivery of sensitive technological information, up to and including SECRET, will be limited to the minimum level of information required to progress activities associated with the integration of indigenous combat system systems into the AEGIS Combat System. This consists primarily of AEGIS Combat System requirements and integration information to support early combat system development activities, in the form of documentation, simulation software, and technical specifications. This information is sensitive as it provides limited insight into AEGIS Combat System capabilities and requirements—as tailored to the Australian AEGIS Combat System configurations.

4. If a technologically advanced adversary were to obtain knowledge of specific hardware, the information could be used to develop countermeasures which might reduce weapons system effectiveness or be used in the development of a system with similar or advanced capabilities.

5. A determination has been made that Australia can provide substantially the same degree of protection for sensitive technology being released as the U.S. Government. This proposed sustainment program is necessary to the furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification.

6. All defense articles and services listed on this transmittal are authorized for release and export to Australia.

[FR Doc. 2018–16374 Filed 7–30–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 18–13]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Arms sales notice.

SUMMARY: The Department of Defense is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: DSCA at *dsca.ncr.lmo.mbx.info@mail.mil* or (703) 697–9709.

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 18–13 with attached Policy Justification and Sensitivity of Technology.

Dated: July 26, 2018.

Shelly E. Finke,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

MAY 0 4 2018

The Honorable Paul D. Ryan
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 18-13, concerning the Air Force's proposed Letter(s) of Offer and Acceptance to the Government of Germany for defense articles and services estimated to cost $1.4 billion. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

fy

Charles W. Hooper
Lieutenant General, USA
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology

BILLING CODE 5001–06–C

Transmittal No. 18–13

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Government of Germany

(ii) *Total Estimated Value:*

Major Defense Equipment *	$ .75 billion
Other	$ .65 billion
TOTAL	$1.40 billion

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Major Defense Equipment (MDE):

Three (3) C–130J–30 Aircraft with four (4) each Rolls Royce AE–2100D Turboprop Engines (installed)

Three (3) KC–130J Aircraft with four (4) each Rolls Royce AE–2100D Turboprop Engines (installed)

Four (4) Rolls Royce AE 2100D Turboprop Engines (spares)

Eight (8) Link-16 MIDS Terminals (one (1) per aircraft, plus two (2) spares)

Non-MDE: Also includes eight (8) AN/ALE 47 Electronic Countermeasure Dispensers (1 per aircraft, plus 2 spares); eight (8) AN/AAR–47A(V)2 Missile Warning Systems (1 per aircraft, plus spares); eight (8) AN/ALR–56M Radar Warning Receivers (1 per aircraft, plus 2 spares); eight (8) MX–20 Electro-Optical/Infrared Imaging Systems (1 per aircraft, plus 2 spares); AN/APX–114/119 Identification Friend or Foe (IFF) Mode 5; Joint Mission Planning System (JMPS); secure communications; precision navigation and cryptographic equipment; night vision devices; support and test equipment; publications and technical documentation; personnel training and training equipment; U.S. Government and contractor engineering; technical and logistics support services; and other related elements of logistical and program support.

(iv) *Military Department:* Air Force (GY–D–SUA)

(v) *Prior Related Cases, if any:* None

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Attached Annex

(viii) *Date Report Delivered to Congress:* May 4, 2018

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Government of Germany—C–130J and KC–130J Aircraft

The Government of Germany has requested to buy three (3) C–130J–30 aircraft with four (4) each Rolls Royce AE–2100D turboprop engines (installed); three (3) KC–130J aircraft with four (4) each Rolls Royce AE–2100D turboprop engines (installed); four (4) Rolls Royce AE 2100D turboprop engines (spares); and eight (8) Link-16 MIDS Terminals (one (1) per aircraft, plus two (2) spares). Also includes eight (8) AN/ALE 47 Electronic Countermeasure Dispensers (1 per aircraft, plus 2 spares); eight (8) AN/AAR–47A(V)2 Missile Warning Systems (1 per aircraft, plus spares); eight (8) AN/ALR–56M Radar Warning Receivers (1 per aircraft, plus 2 spares); eight (8) MX–20 Electro-Optical/Infrared Imaging Systems (1 per aircraft, plus 2 spares); AN/APX–114/119 Identification Friend or Foe (IFF) Mode 5; Joint Mission Planning System (JMPS); secure communications; precision navigation and cryptographic equipment; night vision devices; support and test equipment; publications and technical documentation; personnel training and training equipment; U.S. Government and contractor engineering; technical and logistics support services; and other related elements of logistical and program support. The total estimated value is $1.40 billion.

This proposed sale will contribute to the foreign policy and national security of the United States by helping to improve the security of a NATO ally which is an important force for political and economic stability in Europe. The proposed sale will increase the airlift, air refueling, and air drop capabilities of the German Air Force. Providing these capabilities to the German Air Force will greatly increase interoperability between the U.S. Air Force and the German Air Force as well as other NATO allies.

The German Air Force will use these aircraft to conduct airlift, air refueling, and air drop missions as part of a French-German allied squadron based in Evreux, France. This common air transport squadron will have unrestricted exchange of aircraft, air crews, and maintainers, as well as technical and logistical support based on a common pool of spare parts and a common service support contract. These exchanges would be carried out pursuant to separate authorizations from the United States. The C–130Js will provide crucial air refueling capability to German and French fighter and light transport aircraft, as well as helicopters. Germany requests these capabilities to provide for the support of its deployed troops, regional security, and interoperability with France and the United States. Germany will have no difficulty absorbing these aircraft into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The prime contractor will be Lockheed Martin, Ft Worth, TX. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale may require multiple trips but no long-term stationing for U.S. contractor representatives to Germany and potentially deployed locations to provide initial launch recovery, and maintenance support.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 18–13

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. The C–130J Hercules with Rolls Royce AE 2100D Turboprop Engines is a military airlift aircraft that performs primarily the tactical portion of the airlift mission. The aircraft is capable of operating from rough, dirt strips and is the prime transport for air dropping troops and equipment into hostile areas. The C–130J improvements over the C–130E include improved maximum speed, climb time, cruising altitude and range. The C–130J has 55 feet of cargo compartment length,—an additional 15 feet over the original ''short'' aircraft. Hardware is UNCLASSIFIED. Technical data and documentation to be provided is UNCLASSIFIED.

2. The KC–130J is a tanker version of the C–130J Hercules aircraft modified to provide air-to-air refueling and assault-support. Hardware is UNCLASSIFIED. Technical data and documentation to be provided is UNCLASSIFIED.

3. Multifunctional Information Distribution System (MIDS) is an advanced Link-16 command, control, communications, and intelligence (C3I) system incorporating high-capacity, jam-resistant, digital communication links for exchange of near real-time tactical information, including both data and voice, among air, ground, and sea elements. The MIDS terminal hardware, publications, performance specifications, operational capability, parameters, vulnerabilities to countermeasures, and software documentation are classified CONFIDENTIAL. The classified information to be provided consists of

that which is necessary for the operation, maintenance, and repair (through intermediate level) of the data link terminal, installed systems, and related software.

4. The AN/ALE–47 Counter-Measures Dispensing System (CMOS) is an integrated, threat-adaptive, software-programmable dispensing system capable of dispensing chaff, flares, and active radio frequency expendables. The threats countered by the CMOS include radar-directed anti-aircraft artillery (AAA), radar command-guided missiles, radar homing guided missiles, and infrared (IR) guided missiles. The system is internally mounted and may be operated as a stand-alone system or may be integrated with other on-board EW and avionics systems. The AN/ALE–47 uses threat data received over the aircraft interfaces to assess the threat situation and to determine a response. Expendable routines tailored to the immediate aircraft and threat environment may be dispensed using one of four operational modes. Hardware is UNCLASSIFIED. Technical data and documentation to be provided is UNCLASSIFIED.

5. The AN/AAR–47A(V)2 Missile Warning System is a small, lightweight, passive, electro-optic, threat warning device used to detect surface-to-air missiles fired at helicopters and low-flying fixed-wing aircraft and automatically provide countermeasures, as well as audio and visual-sector warning messages to the aircrew. The basic system consists of multiple Optical Sensor Converter (OSC) units, a Computer Processor (CP) and a Control Indicator (Cl). The set of OSC units, which normally consist of four, is mounted on the aircraft exterior to provide omni-directional protection. The OSC detects the rocket plume of missiles and sends appropriate signals to the CP for processing. The CP analyses the data from each OSC and automatically deploys the appropriate countermeasures. The CP also contains comprehensive BIT circuitry. The CI displays the incoming direction of the threat, so that the pilot can take appropriate action. Hardware is UNCLASSIFIED. Technical data and documentation to be provided is UNCLASSIFIED.

6. The AN/ALR–56M Advanced Radar Warning Receiver continuously detects and intercepts RF signals in certain frequency ranges and analyzes and separates threat signals from non-threat signals. It contributes to full-dimensional protection by providing individual aircraft probability of survival through improved aircrew situational awareness of the radar guided threat environment. The ALR–56M is designed to provide improved performance in a dense signal environment and improved detection of modern threats signals. Hardware is UNCLASSIFIED. Technical data and documentation to be provided is UNCLASSIFIED.

7. An AN/APX–114/119 Identification Friend or Foe (IFF) combined transponder interrogator system is UNCLASSIFIED unless Mode 4 or 5 operational evaluator parameters, which are SECRET, are loaded into the equipment.

8. Joint Mission Planning System (JMPS) is a multi-platform PC based mission planning system. JMPS hardware is UNCLASSIFIED but the software is classified up to SECRET.

9. This sale will involve the release of sensitive and/or classified cryptographic equipment for secure communications radios, precision navigation, and cryptographic appliques and keying equipment. The hardware is UNCLASSIFIED, except where systems are loaded with cryptographic software, which may be classified up to SECRET.

10. If a technologically advanced adversary were to obtain knowledge of the specific hardware and software elements, the information could be used to develop countermeasures that might reduce weapon system effectiveness or be used in the development of a system with similar or advanced capabilities.

11. A determination has been made that the recipient country can provide substantially the same degree of protection for the sensitive technology being released as the U.S. Government. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification.

12. All defense articles and services listed in this transmittal are authorized for release and export to the Government of Germany.

[FR Doc. 2018–16318 Filed 7–30–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 18–12]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Arms sales notice.

SUMMARY: The Department of Defense is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: DSCA at *dsca.ncr.lmo.mbx.info@mail.mil* or (703) 697–9709.

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 18–12 with attached Policy Justification and Sensitivity of Technology.

Dated: July 26, 2018.

Shelly E. Finke,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

APR 2 4 2018

The Honorable Paul D. Ryan
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 18-12, concerning the Army's proposed Letter(s) of Offer and Acceptance to the Government of the Netherlands for defense articles and services estimated to cost $70 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

Charles W. Hooper
Lieutenant General, USA
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology

BILLING CODE 5001–06–C

Transmittal No. 18–12

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser: Government of the Netherlands*

(ii) *Total Estimated Value:*

Major Defense Equipment *	$60 million
Other	$10 million
TOTAL	$70 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Major Defense Equipment (MDE): Three thousand five hundred (3,500) M1156 Precision Guided Kit (PGK)

Non-MDE: Also included are six (6) PGK settable trainers; two (2) PGK cut away models; one hundred (100) M76 PGK fuze wrenches; ten (10) Extended Length Artillery Projectile Extractors (ELAPEs); PGK technical data and publications; U.S. Government engineering and technical support services; and other related elements of logistics and program support.

(iv) *Military Department:* Army (NE–B–WKA)

(v) *Prior Related Cases, if any:* None

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Attached Annex

(viii) *Date Report Delivered to Congress:* April 24, 2018

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Netherlands—M1156 Precision Guided Kits

The Netherlands has requested to buy three thousand five hundred (3,500) M1156 Precision Guided Kits. Also included are six (6) PGK settable trainers; two (2) PGK cut away models; one hundred (100) M76 PGK fuze wrenches; ten (10) Extended Length Artillery Projectile Extractors (ELAPEs); PGK technical data and publications; U.S. Government engineering and technical support services; and other related elements of logistics and program support. The estimated total cost is $70 million.

This proposed sale will support the foreign policy and national security objectives of the United States by helping to improve the security of the Netherlands which is an important force for political stability and economic progress in Europe. It is important to the U.S. national interests to assist the Netherlands to develop and maintain a strong and ready self-defense capability. The Netherlands has been a consistent coalition partner supporting the United States in various coalition combat operations to include counter-ISIS, Stabilization Force in Iraq, and Afghanistan.

The proposed sale of PGK will provide a precision guided capability to 155mm artillery projectiles and improve Netherlands's capability to meet current and future enemy threats. The Netherlands will use the enhanced capability to strengthen its homeland defenses, deter regional threats, and provide direct support to coalition and security cooperation efforts. The Netherlands will have no difficulty absorbing this equipment into its armed forces.

The proposed sale of this equipment will not impact the basic military balance in the region.

The principal contractor will be Orbital ATK. There are no known offset agreements proposed in connection with this potential sale. The purchaser typically requests offsets. Any offset agreement will be defined in negotiations between the purchaser and the contractor.

Implementation of this sale will not require the assignment of any additional U.S. or contractor representatives to the Netherlands.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 18–12

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. The M1156 Precision Guidance Kit (PGK) is a Global Positioning System (GPS) Precise Positioning Service (PPS) guided 155mm artillery projectile fuze. This effort includes the qualification of PGK on the Assegai M1711 Insensitive High Explosive (IHE) Base Bleed (BB) projectile with modular charges DM92 Charge 6 and PGK on the Assegai M1712 IHE Boat Tail (BT) projectile with modular charges DM92 Charges 5 and 6, both fired from the Netherlands' PzH 2000 self-propelled howitzer.

2. The M1156 utilizes the Enhanced Portable Electronic Fuze Setter (EPEFS) to set the PGK and the Portable Electronic Fire Control System (PEFCS) both purchased previously under a previous Excalibur FMS case. The PEFCS contain an Improved Platform Integration Kit (MK) to load GPS coordinates. Both the PGK and PEFCS contain the Selective Availability Anti-Spoofing Module (SAASM). The PGK has 90% commonality with the Army's XM395 Accelerated Precision Mortar Initiative (APMI). The PGK (the end-item) is unclassified. Transfer of the PGK may reveal information up to SECRET.

3. The M1156 utilizes the Army's M782 Multi-Option for Artillery (MOFA) Proximity Height of Burst (HOB) Technology. The HOB sensor is comprised of components with technologies deemed as state of the art, requiring specialized production skills. The sensitive/critical technology is primarily in the design, development, production and manufacturing of the components (integrated circuits and assembly), and the integration methodology required to integrate those components onto an assembly to process embedded (the software-algorithm-working parameters). The HOB technology is classified SECRET.

4. Disclosure of this technology could result in an adversary developing countermeasures, thus lessening the effect of the projectile. Disclosure of test data, countermeasures, vulnerability/susceptibility analyses and threat definition could all aid reverse engineering and could be used by an adversary for possible use against U.S. and Coalition forces. Compromise could jeopardize the U.S. forces inventory through jammer development by adversaries. The risk of compromise has been accessed as moderate. Risk is reduced for fuze/munitions if adequately controlled and protected in storage and on the battlefield. Risk is mitigated by the prevention of disclosure of sensitive classified information (the know-how, software, and associated documentation).

5. If a technologically advanced adversary were to obtain knowledge of the specific hardware and software elements, the information could be used to develop countermeasures which might reduce weapon system effectiveness or be used in the development of a system with similar or advanced capabilities.

6. A determination has been made that the Netherlands can provide the same degree of protection for the sensitive technology being release as the U.S. Government. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification.

7. All defense articles and services listed in this transmittal have been

authorized for release and export to the Netherlands.

[FR Doc. 2018–16316 Filed 7–30–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 18–03]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Arms sales notice.

SUMMARY: The Department of Defense is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: DSCA at *dsca.ncr.lmo.mbx.info@mail.mil* or (703) 697–9709.

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 18–03 with attached Policy Justification and Sensitivity of Technology.

Dated: July 26, 2018.

Shelly E. Finke,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

The Honorable Paul D. Ryan
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

10 JUL 2018

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 18-03, concerning the Air Force's proposed Letter(s) of Offer and Acceptance to the Government of the United Kingdom for defense articles and services estimated to cost $650 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

Charles W. Hooper
Lieutenant General, USA
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology

BILLING CODE 5001–06–C

Transmittal No. 18–03

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* The Government of the United Kingdom

(ii) *Total Estimated Value:*

Major Defense Equipment *	$600 million
Other	$ 50 million
TOTAL	$650 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Major Defense Equipment (MDE): Up to two hundred (200) AIM–120D Advanced Medium-Range Air-to-Air Missiles (AMRAAMs)

Non-MDE: Also included in this sale are missile containers; weapon system support equipment; support and test equipment; site survey; transportation; repair and return support; warranties; spare and repair parts; publications and technical documentation; maintenance and personnel training; training equipment; U.S. Government and contractor engineering, logistics, and technical support services; and other related elements of logistics and program support.

(iv) *Military Department:* Air Force (UK–D–YAM)

(v) *Prior Related Cases, if any:* UK–D–YAL, 6 Sep 17

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Attached Annex

(viii) *Date Report Delivered to Congress:* July 10, 2018

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

United Kingdom—AIM–120D Advanced Medium Range Air-to-Air Missile (AMRAAM)

The Government of the United Kingdom has requested to buy up to two hundred (200) AIM–120D Advanced Medium Range Air-to-Air Missiles (AMRAAMs). Also included in this sale are missile containers; weapon system support equipment; support and test equipment; site survey; transportation; repair and return support; warranties; spare and repair parts; publications and technical documentation; maintenance and personnel training; training equipment; U.S. Government and contractor engineering, logistics, and technical support services; and other related elements of logistics and program support. The estimated cost of the overall possible sale is $650 million.

The proposed sale will support the foreign policy and national security policies of the United States by helping to improve the security of a NATO ally which has been, and continues to be, an important partner on critical foreign policy and defense issues.

The proposed sale will improve the Royal Air Force's aircraft capabilities for mutual defense, regional security, force modernization, and U.S. and NATO interoperability. This sale will enhance the Royal Air Force's ability to defend the United Kingdom against future threats and contribute to future NATO operations. The United Kingdom will have no difficulty absorbing these missiles into its armed forces.

The proposed sale of this equipment will not alter the basic military balance in the region.

The principal contractor will be Raytheon Missile Systems Company, Tucson, AZ. At this time, there are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will not require the assignment of any additional U.S. Government or contractor representatives to the United Kingdom.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 18–03

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. The AIM–120D Advanced Medium Range Air-to-Air Missiles (AMRAAM) is a guided missile featuring digital technology and micro-miniature solid-state electronics. AMRAAM capabilities include look-down/shoot-down, multiple launches against multiple targets, resistance to electronic countermeasures, and interception of high- and low-flying and maneuvering targets. The AMRAAM is classified CONFIDENTIAL, major components and subsystems range from UNCLASSIFIED to CONFIDENTIAL, and technical data and other documentation are classified up to SECRET.

2. The AIM–120D AMRAAM hardware, including the missile guidance section, is classified CONFIDENTIAL. State-of-the-art technology is used in the missile to provide it with unique beyond-visual-range capability. The increase in capability from the AIM–120C–7 to AIM–120D consists of a two-way data link, a more accurate navigation unit, improved High-Angle Off-Boresight (HOBS) capability, and enhanced aircraft-to-missile position handoff.

3. AIM–120D features a target detection device with embedded electronic countermeasures, and an electronics unit within the guidance section that performs all radar signal processing, mid-course and terminal guidance, flight control, target detection, and warhead burst point determination.

4. If a technologically advanced adversary obtains knowledge of the specific hardware and software elements, the information could be used to develop countermeasures or equivalent systems that might reduce weapon system effectiveness or be used in the development of a system with similar or advanced capabilities.

5. A determination has been made that the Government of the United Kingdom can provide substantially the same degree of protection for the sensitive technology being released as the U.S. Government. This proposed sale is necessary to the furtherance of the U.S. foreign policy and national security objectives outlined in the policy justification.

6. All defense articles and services listed in this transmittal are authorized for release and export to the Government of the United Kingdom.

[FR Doc. 2018–16310 Filed 7–30–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 18–19]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Arms sales notice.

SUMMARY: The Department of Defense is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: DSCA at *dsca.ncr.lmo.mbx.info@mail.mil* or (703) 697–9709.

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 18–19 with attached Policy Justification and Sensitivity of Technology.

Dated: July 26, 2018.

Shelly E. Finke,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

JUN 2 6 2018

The Honorable Paul D. Ryan
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 18-19, concerning the Navy's proposed Letter(s) of Offer and Acceptance to the Government of Spain for defense articles and services estimated to cost $860.4 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

for

Charles W. Hooper
Lieutenant General, USA
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology

BILLING CODE 5001–06–C

Transmittal No. 18–19

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Government of Spain

(ii) *Total Estimated Value:*

Major Defense Equipment *	$324.4 million
Other	$536.0 million
TOTAL	$860.4 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Major Defense Equipment (MDE):

Five (5) AEGIS Weapons Systems (AWS) MK7
Six (6) Shipsets Digital Signal Processing
Five (5) Shipsets AWS Computing Infrastructure MARK 1 MOD 0
Five (5) Shipsets Operational Readiness Test Systems (ORTS)
Five (5) Shipsets MK 99 MOD 14 Fire Control System
Five (5) Shipsets MK 41 Baseline VII Vertical Launching Systems (VLS)
Two (2) All-Up-Round MK 54 Mod 0 Lightweight Torpedoes
Twenty (20) SM–2 Block IIIB Missiles and MK 13 Canisters with AN/DKT–71 Warhead Compatible Telemeter

Non-MDE: Also included are one (1) S4 AWS computer program, five (5) shipsets Ultra High Frequency (UHF) Satellite Communications (SATCOM), five (5) shipsets AN/SRQ–4 radio terminal sets, five (5) shipsets ordnance handling equipment, five (5) shipsets Selective Availability Anti-Spoofing Modules (SAASM), five (5) shipsets aviation handling and support equipment, five (5) shipsets AN/SLQ–24E Torpedo countermeasures systems, five (5) shipsets LM04 Thru-Hull XBT Launcher and test canisters, one (1) shipset MK 36 MOD 6 Decoy Launching System, five (5) shipsets Link Level COMSEC (LLC) 7M for LINK 22, five (5) shipsets Maintenance Assist Module (MAM) cabinets, five (5) shipsets technical documentation, five (5) shipsets installation support material, special purpose test equipment, system engineering, technical services, on-site vendor assistance, spare parts, systems training, foreign liaison office and staging services necessary to support ship construction and delivery, spare and repair parts, tools and test equipment, support equipment, repair and return support, personnel training and training equipment, publications and technical documentation, U.S. Government and contractor engineering and logistics support services, and other related elements of logistic and program support.

(iv) *Military Department:* Navy (SP–P–LHM)

(v) *Prior Related Cases, if any:* SP–P–LHL, SP–P–GOL

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Attached Annex

(viii) *Date Report Delivered to Congress:* June 26, 2018

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Spain—AEGIS Combat System

The Government of Spain has requested to buy five (5) AEGIS Weapons Systems (AWS) MK7, six (6) shipsets Digital Signal Processing, five (5) shipsets AWS Computing Infrastructure MARK 1 MOD 0, five (5) shipsets Operational Readiness Test Systems (ORTS), five (5) shipsets MK 99 MOD 14 Fire Control System, five (5) shipsets MK 41 Baseline VII Vertical Launching Systems (VLS), two (2) All-Up-Round MK 54 Mod 0 lightweight torpedoes, twenty (20) SM–2 Block IIIB missiles and MK 13 canisters with AN/DKT–71 warhead compatible telemeter. Also included are one (1) S4 AWS computer program, five (5) shipsets Ultra High Frequency (UHF) Satellite Communications (SATCOM), five (5) shipsets AN/SRQ–4 radio terminal sets, five (5) shipsets ordnance handling equipment, five (5) shipsets Selective Availability Anti-Spoofing Modules (SAASM), five (5) shipsets aviation handling and support equipment, five (5) shipsets AN/SLQ–24E Torpedo countermeasures systems, five (5) shipsets LM04 Thru-Hull XBT Launcher and test canisters, one (1) shipset MK 36 MOD 6 Decoy Launching System, five (5) shipsets Link Level COMSEC (LLC) 7M for LINK 22, five (5) shipsets Maintenance Assist Module (MAM) cabinets, five (5) shipsets technical documentation, five (5) shipsets installation support material, special purpose test equipment, system engineering, technical services, on-site vendor assistance, spare parts, systems training, foreign liaison office and staging services necessary to support ship construction and delivery, spare and repair parts, tools and test equipment, support equipment, repair and return support, personnel training and training equipment, publications and technical documentation, U.S. Government and contractor engineering and logistics support services, and other related elements of logistic and program support. The total estimated program cost is $860.4 million.

The proposed sale will support the foreign policy and national security objectives of the United States by improving the security of a NATO ally that is an important force for political stability and economic progress in Europe. It is vital to the U.S. national interest to assist Spain in developing and maintaining a strong and ready self-defense capability.

The addition of five (5) new AEGIS equipped frigates to Spain's fleet will afford more flexibility and capability to counter regional threats and continue to enhance stability in the region. Spain currently operates 5 AEGIS frigates and is proficient at using the AEGIS system to its fullest capability. Spain has demonstrated the capability, flexibility, and responsibility necessary to acquire this AEGIS system into its fleet and will continue to operate it as required to ensure interoperability as a highly valued NATO partner. Spain will have no difficulty absorbing this equipment and support into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The prime contractors will be Lockheed Martin, Moorestown, NJ, and Manassas, VA; Raytheon Company, Waltham, MA; and General Dynamics, Williston, VT. There are also a significant number of companies under contract with the U.S. Navy that will provide components and systems as well as engineering services during the execution of this effort. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will require multiple trips by U.S. Government and contractor representatives to participate in program and technical reviews plus training and maintenance support in country, on a temporary basis, for a period of twenty-four (24) months. It will also require two (2) contractor representatives to reside in country for a period of two (2) years to support this program.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 18–19

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. The AEGIS Weapon System (AWS) is a multi-mission combat system

providing integrated Air and Missile Defense for surface ships. This sale involves a subset of the AWS Baseline 9 Anti-Air Warfare (AAW) capability called the International AEGIS Fire Control Loop (IAFCL); no integrated Ballistic Missile Defense will be provided. AWS Software, documentation, combat system training and technical services will be provided at the classification levels up to and including SECRET. The manuals and technical documents are limited to those necessary for operational use and organization maintenance.

2. IAFCL hardware include AWS Computing Infrastructure Equipment, including Blade Processors, Fire Control System (FCS) MK 99, Vertical Launching System (VLS) MK 41, combat system support equipment, logistics support equipment, and the Digital Signal Processing Group equipment consisting of the Signal Processor Assembly Cabinet and Radar Data Processor Cabinet. The Digital Signal Processing group will be derived from the Multi-Mission Signal Processor and will be integrated with the Solid-State S-Band Multifunction Radar which is being procured by Spain via Direct Commercial Sale contract. The Digital Signal Processing Group will be capable of Anti-Air Warfare mission only. The hardware is unclassified. The IAFCL meets Anti-Tamper Requirements.

3. The Torpedo Countermeasure Transmitting Set AN/SLQ–25 (Nixie) is a passive, electro-acoustic decoy system used to provide deceptive countermeasures against acoustic homing torpedoes. The AN/SLQ–25 employs an underwater acoustic projector housed in a streamlines body which is towed astern on a combination tow/signal-transfer coaxial cable. An onboard generated signal is used by the towed body to produce an acoustic signal to decoy the hostile torpedo away from the ship. The AN/SLW–25E included improved deceptive countermeasure capabilities, a fiber optic display LAN, a torpedo alertment capability and a towed array sensor, as well as addressing obsolescence issues in previous variants. The highest classification of the hardware to be exported is SECRET. The purchaser currently has the AN/SLQ–25A variant of this weapon system in its inventory.

4. The Common Data Link Hawklink AN/SRQ–4 radio terminal sets provide the shipboard element of a situation awareness system that links airborne terminals with surface warships. The system provides real-time use of aircraft sensors to extend situational awareness over the horizon by enabling surveillance helicopters to data-link radar, video, networking, and acoustic data to various surface ships. It provided the command and control, sensor data transfer, data link operations and built-in test functionality. It supports anti-submarine warfare and anti-ship surveillance and targeting missions. This hardware is unclassified. The purchase currently has the AN/SRQ–4 on 5 of their surface ships.

5. The version of the MK 54 Lightweight Torpedo involved in this is the MK 54 Mod 0. Although the MK 54 Mod 0 is considered state-of-the art technology, there is no Critical Program Information associated with the MK 54 Mod 0 Light Weight Torpedo hardware, technical documentation, or software. The highest classification of the hardware to be exported is SECRET. The highest classification of the technical manual that will be exported is confidential; which is required for the operation and maintenance of the MK 54 Mod 0 Lightweight Torpedo. The highest classification of the software to be exported is SECRET. The MK 54 Mod 0 Lightweight Torpedo meets Anti-Tamper Requirements. The purchaser currently does not have this weapon system in its inventory; however they have the previous version, the MK 46 Lightweight Torpedo.

6. The following MK 54 components and support equipment being conveyed by the proposed sale that is considered sensitive and are classified SECRET include: MK 54 LWT hardware, MK 695 Torpedo System Test Set Software, Torpedo Firing Evaluation equipment Software, and Data Analysis Tool Set software. The Classified MK 54 Publication with the proposed sale include: Torpedo MK 54 Mod 0 General Information Book, MK 54 Employment Manual, MK 20 Mod 1 Exploder Description, Operation, Maintenance, and Illustrated Parts Breakdown, and MK 440 Mod 1 Exploder Test Set Description, Operation and Illustrated Parts Breakdown.

7. The MK–36 Mod 6 Super Rapid Blooming Off-board Chaff (SRBOC) and Decoy Launching System is an unclassified shipboard, deck-mounted, 6 barrel mortar-type array that launched chaff countermeasures against a variety of threats. Following launch and dispersion, MK 36 SRBOC chaff and infrared countermeasure are designed to lure hostile missiles away from ships under attack by creating false target sets.

8. The Standard Missile–2 Block IIIB proposed in this purchase will be used for Anti-Air Warfare test firings during Combat System Ship Qualification Trials. The following Standard Missile–2 BLK IIIB components and support equipment being conveyed by the proposed sale that is considered sensitive and are classified CONFIDENTIAL include completely assembled Standard Missile–2 BLK IIIB with or without a conventional warhead, whether a tactical, telemetry, or inert (training) configuration: Missile component hardware Guidance Section, Target Detection Device, Autopilot Battery Unit; SM–2 operator and maintenance documentation, shipboard operation/firing guidance. The purchaser currently has this missile in its inventory.

9. UHF SATCOM, the RT–1829 UHF SATCOM terminal is a commercially available SATCOM terminal that can provide ship-to-ship or ship-to-shore communications via voice or data connectivity. The device itself is CCI but is not classified until it is keyed with the proper keying material to enable secure communications. A single RT–1829 control interface can operate multiple voice and data communications nets simultaneously. The RT–1829 terminal is KITC and HAS certified to ensure compliance with legacy DAMA Mil-STDs. The purchaser currently has this UHF SATCOM on 5 of their surface ships.

10. The Link Level COMSEC (LLC) 7M device is a GOTS product which was developed by PEO C41/PMQ 150 in coordination with Raytheon and certified by the NSA. The device itself is CCI but is not classified until it is keyed with the proper keying material to enable secure communications via the LINK 22 system. It is a Type 1 COMSEC device which is intended to enable secure interoperable communications between the US, and NATO nations and Allied Forces via the LINK 22 System. Each device is handled by only the USG and the partner Nations COMSEC Custodians/Managers per the FMS agreement and no nation has the ability to tamper with or manipulate/maintain the system. The purchaser has previously purchased the LLC 7M for future integration with LINK 22 on many of their warships.

11. If a technologically advanced adversary were to obtain knowledge of specific hardware, the information could be used to develop countermeasures which might reduce weapons system effectiveness or be used in the development of a system with similar or advanced capabilities.

12. A determination has been made that Spain can provide substantially the same degree of protection for sensitive technology being released as the U.S. Government. This proposed sustainment program is necessary to the furtherance of the U.S. foreign policy

and national security objectives outlined in the Policy Justification.

13. All defense articles and services listed on this transmittal are authorized for release and export to the Government of Spain.

[FR Doc. 2018–16324 Filed 7–30–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 18–0D]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Arms sales notice.

SUMMARY: The Department of Defense is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: DSCA at *dsca.ncr.lmo.mbx.info@mail.mil* or (703) 697–9709.

SUPPLEMENTARY INFORMATION: This 36(b)(5)(C) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 18–0D.

Dated: July 26, 2018.

Shelly E. Finke,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

- 6 JUL 2018

The Honorable Paul D. Ryan
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(5)(C) of the Arms Export Control Act (AECA), as amended, we are forwarding Transmittal No. 18-0D. This report relates to enhancements or upgrades from the level of sensitivity of technology or capability described in the Section 36(b)(1) AECA certification 13-68 of 18 December 2013.

Sincerely,

Charles W. Hooper
Lieutenant General, USA
Director

Enclosures:
1. Transmittal

BILLING CODE 5001–06–C

Transmittal No. 18–0D

REPORT OF ENHANCEMENT OR UPGRADE OF SENSITIVITY OF TECHNOLOGY OR CAPABILITY (SEC. 36(B)(5)(C)), (AECA)

(i) *Purchaser:* Government of Norway

(ii) *Sec. 36(b)(1), AECA Transmittal No.:* 13–68

Date: December 18, 2013

Military Department: Air Force

(iii) *Description:* On December 18, 2013, Congress was notified by Congressional certification transmittal number 13–68, of the possible sale under Section 36(b)(1) of the Arms Export Control Act of C–130J technical, engineering and software support; software updates and patches; familiarization training for the Portable Flight Planning System (PFPS) and Joint Mission Planning System (JMPS); spare and repair parts; U.S. Government and contractor technical support services; and other related elements of logistics and program support. The estimated cost was $107 million, with no Major Defense Equipment (MDE).

This transmittal notifies the extension of non-MDE support provided to Norway's C–130J aircraft sustainment program, including additional distribution support for unclassified and classified software. Extending the sustainment case will result in an increase in non-MDE cost of $123 million. The total case value will increase to $230 million.

(iv) *Significance:* The addition of this funding to Norway's C–130J sustainment program represents an increase in capability over what was originally notified. The proposed sale will allow Norway to continue to effectively maintain its current fleet of C–130J fleet.

(v) *Justification:* This proposed sale will contribute to the foreign policy and national security of the United States by helping to improve the security of a NATO ally. Norway intends to use this technical, engineering, and software support to provide successful operation of the PFPS and JMPS. This program will increase Norway's ability to contribute to future NATO operations, support U.S. national security interests, and strengthen a critical, long-term strategic military partnership.

(vi) *Date Report Delivered to Congress:* July 6, 2018

[FR Doc. 2018–16308 Filed 7–30–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 18–14]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Arms sales notice.

SUMMARY: The Department of Defense is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: DSCA at *dsca.ncr.lmo.mbx.info@mail.mil* or (703) 697–9709.

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 18–14 with attached Policy Justification.

Dated: July 26, 2018.

Shelly E. Finke,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

APR 2 4 2018

The Honorable Paul D. Ryan
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 18-14, concerning the Air Force's proposed Letter(s) of Offer and Acceptance to the Government of the Netherlands for defense articles and services estimated to cost $110 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

For Charles W. Hooper
Lieutenant General, USA
Director

Enclosures:
1. Transmittal
2. Policy Justification

BILLING CODE 5001–06–C

Transmittal No. 18–14

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* The Government of the Netherlands

(ii) *Total Estimated Value:*

Major Defense Equipment *	$ 0.5 million
Other	$109.5 million
TOTAL	$110.0 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for*

Purchase: The Government of the Netherlands has requested to buy defense articles and services in support of continuation of a Continental United States (CONUS) based Royal Netherlands Air Force F–16 Formal Training Unit.

Major Defense Equipment (MDE): Up to twenty-seven (27) GBU–12 Inert Paveway IIs

Non-MDE: Also included are PGU–27 Inert training rounds, Impulse Cartridges, MJU–7/B Flares, RR–188 Chaff, BDU–33/B and BDU–50/B training munitions, fuel and air refueling support, airlift services, base operating support, facilities, publications and technical documentation, pilot training, personnel training and training equipment, weapon system and software support, U.S. Government and contractor technical, engineering, and logistics personnel services, and other related elements of logistics and program support.

(iv) *Military Department:* Air Force (NE–D–NZW)

(v) *Prior Related Cases, if any:* NE–D–NXZ—$ 149.3 million; 19 Sep 13

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* None

(viii) *Date Report Delivered to Congress:* April 24, 2018

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

The Netherlands—F–16 Formal Training Unit at Tucson Air National Guard Base (ANGB), Arizona

The Government of the Netherlands has requested to buy defense articles and services in support of continuation of a Continental United States (CONUS) based Royal Netherlands Air Force F–16 Formal Training Unit, to include up to twenty-seven (27) GBU–12 Inert Paveway IIs. Also included are PGU–27 Inert training rounds, Impulse Cartridges, MJU–7/B Flares, RR–188 Chaff, BDU–33/B and BDU–50/B training munitions, fuel and air refueling support, airlift services, base operating support, facilities, publications and technical documentation, pilot training, personnel training and training equipment, weapon system and software support, U.S. Government and contractor technical, engineering, and logistics personnel services, and other related elements of logistics and program support. The estimated program value is $110 million.

This proposed sale will support the foreign policy and national security objectives of the United States by improving the security of a NATO Ally which is an important force for political stability and economic progress in Europe.

This potential sale will continue to improve the Royal Netherlands Air Force's (RNLAF) ability to develop mission-ready and experienced pilots to support its F–16 aircraft inventory. The well-established pilot proficiency training program at Tucson Air National Guard Base will train pilots in F–16 operations, tactics, techniques, and procedures. This training will enhance the RNLAF's ability to continue contributions to Overseas Contingency Operations and to NATO air policing operations, as well as, to possible future coalitions operations. The Netherlands will have no difficulty absorbing this training.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

There is no prime contractor involved in this proposed sale. The Tucson Air National Guard will provide instruction, flight operations, and maintenance support and facilities with defense articles anticipated to come from U.S. stocks, as needed. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will not require the assignment of any additional U.S. Government personnel or contractor representatives to the Netherlands.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

[FR Doc. 2018–16317 Filed 7–30–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 18–18]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Arms sales notice.

SUMMARY: The Department of Defense is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: DSCA at *dsca.ncr.lmo.mbx.info@mail.mil* or (703) 697–9709.

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 18–18 with attached Policy Justification and Sensitivity of Technology.

Dated: July 26, 2018.

Shelly E. Finke,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

JUN 1 2 2018

The Honorable Paul D. Ryan
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 18-18, concerning the Army's proposed Letter(s) of Offer and Acceptance to the Government of India for defense articles and services estimated to cost $930 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

Charles W. Hooper
Lieutenant General, USA
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology

BILLING CODE 5001–06–C

Transmittal No. 18–18

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Government of India

(ii) *Total Estimated Value:*

Major Defense Equipment *	$340 million
Other	$590 million
TOTAL	$930 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:* The Government of India has requested the sale of the following items in support of a proposed direct commercial sale of six (6) AH–64E Apache helicopters:

Major Defense Equipment (MDE):

Fourteen (14) T700–GE–701D

Four (4) AN/APG–78 Fire Control Radars

Four (4) Radar Electronic Units (REU) Block III

Four (4) AN/APR–48B Modernized Radar Frequency Interferometers (M–RFI's)

One hundred eighty (180) AGM–114L–3 Hellfire Longbow Missiles

Ninety (90) AGM–114R–3 Hellfire II Missiles

Two hundred (200) Stinger Block I–92H Missiles

Seven (7) Modernized Target Acquisition and Designation Sights (MTADS)/Pilot Night Vision Sensors (PNVS)

Fourteen (14) Embedded Global Positioning System/Inertial Navigation Systems (EGI)

Non-MDE: Also included are 2.75'' HE M151 rockets, training and dummy missiles, 30 mm cannons and ammunition, transponders, simulators, communication equipment, spare and repair parts, tools and test equipment, support equipment, repair and return support, personnel training and training equipment, publications and technical documentation, U.S. Government and contractor engineering and logistics support services, and other related elements of logistic and program support.

(iv) *Military Department:* Army (IN–B–UAN)

(v) *Prior Related Cases, if any:* IN–B–UAH

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Attached Annex

(viii) *Date Report Delivered to Congress:* June 12, 2018

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

India—Support for Direct Commercial Sale of AH–64E Apache Helicopters

The Government of India has requested to buy the following items in support of a proposed direct commercial sale of six (6) AH–64E Apache helicopters: fourteen (14) T700–GE–701D engines; four (4) AN/APG–78 Fire Control Radars; four (4) Radar Electronic Units (REU) Block III; four (4) AN/APR–48B Modernized Radar Frequency Interferometers (M–RFI's); one hundred eighty (180) AGM–114L–3 Hellfire Longbow missiles; ninety (90) AGM–114R–3 Hellfire II missiles; two hundred (200) Stinger Block I–92H missiles; seven (7) Modernized Target Acquisition Designation Sight/Pilot Night Vision Sensors (MTADS–PNVS); and fourteen (14) Embedded GPS Inertial Navigation Systems (EGI). Also included are rockets, training and dummy missiles, 30 mm cannons and ammunition, transponders, simulators, communication equipment, spare and repair parts, tools and test equipment, support equipment, repair and return support, personnel training and training equipment, publications and technical documentation, U.S. Government and contractor engineering and logistics support services, and other related elements of logistic and program support. The total estimated program cost is $930 million.

This proposed sale will contribute to the foreign policy and national security of the United States by helping to strengthen the U.S.-Indian strategic relationship and to improve the security of an important partner which continues to be an important force for political stability, peace, and economic progress in South Asia.

The proposed sale is in conjunction with and in support of a proposed direct commercial sale of six (6) AH–64E Apache helicopters, and will strengthen India's ability to defend its homeland and deter regional threats. This support for the AH–64E will provide an increase in India's defensive capability to counter ground-armored threats and modernize its armed forces. India will have no difficulty absorbing the helicopters and support equipment into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The prime contractors will be Lockheed Martin Corporation, Orlando, FL; General Electric Company, Cincinnati, OH; Lockheed Martin Mission Systems and Sensors, Owego, NY; Longbow Limited Liability Corporation, Orlando, FL; and Raytheon Company, Tucson, AZ. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will require U.S. Government or contractor representatives to travel to India for a period of one week at a time to conduct a detailed discussion of the various aspects of the hybrid program with Government of India representatives. Additional travel will be required for equipment de-processing/fielding, system checkout and new equipment training and Contractor Furnished Service Representatives (CFSR) for a period of thirty months.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 18–18

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. The AN/APG–78 Fire Control Radar (FCR) is an active, low-probability of intercept, millimeter-wave radar, combined with a passive Modernized Radar Frequency Interferometer (MRFI) mounted on top of the helicopter mast. The FCR Ground Targeting Mode detects, locates, classifies and prioritizes stationary or moving armored vehicles, tanks and mobile air defense systems as well as hovering helicopters, helicopters, and fixed wing aircraft in normal flight. The MRFI detects threat radar emissions and determines the type of radar and mode of operation. The FCR data and MRFI data are fused for maximum synergism. If desired, the radar data can be used to refer targets to the regular electro-optical Target Acquisition and Designation Sight (TADS), Modernized Target Acquisition and Designation Sight (MTADS), permitting additional visual/infrared imagery and control of weapons, including the semi active laser version of the Hellfire. Critical system information is stored in the FCR in the form of mission executable code, target detection, classification algorithms and coded threat parametrics. This information is provided in a form that cannot be extracted by the foreign user due to anti-tamper provisions built into the system. The content of these items is classified SECRET.

2. The Modernized Target Acquisition and Designation Sight/Modernized Pilot Night Vision Sensor (M–TADS/M–PNVS) provides second generation day, night, limited adverse weather target

information, as well as night navigation capabilities. The MPNVS provides second generation thermal imaging that permits nap-of-the-earth flight to, from, and within the battle area, while M–TADS provides the co-pilot gunner with improved search, detection, recognition, and designation by means of Direct View Optics (DVO), I^2 television, second generation Forward Looking Infrared (FLIR) sighting systems that may be used singularly or in combinations. Hardware and releasable technical manuals are UNCLASSIFIED.

3. The AN/APR–48B Modernized Radar Frequency Interferometer (M–RFI) is an updated version of the passive radar detection and direction finding system. It utilizes a detachable User Data Module (UDM) on the M–RFI processor, which contains the Radar Frequency (RF) threat library. The UDM, which is a hardware assemblage item, is classified CONFIDENTIAL when programmed with threat parametrics, threat priorities and/or techniques derived from U.S. intelligence information. Hardware becomes CLASSIFIED when populated with threat parametric data. Releasable technical manuals are UNCLASSIFIED.

4. The Hellfire AGM–114 missile is an air-to-surface missile with a multi-mission, multi target, precision strike capability. The Hellfire can be launched from multiple air platforms and is the primary precision weapon for the United States.

a. The Hellfire Longbow Missile (AGM–114L3) provides an adverse weather, fire-and-forget missile version of the Hellfire Missile System, incorporating a millimeter wave radar seeker on a Hellfire II aft section bus. The Hellfire Longbow Missile is designed to engage and defeat individual hardpoint targets and minimize exposure time to enemy fire, which greatly increases the AH–64E Longbow survivability factor. The AGM–114L3 non-NATO export version will be provided. The weapon system hardware, as an ''All Up Round'', is UNCLASSIFIED. The AGM–114L3 missile software is SECRET. The highest level of classified information that could be disclosed by a proposed sale or by testing of the end item is SECRET and the highest level that must be disclosed for production, maintenance, or training is CONFIDENTIAL. Vulnerability data, countermeasures, vulnerability/susceptibility analyses, and threat definitions are classified SECRET or CONFIDENTIAL.

b. The highest level for release of the AGM–114R Hellfire II missile is SECRET, based upon the software. The highest level of classified information that could be disclosed by a proposed sale or by testing the end item is SECRET; the highest level that must be disclosed for production, maintenance, or training is CONFIDENTIAL. Reverse engineering could reveal CONFIDENTIAL information. Vulnerability data, Countermeasures, vulnerability/susceptibility analyses, and threat definitions are classified up to SECRET.

5. The STINGER Block I 92H International Missile System, hardware, software and documentation contain SENSITIVE technology and are classified CONFIDENTIAL. The guidance section of the missile and captive flight trainer contain highly SENSITIVE technology and are classified CONFIDENTIAL. No man-portable grip stocks will be sold under this LOA.

Missile system hardware and fire unit components contain SENSITIVE critical technologies. STINGER critical technology is primarily in the area of design and production know-how and not end-items. This SENSITIVE/critical technology is inherent in the hybrid microcircuit assemblies; microprocessors; magnetic and amorphous metals; purification; firmware; printed circuit boards; laser range finder; dual detector assembly; detector filters; missile software; optical coatings; ultraviolet sensors; semi-conductor detectors infrared band sensors; compounding and handling of electronic, electro-optic, and optical materials; equipment operating instructions; energetic materials formulation technology; energetic materials fabrication and loading technology; and warhead components seeker assembly. Information on vulnerability to electronic countermeasures and countermeasures, system performance capabilities and effectiveness, and test data are classified up to SECRET.

6. The Stinger Captive Flight Trainer (CFT) is a Stinger missile guidance assembly in a launch tube. The CFT provides operator training in target acquisition, tracking, engagement, loading/unloading and sustainment training at the unit. The hardware is classified CONFIDENTIAL. Releasable technical manuals are UNCLASSIFIED.

7. If a technologically advanced adversary were to obtain knowledge of specific hardware, the information could be used to develop countermeasures which might reduce weapons system effectiveness or be used in the development of a system with similar or advanced capabilities.

8. A determination has been made that India can provide substantially the same degree of protection for sensitive technology being released as the U.S. Government. This proposed sustainment program is necessary to the furtherance of the U.S. foreign policy and national security objectives outlined in the policy justification.

9. All defense articles and services listed on this transmittal are authorized for release and export to the Government of the India.

[FR Doc. 2018–16323 Filed 7–30–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 17–37]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Arms sales notice.

SUMMARY: The Department of Defense is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: DSCA at *dsca.ncr.lmo.mbx.info@mail.mil* or (703) 697–9709.

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 17–37 with attached Policy Justification.

Dated: July 25, 2018.

Shelly E. Finke,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–60–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

The Honorable Paul D. Ryan
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

MAY 17 2018

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 17-37, concerning the Air Force's proposed Letter(s) of Offer and Acceptance to the Government of Bahrain for defense articles and services estimated to cost $45 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

for

Charles W. Hooper
Lieutenant General, USA
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Regional Balance (Classified document provided under separate cover)

BILLING CODE 5001–60–C

Transmittal No. 17–37

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Government of Bahrain

(ii) *Total Estimated Value:*

Major Defense Equipment *	$38 million
Other	$ 7 million
TOTAL	$45 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Major Defense Equipment (MDE):

One thousand five hundred (1,500) MK–82 (500lbs) General Purpose (GP) Bomb Bodies

Six hundred (600) MK–83 (1,000lbs) GP Bomb Bodies

Six hundred (600) MK–84 (2,000lbs) GP Bomb Bodies

Five hundred (500) BLU–109 (2,000lbs) Penetrator Warhead Bomb Bodies

Non-MDE includes: Also included are spares, and repair parts, support equipment, personnel training and training equipment, shipping and logistics services, publications and technical documentation, U.S. Government and contractor technical support services, containers, munitions components, test equipment, and other related elements of logistics and program support.

(iv) *Military Department:* Air Force (X7–D–AAN)

(v) *Prior Related Cases, if any:* None

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* None

(viii) *Date Report Delivered to Congress:* May 17, 2018

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Government of Bahrain—Munitions

The Government of Bahrain has requested three thousand two hundred (3,200) General Purpose (GP) and Penetrator Warhead bomb bodies to include: one thousand five hundred (1,500) MK–82 (500lbs) GP bomb bodies, six hundred (600) MK–83 (1,000lbs) GP bomb bodies, six hundred (600) MK–84 (2,000lbs) GP bomb bodies, and five hundred (500) BLU–109 (2,000lbs) Penetrator Warhead bomb bodies. Also included are spares and repair parts, support equipment, personnel training and training equipment, shipping and logistics services, publications and technical documentation, U.S. Government and contractor technical support services, containers, munitions components, test equipment, and other related elements of logistics and program support. The estimated total cost is $45 million.

This proposed sale will enhance the foreign policy and national security objectives of the United States by helping to improve the security of a major non-NATO ally which is an important security partner in the region. The purchase of these munitions will bolster the Royal Bahraini Air Force's ability to conduct and sustain air operations with its F–16 combat aircraft. Our mutual defense interests anchor our relationship and the Royal Bahraini Air Force plays a significant role in Bahrain's defense.

The proposed sale will improve Bahrain's capability to meet current and future security threats. Bahrain will use these munitions as a deterrent to regional threats, strengthen its homeland defense, and execute counter-terrorism operations. The GP bomb bodies would also better equip Bahrain to operate with U.S.-led and U.S.-supported coalition operations. Bahrain will have no difficulty absorbing these munitions into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

There is no prime contractor planned for this effort; the munitions will be provided by the U.S. Government out of stock. There are no offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will not require the assignment of any additional U.S. or contractor representatives to Bahrain.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

[FR Doc. 2018–16304 Filed 7–30–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 18–24]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Arms sales notice.

SUMMARY: The Department of Defense is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: DSCA at *dsca.ncr.lmo.mbx.info@mail.mil* or (703) 697–9709.

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 18–24 with attached Policy Justification and Sensitivity of Technology.

Dated: July 26, 2018.

Shelly E. Finke,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

The Honorable Paul D. Ryan
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

10 JUL 2018

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 18-24, concerning the Air Force's proposed Letter(s) of Offer and Acceptance to the Kingdom of Denmark for defense articles and services estimated to cost $90 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

Charles W. Hooper
Lieutenant General, USA
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology

BILLING CODE 5001–06–C

Transmittal No. 18–24

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Kingdom of Denmark

(ii) *Total Estimated Value:*

Major Defense Equipment *	$75 million
Other	$15 million
TOTAL	$90 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Major Defense Equipment (MDE):

Twenty-eight (28) AIM–120 C–7 Advanced Medium Range Air-to-Air Missiles (AMRAAM)

One (1) AMRAAM Spare Guidance Section

Non-MDE: Also included are missile containers, control section spares, weapon systems support, test equipment, spare and repair parts, publications and technical documentation, personnel training, training equipment, U.S. Government and contractor engineering, logistics, and technical support services, and other related elements of logistics and program support.

(iv) *Military Department:* Air Force (DE–D–YAO)

(v) *Prior Related Cases, if any:* DE–D–YAS (AIM–120B)

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services*

Proposed to be Sold: See Attached Annex

(viii) *Date Report Delivered to Congress:* July 10, 2018

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Denmark—AIM–120 C–7 Advanced Medium Range Air-to-Air Missile (AMRAAM)

The Government of Denmark has requested to buy twenty-eight (28) AIM–120 C–7 Advanced Medium Range Air-to-Air Missiles (AMRAAM) and one (1) AMRAAM spare guidance section. Also included are missile containers, control section spares, weapon systems support, test equipment, spare and repair parts, publications and technical documentation, personnel training, training equipment, U.S. Government and contractor engineering, logistics, and technical support services, and other related elements of logistics and program support. The total estimated program cost is $90 million.

This proposed sale will contribute to the foreign policy and national security of the United States by helping to improve the security of a NATO ally that is an important force for political stability and economic progress in the European region.

This proposed sale would support Denmark's F–16 and future F–35 fighter programs and enhance Denmark's ability to provide for its own territorial defense and support coalition operations. The proposed sale also enables interoperability and standardization between the armed forces of Denmark and the United States. Denmark already maintains the AIM–120B in its inventory and will have no difficulty absorbing this additional equipment and support into its armed forces.

The proposed sale of these systems and equipment will not alter the basic military balance in the region.

The principal contractor will be Raytheon Cooperation in Tucson, Arizona. The purchaser has requested offsets. At this time, agreements are undetermined and will be defined in negotiations between the purchaser and contractor.

Implementation of this proposed sale will not require the assignment of any additional U.S. Government or contractor representatives to Denmark.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 18–24

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. AIM–120C Advance Medium Range Air-to-Air (AMRAAM) is a radar-guided missile featuring digital technology and micro-miniature solid-state electronics. AMRAAM capabilities include look-down/shoot-down, multiple launches against multiple targets, resistance to electronic counter measures, and interception of high flying and low flying and maneuvering targets. The AMRAAM All Up Round is classified CONFIDENTIAL, major components and subsystems range from UNCLASSIFIED to CONFIDENTIAL, and technology data and other documentation are classified up to SECRET.

2. If a technologically advanced adversary were to obtain knowledge of the hardware and software elements, the information could be used to develop countermeasures or equivalent systems which might reduce system effectiveness or be used in the development of a system with similar or advanced capabilities.

3. A determination has been made that Denmark can provide substantially the same degree of protection for the sensitive technology being released as the U.S. Government. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification.

4. All defense articles and services listed in this transmittal have been authorized for release and export to Denmark.

[FR Doc. 2018–16373 Filed 7–30–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Technical Assistance and Dissemination To Improve Services and Results for Children With Disabilities—Technical Assistance and Dissemination Center on Improving Literacy Through Supporting Elementary School Leaders

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Notice.

SUMMARY: The Department of Education (Department) is issuing a notice inviting applications for new awards for fiscal year (FY) 2018 for Technical Assistance and Dissemination to Improve Services and Results for Children With Disabilities—Technical Assistance and Dissemination Center on Improving Literacy through Supporting Elementary School Leaders, Catalog of Federal Domestic Assistance (CFDA) number 84.326L.

DATES:

Applications Available: July 31, 2018.

Deadline for Transmittal of Applications: August 30, 2018.

ADDRESSES: For the addresses for obtaining and submitting an application, please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 12, 2018 (83 FR 6003) and available at *www.gpo.gov/fdsys/pkg/FR-2018-02-12/pdf/2018-02558.pdf.*

FOR FURTHER INFORMATION CONTACT: Kristen Rhoads, U.S. Department of Education, 400 Maryland Avenue SW, Room 5142, Potomac Center Plaza, Washington, DC 20202–5108.

Telephone: (202) 245–6715. Email: *Kristen.Rhoads@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purpose of the Technical Assistance and Dissemination to Improve Services and Results for Children with Disabilities program is to promote academic achievement and to improve results for children with disabilities by providing technical assistance (TA), supporting model demonstration projects, disseminating useful information, and implementing activities that are supported by scientifically based research.

Priority: In accordance with 34 CFR 75.105(b)(2)(v), this priority is from allowable activities specified in the statute (see sections 663 and 681(d) of the Individuals with Disabilities Education Act (IDEA); 20 U.S.C. 1463 and 1481(d)).

Absolute Priority: For FY 2018 and any subsequent year in which we make awards from the list of unfunded applications from this competition, this priority is an absolute priority. Under 34 CFR 75.105(c)(3), we consider only applications that meet this priority.

This priority is:

Technical Assistance and Dissemination Center on Improving Literacy through Supporting Elementary School Leaders.

Background:

The mission of the Office of Special Education and Rehabilitative Services (OSERS) is to improve early childhood, educational, and employment outcomes and raise expectations for all people with disabilities, their families, their communities, and the Nation.

The National Reading Panel report (2000) and RAND report *Reading for Understanding* (Snow, 2001) have influenced reading instruction in the United States for the last two decades (Connor & Al Otaiba, 2015). During this time, reading instruction in the primary grades has improved by targeting important literacy skills highlighted in the reports and becoming more systematic in how these skills are taught (S. Baker, Fien, & Baker, 2010).

Despite noted improvements in reading instruction, the gap between students with disabilities and their peers on the National Assessment of Educational Progress (NAEP) has increased in both fourth and eighth grades since 2009 (U.S. Department of Education, 2017). In addition, less than 50 percent of teachers surveyed report that they adhere to their core reading curricula, and more than 60 percent of teachers report that they continue to use an ''eclectic approach'' combining different instructional methods for teaching reading (Kretlow & Helf, 2013). Kretlow and Helf also reported that most of the curricula teachers used had not been evaluated for impact on student learning. Also, according to the Schools and Staffing Survey (Rotermund, DeRoche, & Ottem, 2017), 43 percent of teachers reported receiving no professional development on reading instruction in the last 12 months. Further, in a separate survey, two-thirds of teachers reported receiving fewer than eight hours of professional development on reading instruction during the last year, an intensity unlikely to improve the quality of reading instruction that they provide or result in improved student outcomes (Wei, Darling-Hammond, & Adamson, 2010; Yoon, Duncan, Lee, Scarloss, & Shapley, 2007).

School leaders (as defined in this notice) have the ability to affect these trends, and research has clearly demonstrated the effects that they can have on the academic performance of their schools (Herman et al., 2017; Horng, Kalogrides, & Loeb, 2009; Leithwood, Seashore-Louis, Anderson, & Wahlstrom, 2004). The Professional Standards for Educational Leaders,[1] developed by the National Policy Board for Educational Administration (2015), illustrate the variety of activities under the purview of school leaders. School leaders' responsibilities include managing school operations and resources, including managing budgets, resources, and hiring personnel; overseeing curriculum, instruction, and assessment; striving for equity in educational opportunity for each student; developing the professional capacity and practice of school personnel; and engaging in internal and external relations including fostering a professional community of school personnel and engaging families and the community (Horng, Klasik, & Loeb, 2010; National Policy Board for Educational Administration, 2015).

School leaders' organizational management activities, such as managing budget and resources and hiring staff, make the school organization work and provide support for teaching and learning (Grissom & Loeb, 2011). These types of activities, as well as school leaders spending more time on them, have shown consistent associations with positive student academic outcomes (Grissom & Loeb, 2011).

There have been mixed findings regarding the extent to which school leaders' instruction-related activities, such as overseeing the curriculum and providing professional development for staff, are associated with improved student outcomes (Horng et al., 2010; Robinson, Lloyd, & Rowe, 2008). A number of possible explanations for this variation exist, including potential variation in the quantity of time spent on instructional management, the specific types of instruction-related activities school leaders engage in (Grissom, Loeb, & Master, 2013), and the quality of instructional management training received by school leaders. In particular, some researchers have argued that current training on instruction-related activities may be too narrow and may not include training in the organizational management skills that help school leaders target resources effectively in addressing the instructional needs of their students (Grissom & Loeb, 2011).

The Center on Improving Literacy through Supporting Elementary School Leaders (the Center) will provide TA for school leaders on instructional content and leadership skills to improve teacher implementation of evidence-based (as defined in this notice) literacy practices and literacy skills of students with, or at risk for, literacy-related disabilities. Specifically, the Center will provide TA for LEAs and their school leaders on a variety of topics, namely: Providing professional development, including coaching, to their teachers and other instructional personnel on literacy; developing education programming related to literacy; allocating resources efficiently and effectively so that students with, or at risk for, literacy-related disabilities have access to literacy instruction and interventions that meet their individual needs; and improving teacher implementation of evidence-based literacy instruction in their schools and, ultimately, literacy outcomes for their students with, or at risk for, literacy-related disabilities. The Center may build upon the work of, and collaborate with, other Department TA centers including the National Center on Improving Literacy, the National Center on Intensive Intervention, and the Center on Great Teachers and Leaders. The work of this Center will not duplicate work being conducted by

[1] For more information about the Professional Standards for Educational Leaders, please see *http://npbea.org/wp-content/uploads/2017/06/PSEL-WebinarPowerPointSlides.pdf.*

other Department TA Centers. This priority is consistent with the Secretary's Final Supplemental Priorities and Definitions for Discretionary Grant Programs, published in the **Federal Register** on March 2, 2018 (83 FR 9096) (Supplemental Priorities): Supplemental Priority 5—Meeting the Unique Needs of Students and Children With Disabilities and/or Those With Unique Gifts and Talents; Supplemental Priority 7—Promoting Literacy; and Supplemental Priority 8—Promoting Effective Instruction in Classrooms and Schools.

Priority:

The purpose of this priority is to fund a cooperative agreement to establish and operate a Center on Improving Literacy through Supporting Elementary School Leaders (Literacy through Leaders). The Center will provide targeted TA to school leaders on literacy skills and concepts (*e.g.,* phonemic awareness, comprehension) and leadership skills (*e.g.,* coaching, instructional management and programming, organizational management) related to improving teachers' implementation of evidence-based literacy practices and literacy outcomes for their students with, or at risk for, literacy-related disabilities. The Center will support school leaders in recognizing evidence-based literacy practices for students with, or at risk for, literacy-related disabilities and facilitating the implementation of these practices through developing education programming and professional development efforts, including coaching teachers. The Center must achieve, at a minimum, the following expected outcomes:

(a) Improved literacy achievement and skills of students with, or at risk for, literacy-related disabilities;

(b) Improved capacity of school leaders for identifying and supporting the implementation of evidence-based literacy practices, including assessments, that improve teachers' practices as well as literacy achievement and skills of students with, or at risk for, literacy-related disabilities;

(c) Improved capacity of teachers and other instructional personnel to implement with fidelity evidence-based literacy practices, including assessments, that improve literacy achievement and skills of students with, or at risk for, literacy-related disabilities;

(d) Improved quality of literacy instruction throughout the school; and

(e) Reduction in the number of students inappropriately referred for special education and related services.

In addition to these programmatic requirements, to be considered for funding under this priority, applicants must meet the application and administrative requirements in this priority, which are:

(a) Demonstrate, in the narrative section of the application under ''Significance of the Project,'' how the proposed project will—

(1) Address current and emerging needs of elementary school leaders to improve teacher implementation of evidence-based literacy practices and outcomes of their students with, or at risk for, literacy-related disabilities. To meet this requirement the applicant must—

(i) Present applicable national, State, regional, or local data demonstrating the need to address elementary school leaders' knowledge of evidence-based literacy practices and leadership skills with the goal of improving teacher implementation of evidence-based literacy practices and, ultimately, the literacy outcomes of their students with, or at risk for, literacy-related disabilities;

(ii) Demonstrate knowledge of current educational issues and policy initiatives relating to implementing and sustaining professional learning practices and activities for elementary school leaders that have evidence for producing positive effects on teacher implementation of evidence-based literacy practices in their schools, students' literacy achievement, or reducing the numbers of students inappropriately referred for needing special education and related services; and

(iii) Present information about the current level of implementation of:

(A) Practices and activities focused on improving leadership skills of elementary school leaders, including developing educational programming, allocating resources for instruction and intervention effectively and efficiently, and providing professional development to teachers in their schools; and

(B) Evidence-based literacy instruction, intervention, and assessment for students with, or at risk for, literacy-related disabilities in elementary schools;

(2) Improve elementary school leaders' literacy-related knowledge and leadership skills; their schools' literacy-related core instruction, supplemental intervention, and assessment; and literacy-related outcomes for students with, or at risk for, disabilities and indicate the likely magnitude or importance of the improvements.

(b) Demonstrate, in the narrative section of the application under ''Quality of the Project Services,'' how the proposed project will—

(1) Ensure equal access and treatment for members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability. To meet this requirement, the applicant must describe how it will—

(i) Identify the needs of the intended recipients for TA and information; and

(ii) Ensure that services and products meet the needs of the intended recipients of the grant;

(2) Achieve its goals, objectives, and intended outcomes. To meet this requirement, the applicant must provide—

(i) Measurable intended project outcomes; and

(ii) In Appendix A, the logic model (as defined in this notice) by which the proposed project will achieve its intended outcomes that depicts, at a minimum, the goals, activities, outputs, and intended outcomes of the proposed project;

(3) Use a conceptual framework (and provide a copy in Appendix A) to develop project plans and activities, describing any underlying concepts, assumptions, expectations, beliefs, or theories, as well as the presumed relationships or linkages among these variables, and any empirical support for this framework;

Note: The following websites provide more information on logic models and conceptual frameworks: *www.osepideasthatwork.org/logicModel* and *www.osepideasthatwork.org/resources-grantees/program-areas/ta-ta/tad-project-logic-model-and-conceptual-framework.*

(4) Be based on current research and make use of evidence-based practices (EBPs). To meet this requirement, the applicant must describe—

(i) The current research on professional learning practices for school leaders, particularly elementary school leaders, and school leader behaviors or characteristics that are associated with improved classroom teaching practices and positive student literacy-related outcomes and on related EBPs that will inform the proposed TA;

(ii) The current research about adult learning principles and implementation science that will inform the proposed TA;

(iii) How the proposed project will incorporate current research and EBPs in the development and delivery of its products and services; and

(5) Develop products and provide services that are of high quality and sufficient intensity and duration to achieve the intended outcomes of the

proposed project. To address this requirement, the applicant must describe—

(i) How it proposes to identify or develop the knowledge base on effective practices for improving literacy knowledge and instructional and organizational management capacity of elementary school leaders;

(ii) Its proposed approaches to providing varying levels of intensity of TA (*i.e.,* universal,[2] targeted,[3] intensive [4]) based on the needs of the field and available resources. The applicant must identify the intended recipients (*e.g.,* local educational agencies (LEAs) and school leaders in sites other than traditional public elementary school settings where students are supported under IDEA, including private schools), including the type and number of recipients, that will receive the products and services through each approach and how they plan to reach a variety of settings and populations (*e.g.,* urban, rural, suburban); and

(A) For implementing targeted, specialized TA, its proposed approach to measure the readiness of potential TA recipients (*e.g.,* LEAs) to work with the project, assessing, at a minimum, their current infrastructure, available resources, and ability to build capacity at the local level; and

(B) For implementing intensive, sustained TA, its proposed approach to measure the readiness of the LEAs and elementary school leaders to work with the project, including their commitment to the initiative, alignment of the initiative to their needs, current infrastructure, available resources, and ability to build capacity at the local district and school level; and its proposed plan for working with appropriate levels of the education system (*e.g.,* State education agencies (SEAs), regional TA providers, districts, schools, families) to ensure that there is communication between each level and that there are systems in place to support the use of evidence-based literacy practices;

(6) Develop products and implement services that maximize efficiency. To address this requirement, the applicant must describe—

(i) How the proposed project will use technology to achieve the intended project outcomes;

(ii) With whom the proposed project will collaborate and not duplicate (*e.g.,* The National Center on Improving Literacy, National Center on Intensive Intervention, State Implementation and Scaling-up of Evidence-based Practices Center, and related professional organizations, including those that offer training programs targeting school leaders) and the intended outcomes of this collaboration; and

(iii) How the proposed project will use non-project resources to achieve the intended project outcomes.

(c) In the narrative section of the application under ''Quality of the Evaluation Plan,'' include an evaluation plan for the project developed in consultation with and implemented by a third-party evaluator.[5] The evaluation plan must—

(1) Articulate formative and summative evaluation questions, including important process and outcome evaluation questions. These questions should be related to the project's proposed logic model required in paragraph (b)(2)(ii) of this notice;

(2) Describe how progress in and fidelity of implementation, as well as project outcomes, including how successfully materials are disseminated to, and used by, relevant stakeholder groups and professional organizations, will be measured to answer the evaluation questions. Specify the measures and associated instruments or sources for data appropriate to the evaluation questions. Include information regarding reliability and validity of measures where appropriate;

(3) Describe strategies for analyzing data and how data collected as part of this plan will be used to inform and improve service delivery over the course of the project and to refine the proposed logic model and evaluation plan, including subsequent data collection;

(4) Provide a timeline for conducting the evaluation, and include staff assignments for completing the plan. The timeline must indicate that the data will be available annually for the Annual Performance Report (APR) and at the end of Year 2 for the review process described under the heading, *Fourth and Fifth Years of the Project;*

(5) Dedicate sufficient funds in each budget year to cover the costs of developing or refining the evaluation plan in consultation with a ''third-party'' evaluator, as well as the costs associated with the implementation of the evaluation plan by the third-party evaluator.

(d) Demonstrate, in the narrative section of the application under ''Adequacy of Project Resources,'' how—

(1) The proposed project will encourage applications for employment from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability, as appropriate;

(2) The proposed key project personnel, consultants, and subcontractors have the qualifications and experience to carry out the proposed activities and achieve the project's intended outcomes;

(3) The applicant and any key partners have adequate resources to carry out the proposed activities; and

(4) The proposed costs are reasonable in relation to the anticipated results and benefits.

(e) Demonstrate, in the narrative section of the application under ''Quality of the Management Plan,'' how—

(1) The proposed management plan will ensure that the project's intended outcomes will be achieved on time and within budget. To address this requirement, the applicant must describe—

(i) Clearly defined responsibilities for key project personnel, consultants, and subcontractors, as applicable; and

(ii) Timelines and milestones for accomplishing the project tasks;

(2) Key project personnel and any consultants and subcontractors will be allocated and how these allocations are

[2] ''Universal, general TA'' means TA and information provided to independent users through their own initiative, resulting in minimal interaction with TA center staff and including one-time, invited or offered conference presentations by TA center staff. This category of TA also includes information or products, such as newsletters, guidebooks, fact sheets, issues briefs, massive open online courses (MOOCs), or research syntheses, downloaded from the TA center's website by independent users. Brief communications by TA center staff with recipients, either by telephone or email, are also considered universal, general TA.

[3] ''Targeted, specialized TA'' means TA services based on needs common to multiple recipients and not extensively individualized. A relationship is established between the TA recipient and one or more TA center staff. This category of TA includes one-time, labor-intensive events, such as facilitating strategic planning or hosting regional or national conferences. It can also include episodic, less labor-intensive events that extend over a period of time, such as facilitating a series of conference calls on single or multiple topics that are designed around the needs of the recipients. Facilitating communities of practice can also be considered targeted, specialized TA.

[4] ''Intensive, sustained TA'' means TA services often provided on-site and requiring a stable, ongoing relationship between the TA center staff and the TA recipient. ''TA services'' are defined as negotiated series of activities designed to reach a valued outcome. This category of TA should result in changes to policy, program, practice, or operations that support increased recipient capacity or improved outcomes at one or more systems levels.

[5] A ''third-party'' evaluator is an independent and impartial program evaluator who is contracted by the grantee to conduct an objective evaluation of the project. This evaluator must not have participated in the development or implementation of any project activities, except for the evaluation activities, nor have any financial interest in the outcome of the evaluation.

appropriate and adequate to achieve the project's intended outcomes;

(3) The proposed management plan will ensure that the products and services provided are of high quality, relevant, and useful to recipients; and

(4) The proposed project will benefit from a diversity of perspectives, including those of families, educators, TA providers, researchers, and policy makers, among others, in its development and operation.

(f) Address the following application requirements. The applicant must—

(1) Include, in Appendix A, personnel-loading charts and timelines, as applicable, to illustrate the management plan described in the narrative;

(2) Include, in the budget, attendance at the following:

(i) A one and one-half day kick-off meeting in Washington, DC, after receipt of the award, and an annual planning meeting in Washington, DC, with the OSEP project officer and other relevant staff during each subsequent year of the project period.

Note: Within 30 days of receipt of the award, a post-award teleconference must be held between the OSEP project officer and the grantee's project director or other authorized representative;

(ii) A two and one-half day project directors' conference in Washington, DC, during each year of the project period;

(iii) One annual trip to attend Department briefings, Department-sponsored conferences, and other meetings, as requested by OSEP; and

(iv) A one-day intensive 3+2 review meeting in Washington, DC, during the last half of the second year of the project period;

(3) Include, in the budget, a line item for an annual set-aside of five percent of the grant amount to support emerging needs that are consistent with the proposed project's intended outcomes, as those needs are identified in consultation with, and approved by, the OSEP project officer. With approval from the OSEP project officer, the project must reallocate any remaining funds from this annual set-aside no later than the end of the third quarter of each budget period;

(4) Maintain a high-quality website, with an easy-to-navigate design, that meets government or industry-recognized standards for accessibility; and

(5) Include, in Appendix A, an assurance to assist OSEP with the transfer of pertinent resources and products and to maintain the continuity of services to States during the transition to this new award period and at the end of this award period, as appropriate.

Fourth and Fifth Years of the Project:

In deciding whether to continue funding the project for the fourth and fifth years, the Secretary will consider the requirements of 34 CFR 75.253(a), as well as—

(a) The recommendation of a 3+2 review team consisting of experts selected by the Secretary. This review will be conducted during a one-day intensive meeting that will be held during the last half of the second year of the project period;

(b) The timeliness with which, and how well, the requirements of the negotiated cooperative agreement have been or are being met by the project; and

(c) The quality, relevance, and usefulness of the project's products and services and the extent to which the project's products and services are aligned with the project's objectives and likely to result in the project achieving its intended outcomes.

References

Baker, S.K., Fien, H., & Baker, D.L. (2010). Robust reading instruction in the early grades: Conceptual and practical issues in the integration and evaluation of tier 1 and tier 2 instructional supports. *Focus on Exceptional Children, 42*(9), 1–20.

Connor, C.M., & Al Otaiba, S. (2015). Primary grade reading instruction in the United States. In A. Pollatsek & R. Treiman (Eds.), The Oxford handbook of reading (pp. 415–430). New York: Oxford University Press.

Grissom, J.A., & Loeb, S. (2011). Triangulating principal effectiveness: How perspectives of parents, teachers, and assistant principals identify the central importance of managerial skills. *American Educational Research Journal, 48*(5), 1091–1123.

Grissom, J.A., Loeb, S., & Master, B. (2013). Effective instructional time use for school leaders: Longitudinal evidence from observations of principals. *Educational Researcher, 42*(8), 433–444.

Herman, R., Gates, S.M., Arifkhanova, A., Bega, A., Chavez-Herrerias, E.R., Han, E., . . . & Wrabel, S. (2017). School leadership interventions under the Every Student Succeeds Act: Evidence review. Santa Monica, CA: RAND Corporation.

Horng, E.L., Kalogrides, D., & Loeb, S. (2009). Principal preferences and the uneven distribution of principals across schools. School Leadership Research Report No. 09–2. Stanford, CA: Stanford University Institute for Research on Education Policy and Practice.

Horng, E.L., Klasik, D., & Loeb, S. (2010). Principal's time use and school effectiveness. *American Journal of Education, 116*(4), 491–523.

Kretlow, A.G., & Helf, S.S. (2013). Teacher implementation of evidence-based practices in tier 1: A national survey. *Teacher Education and Special Education, 36*(3), 167–185.

Leithwood, K., Seashore-Louis, K., Anderson, S., & Wahlstrom, K. (2004). How leadership influences student learning. New York, NY: The Wallace Foundation. Retrieved from *https://conservancy.umn.edu/bitstream/handle/11299/2035/CAREI%20ReviewofResearch%20How%20Leadership%20Influences.pdf?sequence=1&isAllowed=y.*

National Reading Panel. (2000). Teaching children to read: An evidence-based assessment of the scientific research literature on reading and its implications for reading instruction. Washington, DC: National Institutes of Health.

Robinson, V.M., Lloyd, C.A., & Rowe, K.J. (2008). The impact of leadership on student outcomes: An analysis of the differential effects of leadership types. *Educational Administration Quarterly, 44*(5), 635–674.

Rotermund, S., DeRoche, J., & Ottem, R. (2017). *Teacher Professional Development By Selected Teacher and School Characteristics: 2011–2012.* Washington, DC: National Center for Education Statistics, Institute of Education Sciences, U.S. Department of Education.

Snow, C.E. (2001). Reading for understanding. Santa Monica, CA: RAND Education and the Science and Technology Policy Institute.

U.S. Department of Education, Institute of Education Sciences, National Center for Education Statistics. (2015). *National Assessment of Educational Progress (NAEP) Reading Assessments.* Accessed through the NAEP Data Explorer at *http://nces.ed.gov/nationsreportcard/naepdata/.*

Wei, R.C., Darling-Hammond, L., & Adamson, F. (2010). *Professional development in the United States: Trends and challenges* (Vol. 28). Dallas, TX: National Staff Development Council.

Yoon, K.S., Duncan, T., Lee, S.W.Y., Scarloss, B., & Shapley, K.L. (2007). Reviewing the Evidence on How Teacher Professional Development Affects Student Achievement. Issues & Answers. REL 2007-No. 033. *Regional Educational Laboratory Southwest (NJ1).*

Definitions: The following definitions are from 34 CFR 77.1 and section 8101 of the Elementary and Secondary Education Act, as amended by the Every Student Succeeds Act (ESEA), as marked.

Demonstrates a rationale (34 CFR 77.1) means a key project component included in the project's logic model is informed by research or evaluation findings that suggest the project component is likely to improve relevant outcomes.

Evidence-based (34 CFR 77.1) means the proposed project component is supported by one or more of strong evidence, moderate evidence, promising evidence, or evidence that demonstrates a rationale.

Experimental study (34 CFR 77.1) means a study that is designed to compare outcomes between two groups of individuals (such as students) that are otherwise equivalent except for their assignment to either a treatment group receiving a project component or a control group that does not. Randomized controlled trials, regression discontinuity design studies, and single-case design studies are the specific types of experimental studies that, depending on their design and implementation (*e.g.,* sample attrition in randomized controlled trials and regression discontinuity design studies), can meet What Works Clearinghouse (WWC) standards without reservations as described in the WWC Handbook:

(i) A randomized controlled trial employs random assignment of, for example, students, teachers, classrooms, or schools to receive the project component being evaluated (the treatment group) or not to receive the project component (the control group).

(ii) A regression discontinuity design study assigns the project component being evaluated using a measured variable (*e.g.,* assigning students reading below a cutoff score to tutoring or developmental education classes) and controls for that variable in the analysis of outcomes.

(iii) A single-case design study uses observations of a single case (*e.g.,* a student eligible for a behavioral intervention) over time in the absence and presence of a controlled treatment manipulation to determine whether the outcome is systematically related to the treatment.

Logic model (34 CFR 77.1) (also referred to as a theory of action) means a framework that identifies key project components of the proposed project (*i.e.,* the active ''ingredients'' that are hypothesized to be critical to achieving the relevant outcomes) and describes the theoretical and operational relationships among the key project components and relevant outcomes.

Moderate evidence (34 CFR 77.1) means that there is evidence of effectiveness of a key project component in improving a relevant outcome for a sample that overlaps with the populations or settings proposed to receive that component, based on a relevant finding from one of the following:

(i) A practice guide prepared by the WWC using version 2.1 or 3.0 of the WWC Handbook reporting a ''strong evidence base'' or ''moderate evidence base'' for the corresponding practice guide recommendation;

(ii) An intervention report prepared by the WWC using version 2.1 or 3.0 of the WWC Handbook reporting a ''positive effect'' or ''potentially positive effect'' on a relevant outcome based on a ''medium to large'' extent of evidence, with no reporting of a ''negative effect'' or ''potentially negative effect'' on a relevant outcome; or

(iii) A single experimental study or quasi-experimental design study reviewed and reported by the WWC using version 2.1 or 3.0 of the WWC Handbook, or otherwise assessed by the Department using version 3.0 of the WWC Handbook, as appropriate, and that—

(A) Meets WWC standards with or without reservations;

(B) Includes at least one statistically significant and positive (*i.e.,* favorable) effect on a relevant outcome;

(C) Includes no overriding statistically significant and negative effects on relevant outcomes reported in the study or in a corresponding WWC intervention report prepared under version 2.1 or 3.0 of the WWC Handbook; and

(D) Is based on a sample from more than one site (*e.g.,* State, county, city, school district, or postsecondary campus) and includes at least 350 students or other individuals across sites. Multiple studies of the same project component that each meet requirements in paragraphs (iii)(A), (B), and (C) of this definition may together satisfy this requirement.

Project component (34 CFR 77.1) means an activity, strategy, intervention, process, product, practice, or policy included in a project. Evidence may pertain to an individual project component or to a combination of project components (*e.g.,* training teachers on instructional practices for English learners and follow-on coaching for these teachers).

Promising evidence (34 CFR 77.1) means that there is evidence of the effectiveness of a key project component in improving a relevant outcome, based on a relevant finding from one of the following:

(i) A practice guide prepared by WWC reporting a ''strong evidence base'' or ''moderate evidence base'' for the corresponding practice guide recommendation;

(ii) An intervention report prepared by the WWC reporting a ''positive effect'' or ''potentially positive effect'' on a relevant outcome with no reporting of a ''negative effect'' or ''potentially negative effect'' on a relevant outcome; or

(iii) A single study assessed by the Department, as appropriate, that—

(A) Is an experimental study, a quasi-experimental design study, or a well-designed and well-implemented correlational study with statistical controls for selection bias (*e.g.,* a study using regression methods to account for differences between a treatment group and a comparison group); and

(B) Includes at least one statistically significant and positive (*i.e.,* favorable) effect on a relevant outcome.

Quasi-experimental design study (34 CFR 77.1) means a study using a design that attempts to approximate an experimental study by identifying a comparison group that is similar to the treatment group in important respects. This type of study, depending on design and implementation (*e.g.,* establishment of baseline equivalence of the groups being compared), can meet WWC standards with reservations, but cannot meet WWC standards without reservations, as described in the WWC Handbook.

Relevant outcome (34 CFR 77.1) means the student outcome(s) or other outcome(s) the key project component is designed to improve, consistent with the specific goals of the program.

School leader (section 8101 of the ESEA) means a principal, assistant principal, or other individual who is—

(a) An employee or officer of an elementary school or secondary school, local educational agency, or other entity operating an elementary school or secondary school; and

(b) Responsible for the daily instructional leadership and managerial operations in the elementary school or secondary school building.

Strong evidence (34 CFR 77.1) means that there is evidence of the effectiveness of a key project component in improving a relevant outcome for a sample that overlaps with the populations and settings proposed to receive that component, based on a relevant finding from one of the following:

(i) A practice guide prepared by the WWC using version 2.1 or 3.0 of the WWC Handbook reporting a ''strong evidence base'' for the corresponding practice guide recommendation;

(ii) An intervention report prepared by the WWC using version 2.1 or 3.0 of the WWC Handbook reporting a ''positive effect'' on a relevant outcome based on a ''medium to large'' extent of evidence, with no reporting of a ''negative effect'' or ''potentially negative effect'' on a relevant outcome; or

(iii) A single experimental study reviewed and reported by the WWC using version 2.1 or 3.0 of the WWC Handbook, or otherwise assessed by the Department using version 3.0 of the

WWC Handbook, as appropriate, and that—

(A) Meets WWC standards without reservations;

(B) Includes at least one statistically significant and positive (*i.e.,* favorable) effect on a relevant outcome;

(C) Includes no overriding statistically significant and negative effects on relevant outcomes reported in the study or in a corresponding WWC intervention report prepared under version 2.1 or 3.0 of the WWC Handbook; and

(D) Is based on a sample from more than one site (*e.g.,* State, county, city, school district, or postsecondary campus) and includes at least 350 students or other individuals across sites. Multiple studies of the same project component that each meet requirements in paragraphs (iii)(A), (B), and (C) of this definition may together satisfy this requirement.

What Works Clearinghouse Handbook (WWC Handbook) (34 CFR 77.1) means the standards and procedures set forth in the WWC Procedures and Standards Handbook, Version 3.0 or Version 2.1 (incorporated by reference, see 34 CFR 77.2). Study findings eligible for review under WWC standards can meet WWC standards without reservations, meet WWC standards with reservations, or not meet WWC standards. WWC practice guides and intervention reports include findings from systematic reviews of evidence as described in the Handbook documentation.

Waiver of Proposed Rulemaking: Under the Administrative Procedure Act (APA) (5 U.S.C. 553) the Department generally offers interested parties the opportunity to comment on proposed priorities and requirements. Section 681(d) of IDEA, however, makes the public comment requirements of the APA inapplicable to the priority in this notice.

Program Authority: 20 U.S.C. 1463 and 1481.

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 75, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474.

Note: The regulations in 34 CFR part 79 apply to all applicants except federally recognized Indian Tribes.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education (IHEs) only.

II. Award Information

Type of Award: Cooperative agreement.

Estimated Available Funds: $750,000.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in FY 2019 from the list of unfunded applications from this competition.

Maximum Award: We will not make an award exceeding $750,000 for a single budget period of 12 months.

Estimated Number of Awards: 1.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 60 months.

III. Eligibility Information

1. *Eligible Applicants:* SEAs; State lead agencies under Part C of the IDEA; local educational agencies (LEAs), including public charter schools that operate as LEAs under State law; IHEs; other public agencies; private nonprofit organizations; freely associated States and outlying areas; Indian Tribes or Tribal organizations; and for-profit organizations.

2. *Cost Sharing or Matching:* This program does not require cost sharing or matching.

3. *Subgrantees:* Under 34 CFR 75.708(b) and (c) a grantee under this competition may award subgrants—to directly carry out project activities described in its application—to the following types of entities: IHEs and private nonprofit organizations suitable to carry out the activities proposed in the application. The grantee may award subgrants to entities it has identified in an approved application.

4. *Other General Requirements:* (a) Recipients of funding under this competition must make positive efforts to employ and advance in employment qualified individuals with disabilities (see section 606 of IDEA).

(b) Applicants for, and recipients of, funding must, with respect to the aspects of their proposed project relating to the absolute priority, involve individuals with disabilities, or parents of individuals with disabilities ages birth through 26, in planning, implementing, and evaluating the project (see section 682(a)(1)(A) of IDEA).

IV. Application and Submission Information

1. *Application Submission Instructions:* For information on how to submit an application please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 12, 2018 (83 FR 6003) and available at *www.gpo.gov/fdsys/pkg/FR-2018-02-12/pdf/2018-02558.pdf.*

2. *Intergovernmental Review:* This competition is subject to Executive Order 12372 and the regulations in 34 CFR part 79. However, under 34 CFR 79.8(a), we waive intergovernmental review in order to make an award by the end of FY 2018.

3. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

4. *Recommended Page Limit:* The application narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. We recommend that you (1) limit the application narrative to no more than 70 pages, and (2) use the following standards:

- A ''page'' is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double-space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, reference citations, and captions, as well as all text in charts, tables, figures, graphs, and screen shots.
- Use a font that is 12 point or larger.
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial.

The recommended page limit does not apply to Part I, the cover sheet; Part II, the budget section, including the narrative budget justification; Part IV, the assurances and certifications; or the abstract (follow the guidance provided in the application package for completing the abstract), the table of contents, the list of priority requirements, the resumes, the reference list, the letters of support, or the appendices. However, the recommended page limit does apply to all of the application narrative, including all text in charts, tables, figures, graphs, and screen shots.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this competition are from 34 CFR 75.210 and are listed below:

(a) *Significance (10 points).*

(1) The Secretary considers the significance of the proposed project.

(2) In determining the significance of the proposed project, the Secretary considers the following factors:

(i) The extent to which specific gaps or weaknesses in services, infrastructure, or opportunities have been identified and will be addressed by the proposed project, including the nature and magnitude of those gaps or weaknesses.

(ii) The importance or magnitude of the results or outcomes likely to be attained by the proposed project.

(b) *Quality of project services (35 points).*

(1) The Secretary considers the quality of the services to be provided by the proposed project.

(2) In determining the quality of the services to be provided by the proposed project, the Secretary considers the quality and sufficiency of strategies for ensuring equal access and treatment for eligible project participants who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability.

(3) In addition, the Secretary considers the following factors:

(i) The extent to which the goals, objectives, and outcomes to be achieved by the proposed project are clearly specified and measurable.

(ii) The extent to which there is a conceptual framework underlying the proposed research or demonstration activities and the quality of that framework.

(iii) The extent to which the services to be provided by the proposed project reflect up-to-date knowledge from research and effective practice.

(iv) The extent to which the training or professional development services to be provided by the proposed project are of sufficient quality, intensity, and duration to lead to improvements in practice among the recipients of those services.

(v) The extent to which the technical assistance services to be provided by the proposed project involve the use of efficient strategies, including the use of technology, as appropriate, and the leveraging of non-project resources.

(c) *Quality of the project evaluation (20 points).*

(1) The Secretary considers the quality of the evaluation to be conducted of the proposed project.

(2) In determining the quality of the evaluation, the Secretary considers the following factors:

(i) The extent to which the methods of evaluation are thorough, feasible, and appropriate to the goals, objectives, and outcomes of the proposed project.

(ii) The extent to which the methods of evaluation provide for examining the effectiveness of project implementation strategies.

(iii) The extent to which the methods of evaluation will provide performance feedback and permit periodic assessment of progress toward achieving intended outcomes.

(iv) The extent to which the methods of evaluation include the use of objective performance measures that are clearly related to the intended outcomes of the project and will produce quantitative and qualitative data to the extent possible.

(d) *Adequacy of resources and quality of project personnel (15 points).*

(1) The Secretary considers the adequacy of resources for the proposed project and the quality of the personnel who will carry out the proposed project.

(2) In determining the quality of project personnel, the Secretary considers the extent to which the applicant encourages applications for employment from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability.

(3) In addition, the Secretary considers the following factors:

(i) The qualifications, including relevant training and experience, of the project director or principal investigator.

(ii) The qualifications, including relevant training and experience, of key project personnel.

(iii) The qualifications, including relevant training and experience, of project consultants or subcontractors.

(iv) The qualifications, including relevant training, experience, and independence, of the evaluator.

(v) The adequacy of support, including facilities, equipment, supplies, and other resources, from the applicant organization or the lead applicant organization.

(vi) The relevance and demonstrated commitment of each partner in the proposed project to the implementation and success of the project.

(vii) The extent to which the budget is adequate to support the proposed project.

(viii) The extent to which the costs are reasonable in relation to the objectives, design, and potential significance of the proposed project.

(e) *Quality of the management plan (20 points).*

(1) The Secretary considers the quality of the management plan for the proposed project.

(2) In determining the quality of the management plan for the proposed project, the Secretary considers the following factors:

(i) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks.

(ii) The extent to which the time commitments of the project director and principal investigator and other key project personnel are appropriate and adequate to meet the objectives of the proposed project.

(iii) The adequacy of mechanisms for ensuring high-quality products and services from the proposed project.

(iv) How the applicant will ensure that a diversity of perspectives are brought to bear in the operation of the proposed project, including those of parents, teachers, the business community, a variety of disciplinary and professional fields, recipients or beneficiaries of services, or others, as appropriate.

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department of Education (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Additional Review and Selection Process Factors:* In the past, the Department has had difficulty finding peer reviewers for certain competitions because so many individuals who are eligible to serve as peer reviewers have conflicts of interest. The standing panel requirements under section 682(b) of IDEA also have placed additional constraints on the availability of reviewers. Therefore, the Department has determined that for some discretionary grant competitions, applications may be separated into two or more groups and ranked and selected for funding within specific groups. This procedure will make it easier for the Department to find peer reviewers by ensuring that greater numbers of individuals who are eligible to serve as reviewers for any particular group of applicants will not have conflicts of

interest. It also will increase the quality, independence, and fairness of the review process, while permitting panel members to review applications under discretionary grant competitions for which they also have submitted applications.

4. *Risk Assessment and Specific Conditions:* Consistent with 2 CFR 200.205, before awarding grants under this competition the Department conducts a review of the risks posed by applicants. Under 2 CFR 3474.10, the Secretary may impose specific conditions and, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

5. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently $150,000), under 2 CFR 200.205(a)(2) we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through the System for Award Management. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds $10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Open Licensing Requirements:* Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department grant funds. When the deliverable consists of modifications to pre-existing works, the license extends only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. Additionally, a grantee or subgrantee that is awarded competitive grant funds must have a plan to disseminate these public grant deliverables. This dissemination plan can be developed and submitted after your application has been reviewed and selected for funding. For additional information on the open licensing requirements please refer to 2 CFR 3474.20.

4. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

5. *Performance Measures:* Under the Government Performance and Results Act of 1993, the Department has established a set of performance measures, including long-term measures, that are designed to yield information on various aspects of the effectiveness and quality of the Technical Assistance and Dissemination to Improve Services and Results for Children With Disabilities program. These measures are:

- Program Performance Measure #1: The percentage of Technical Assistance and Dissemination products and services deemed to be of high quality by an independent review panel of experts qualified to review the substantive content of the products and services.
- Program Performance Measure #2: The percentage of Special Education Technical Assistance and Dissemination products and services deemed by an independent review panel of qualified experts to be of high relevance to educational and early intervention policy or practice.
- Program Performance Measure #3: The percentage of all Special Education Technical Assistance and Dissemination products and services deemed by an independent review panel of qualified experts to be useful in improving educational or early intervention policy or practice.
- Program Performance Measure #4: The cost efficiency of the Technical Assistance and Dissemination Program includes the percentage of milestones achieved in the current annual performance report period and the percentage of funds spent during the current fiscal year.
- Long-term Program Performance Measure: The percentage of States receiving Special Education Technical Assistance and Dissemination services regarding scientifically or evidence-based practices for infants, toddlers, children, and youth with disabilities that successfully promote the implementation of those practices in school districts and service agencies.

The measures apply to projects funded under this competition, and grantees are required to submit data on these measures as directed by OSEP.

Grantees will be required to report information on their project's performance in annual and final performance reports to the Department (34 CFR 75.590).

6. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and,

if the Secretary has established performance measurement requirements, the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Other Information

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) by contacting the Management Support Services Team, U.S. Department of Education, 400 Maryland Avenue SW, room 5113, Potomac Center Plaza, Washington, DC 20202–2500. Telephone: (202) 245–7363. If you use a TDD or a TTY, call the FRS, toll free, at 1–800–877–8339.

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You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: July 26, 2018.

Johnny W. Collett,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 2018–16382 Filed 7–30–18; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

[OE Docket No. EA–458]

Application to Export Electric Energy; Sempra Gas & Power Marketing, LLC

AGENCY: Office of Electricity, DOE.

ACTION: Notice of application.

SUMMARY: Sempra Gas & Power Marketing, LLC (Applicant) has applied for authority 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 August 30, 2018.

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: Exports of electricity from the United States to a foreign country are regulated by the United States Department of Energy (DOE) pursuant to sections 301(b) and 402(f) of the Department of Energy Organization Act (42 U.S.C. 7151(b) and 7172(f)) and require authorization under section 202(e) of the Federal Power Act (16 U.S.C. 824a(e)).

On July 23, 2018, DOE received an application from the Applicant for authority to transmit electric energy from the United States to Mexico as a power marketer for a five-year term using existing international transmission facilities.

In its application, the Applicant states that it does not own or control any electric generation or transmission facilities, and it does not have a franchised service area. The electric energy that the Applicant proposes to export to Mexico would be surplus energy purchased from third parties such as electric utilities and Federal power marketing agencies pursuant to voluntary agreements. 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's) Rules of Practice and Procedure (18 CFR 385.211). Any person desiring to become a party to these proceedings 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 Applicant's application to export electric energy to Mexico should be clearly marked with OE Docket No. EA–458. An additional copy is to be provided to both Daniel A. King, Sempra Infrastructure, LLC, 488 8th Avenue, HQ12, San Diego, CA 92101 and Kevin Ding, Sempra Infrastructure, LLC, 488 8th Avenue, HQ11, San Diego, CA 92101.

A final decision will be made on this application after the environmental impacts have been evaluated pursuant to DOE's National Environmental Policy Act Implementing Procedures (10 CFR part 1021) and after a determination is made by DOE 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 this 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 July 24, 2018.

Christopher Lawrence,

Electricity Policy Analyst, Office of Electricity.

[FR Doc. 2018–16349 Filed 7–30–18; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL18–188–000]

NRG Curtailment Solutions, Inc. v. New York Independent System Operator; Notice of Complaint

Take notice that on July 24, 2018, pursuant to sections 206 and 306 of the Federal Power Act, 16 U.S.C. 824e and 825e and Rule 206 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.206, NRG Curtailment Solutions, Inc. (Complainant) filed a formal complaint against New York Independent System Operator (Respondent) alleging that, Respondent's rules that Curtailment Service Providers and Responsible Interface Parties must be certified by the New York Department of Public Service is unjust and unreasonable, all as more fully explained in the complaint.

The Complainant certifies that copies of the complaint were served on the contacts for the Respondent as listed on the Commission's list of Corporate Officials.

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. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainants.

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 electronic 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 August 13, 2018.

Dated: July 25, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–16357 Filed 7–30–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP18–982–001.

Applicants: Eastern Shore Natural Gas Company.

Description: Tariff Amendment: Amended Negotiated Rate and Non-Conforming Agreements to be effective 7/20/2018.

Filed Date: 7/23/18.

Accession Number: 20180723–5196.

Comments Due: 5 p.m. ET 8/6/18.

Docket Numbers: RP18–989–001.

Applicants: Transcontinental Gas Pipe Line Company, LLC.

Description: Tariff Amendment: Atlantic Sunrise Tariff Rate Filing—Amendment to be effective 8/20/2018.

Filed Date: 7/23/18.

Accession Number: 20180723–5211.

Comments Due: 5 p.m. ET 8/6/18.

Docket Numbers: RP18–991–000.

Applicants: Texas Eastern Transmission, LP.

Description: § 4(d) Rate Filing: GT&C Section 3.13 Jul 2018 Cleanup Filing to be effective 8/23/2018.

Filed Date: 7/23/18.

Accession Number: 20180723–5072.

Comments Due: 5 p.m. ET 8/6/18.

Docket Numbers: RP18–992–000.

Applicants: Dauphin Island Gathering Partners.

Description: 2018 Cash Out Report of Dauphin Island Gathering Partners.

Filed Date: 7/23/18.

Accession Number: 20180723–5115.

Comments Due: 5 p.m. ET 8/6/18.

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: July 25, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–16356 Filed 7–30–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

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

Docket Numbers: ER10–2895–017; ER10–2917–017; ER10–2918–018; ER10–2920–017; ER10–2921–017; ER10–2922–017; ER10–2966–017; ER10–3167–009; ER11–2292–018; ER11–2293–018; ER11–2294–016; ER11–2383–012; ER11–3941–015; ER11–3942–017; ER12–2447–016; ER13–1613–010; ER13–203–009; ER13–2143–010; ER14–1964–008; ER16–287–003; ER17–482–002; ER11–3417–013; ER10–2460–014; ER10–2461–015; ER10–2463–014; ER10–2466–015; ER10–2895–018; ER10–2917–018; ER10–2918–019; ER10–2920–018; ER10–2921–018; ER10–2922–018; ER10–2966–018; ER10–3167–010; ER10–3178–010; ER11–2201–018; ER11–2292–019; ER11–2293–019; ER11–2294–017; ER11–2383–013; ER11–3941–016; ER11–3942–018; ER11–4029–014; ER12–1311–014; ER12–161–018; ER12–2068–014; ER12–2447–017; ER12–645–019; ER12–682–015; ER13–1139–017; ER13–1346–009; ER13–1613–011; ER13–17–012; ER13–203–010; ER13–2143–011; ER14–1964–009; ER14–25–014; ER14–2630–010; ER16–287–004; ER17–482–003.

Applicants: Bear Swamp Power Company LLC, BIF II Safe Harbor Holdings LLC, BIF III Holtwood LLC, Black Bear Development Holdings, LLC, Black Bear Hydro Partners, LLC, Black Bear SO, LLC, BREG Aggregator LLC, Brookfield Energy Marketing Inc., Brookfield Energy Marketing LP, Brookfield Energy Marketing US LLC, Brookfield Power Piney & Deep Creek LLC, Brookfield Renewable Energy Marketing US LLC, Brookfield Smoky Mountain Hydropower LLC, Brookfield White Pine Hydro LLC, Carr Street Generating Station, L.P., Erie Boulevard Hydropower, L.P., Granite Reliable Power, LLC, Great Lakes Hydro America, LLC, Hawks Nest Hydro LLC, Rumford Falls Hydro LLC, Safe Harbor Water Power Corporation, Alta Wind VIII, LLC, Bear Swamp Power Company LLC, BIF II Safe Harbor Holdings LLC, BIF III Holtwood LLC, Black Bear Development Holdings, LLC, Black Bear Hydro Partners, LLC, Black Bear SO, LLC, BREG Aggregator LLC, Brookfield Energy Marketing Inc., Brookfield Energy Marketing LP, Brookfield Energy Marketing US LLC, Brookfield Power Piney & Deep Creek LLC, Brookfield

Renewable Energy Marketing US, LLC, Brookfield Smoky Mountain Hydropower LLC, Brookfield White Pine Hydro LLC, Carr Street Generating Station, L.P., Erie Boulevard Hydropower, L.P., Granite Reliable Power, LLC, Great Lakes Hydro America, LLC, Hawks Nest Hydro LLC, Mesa Wind Power Corporation, Rumford Falls Hydro LLC, Safe Harbor Water Power Corporation, Windstar Energy, LLC, Bishop Hill Energy LLC, Blue Sky East, LLC, California Ridge Wind Energy LLC, Canandaigua Power Partners, LLC, Canandaigua Power Partners II, LLC, Erie Wind, LLC, Evergreen Wind Power, LLC, Evergreen Wind Power III, LLC, Imperial Valley Solar 1, LLC, Niagara Wind Power, LLC, Prairie Breeze Wind Energy LLC, Regulus Solar, LLC, Stetson Holdings, LLC, Stetson Wind II, LLC, Vermont Wind, LLC.

Description: Supplement to the February 20, 2018 Supplement to Updated Market Power Analysis, et al. for the Northeast Region of the Brookfield Companies, et al.

Filed Date: 7/24/18.

Accession Number: 20180724–5180.

Comments Due: 5 p.m. ET 8/14/18.

Docket Numbers: ER18–1947–001.

Applicants: Alabama Power Company.

Description: Tariff Amendment: Amendment to Southern Company System IIC Amendment Filing to be effective 12/31/9998.

Filed Date: 7/24/18.

Accession Number: 20180724–5139.

Comments Due: 5 p.m. ET 8/14/18.

Docket Numbers: ER18–1948–001.

Applicants: Georgia Power Company.

Description: Tariff Amendment: Amendment of Southern Company System IIC Amendment Filing to be effective 12/31/9998.

Filed Date: 7/24/18.

Accession Number: 20180724–5140.

Comments Due: 5 p.m. ET 8/14/18.

Docket Numbers: ER18–1949–001.

Applicants: Gulf Power Company.

Description: Tariff Amendment: Amendment of Southern Company System IIC Amendment Filing to be effective 12/31/9998.

Filed Date: 7/24/18.

Accession Number: 20180724–5144.

Comments Due: 5 p.m. ET 8/14/18.

Docket Numbers: ER18–1950–001.

Applicants: Mississippi Power Company.

Description: Tariff Amendment: Amendment of Southern Company System IIC Amendment Filing to be effective 12/31/9998.

Filed Date: 7/24/18.

Accession Number: 20180724–5145.

Comments Due: 5 p.m. ET 8/14/18.

Docket Numbers: ER18–1951–001.

Applicants: Southern Power Company.

Description: Tariff Amendment: Amendment of Southern Company System IIC Amendment Filing to be effective 12/31/9998.

Filed Date: 7/24/18.

Accession Number: 20180724–5146.

Comments Due: 5 p.m. ET 8/14/18.

Docket Numbers: ER18–2060–000.

Applicants: American Transmission Systems, Incorporated, PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: ATSI submits ECSAs, Service Agreement Nos. 4890, 4891, 4938, 4939, 4964 et al. to be effective 9/30/2018.

Filed Date: 7/25/18.

Accession Number: 20180725–5027.

Comments Due: 5 p.m. ET 8/15/18.

Docket Numbers: ER18–2061–000.

Applicants: NorthWestern Corporation.

Description: Initial rate filing: RS 324—Interface Capacity Settlement Agreement with BPA to be effective 9/24/2018.

Filed Date: 7/25/18.

Accession Number: 20180725–5037.

Comments Due: 5 p.m. ET 8/15/18.

Docket Numbers: ER18–2062–000.

Applicants: West Penn Power Company, PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: West Penn Power Company submits Amended IA SA No. 3999 to be effective 10/1/2018.

Filed Date: 7/25/18.

Accession Number: 20180725–5110.

Comments Due: 5 p.m. ET 8/15/18.

Docket Numbers: ER18–2063–000.

Applicants: Flemington Solar, LLC.

Description: Baseline eTariff Filing: Reactive Power Rate Filing of Flemington Solar, LLC to be effective 10/1/2018.

Filed Date: 7/25/18.

Accession Number: 20180725–5116.

Comments Due: 5 p.m. ET 8/15/18.

Docket Numbers: ER18–2064–000.

Applicants: Uniper Global Commodities North America LLC.

Description: § 205(d) Rate Filing: UGCNA MBR Tariff Update Change in Status 2018.07.25 to be effective 9/24/2018.

Filed Date: 7/25/18.

Accession Number: 20180725–5138.

Comments Due: 5 p.m. ET 8/15/18.

Docket Numbers: ER18–2065–000.

Applicants: Mid-Atlantic Interstate Transmission, LLC, PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: MAIT submits IA SA Nos. 3996 and 4577 to be effective 10/1/2018.

Filed Date: 7/25/18.

Accession Number: 20180725–5193.

Comments Due: 5 p.m. ET 8/15/18.

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: July 25, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–16355 Filed 7–30–18; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2017–0692; FRL–9980–29]

Agency Information Collection Activities; Proposed Renewal of an Existing Collection (EPA ICR No. 2507.02); Comment Request

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA), this document announces that EPA is planning to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB). The ICR, entitled: ''Lead Training, Certification, Accreditation and Authorization Activities'' and identified by EPA ICR No. 2507.02 and OMB Control No. 2070–0195, represents the renewal of an existing ICR that is scheduled to expire on January 31, 2019. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection that is summarized in this document. The ICR and accompanying material are available in the docket for public review and comment.

DATES: Comments must be received on or before October 1, 2018.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2017–0692, 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:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 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 technical information contact: John Yowell, National Program Chemicals Division, (7404T), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–1213; email address: *yowell.john@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. What information is EPA particularly interested in?

Pursuant to PRA section 3506(c)(2)(A) (44 U.S.C. 3506(c)(2)(A)), EPA specifically solicits comments and information to enable it to:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility.

2. Evaluate the accuracy of the Agency's estimates of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.

3. Enhance the quality, utility, and clarity of the information to be collected.

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

II. What information collection activity or ICR does this action apply to?

Title: Information Collection for Lead Training, Certification, Accreditation, and Authorization Activities (Lead-Based Paint Activities Rule and Renovation, Repair, and Painting Rule).

ICR number: EPA ICR No. 2507.02.

OMB control number: OMB Control No. 2070–0195.

ICR status: This ICR is currently scheduled to expire on January 31, 2019. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the Code of Federal Regulations (CFR), after appearing in the **Federal Register** when approved, are listed in 40 CFR part 9, are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers for certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: This information collection involves third-party notification, required under section 406(b) of the Toxic Substances Control Act (TSCA), to owners and occupants of housing that will inform such individuals about the dangers of lead-contaminated dust and lead-based paint debris that are sometimes generated during renovations of housing where lead-based paint is present, thereby aiding them in avoiding potentially hazardous exposures and protecting public health. Since young children are especially susceptible to the hazards of lead, owners and occupants with children can take action to protect their children from lead poisonings. Section 406(b) of TSCA requires EPA to promulgate regulations requiring certain persons who perform renovations for compensation on target housing to provide a lead hazard information pamphlet (developed under TSCA section 406(a)) to the owner and occupants of such housing prior to beginning the renovation. Further, the firm performing the renovation must keep records acknowledging receipt of the pamphlet on file for three years after completion of work. Those who fail to provide the pamphlet or keep records as required may be subject to both civil and criminal sanctions.

This information collection also addresses the reporting and recordkeeping requirements for individuals or firms conducting lead-based paint activities or renovation in or on houses, apartments, or child-occupied facilities built before 1978, under the authority of sections 402 and 404 of TSCA. These sections and their implementing regulations require EPA to develop and administer a training and certification program as well as work practice standards for persons who perform lead-based paint activities and/or renovations. 40 CFR part 745, subpart E, covers work practice standards, recordkeeping and reporting requirements, individual and firm certification, and enforcement for renovations done in target housing or child-occupied facilities. 40 CFR part 745, subpart L, covers inspections, lead hazard screens, risk assessments, and abatement activities (referred to as ''lead-based paint activities'') done in target housing and child-occupied facilities. 40 CFR part 745, subpart Q, establishes the requirements that state or tribal programs must meet for authorization to administer the standards, regulations, or other requirements established under TSCA Section 402. Section 401 of TSCA defines target housing as any housing constructed prior to 1978, except housing for the elderly or persons with disabilities or any 0-bedroom dwelling (unless any child who is less than 6 years of age resides or is expected to reside in such housing).

Responses to the collection of information are mandatory (see 40 CFR part 745). Respondents may claim all or part of a document confidential. EPA will disclose information that is covered by a claim of confidentiality only to the extent permitted by, and in accordance with, the procedures in TSCA section 14 and 40 CFR part 2.

Burden statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 0.2 hours per response. Burden is defined in 5 CFR 1320.3(b).

The ICR, which is available in the docket along with other related materials, provides a detailed explanation of the collection activities and the burden estimate that is only briefly summarized here:

Respondents/Affected Entities: Entities potentially affected by this ICR

include persons who are engaged in lead-based paint activities and/or perform renovations of target housing or child-occupied facilities for compensation, dust sampling, or dust testing; or who perform lead-based paint inspections, lead hazard screens, risk assessments or abatements in target housing or child-occupied facilities; or who provide training or operate a training program for individuals who perform any of these activities; or state, territorial or tribal agencies that administer lead-based paint activities and/or renovation programs.

Estimated total number of potential respondents: 770,564.

Frequency of response: On occasion.

Estimated total average number of responses for each respondent: 30.3.

Estimated total annual burden hours: 5,251,320 hours.

Estimated total annual costs: $303,099,637. This includes an estimated burden cost of $303,099,637 and an estimated cost of $0 for capital investment or maintenance and operational costs.

III. Are there changes in the estimates from the last approval?

There is a decrease of 1,211,977 hours in the total estimated respondent burden compared with that identified in the ICR currently approved by OMB. This decrease reflects adjustments in EPA's estimates of the burden. The ICR supporting statement provides a detailed analysis of the change in burden estimate. This change is an adjustment.

IV. What is the next step in the process for this ICR?

EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval pursuant to 5 CFR 1320.12. EPA will issue another **Federal Register** document pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB. If you have any questions about this ICR or the approval process, please contact the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: July 16, 2018.

Charlotte Bertrand,

Acting Principal Deputy Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2018–16370 Filed 7–30–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2017–0648; FRL–9980–28]

Agency Information Collection Activities; Proposed Renewal of an Existing Collection (EPA ICR No. 1884.10); Comment Request

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA), this document announces that EPA is planning to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB). The ICR, entitled: ''Partial Update of the TSCA Section 8(b) Inventory Data Base, Production and Site Reports (Chemical Data Reporting)'' and identified by EPA ICR No. 1884.10 and OMB Control No. 2070–0162, represents the renewal of an existing ICR that is scheduled to expire on October 31, 2018. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection that is summarized in this document. The ICR and accompanying material are available in the docket for public review and comment.

DATES: Comments must be received on or before October 1, 2018.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2017–0648, 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:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 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 technical information contact: Meredith Comnes, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–3193; email address: *comnes.meredith@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. What information is EPA particularly interested in?

Pursuant to PRA section 3506(c)(2)(A) (44 U.S.C. 3506(c)(2)(A)), EPA specifically solicits comments and information to enable it to:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility.

2. Evaluate the accuracy of the Agency's estimates of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.

3. Enhance the quality, utility, and clarity of the information to be collected.

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

II. What information collection activity or ICR does this action apply to?

Title: Partial Update of the TSCA Section 8(b) Inventory Data Base, Production and Site Reports (Chemical Data Reporting).

ICR number: EPA ICR No. 1884.10.

OMB control number: OMB Control No. 2070–0162.

ICR status: This ICR is currently scheduled to expire on October 31, 2018. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the Code of Federal Regulations

(CFR), after appearing in the **Federal Register** when approved, are listed in 40 CFR part 9, are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers for certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: The Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, requires EPA to compile and keep current a complete list of chemical substances manufactured (including imported) or processed in the United States. EPA updates this inventory of chemicals every four years by requiring manufacturers, including importers, to provide production volume, plant site information and other chemical manufacturing, processing, and use information. Through the CDR regulation, EPA collects basic exposure-related manufacturing, processing, and use information used by the Agency and others in a wide range of activities This information allows EPA to identify what chemicals are currently in commerce and to take appropriate regulatory action as necessary. The information collected enables EPA to better understand and interpret the state of U.S. chemical manufacturing, processing, and use, and further enhances EPA's ability to identify, evaluate, and manage potential chemical risks. This ICR addresses the collection of inventory-related information.

Responses to the collection of required information are mandatory (see 40 CFR part 710). Respondents may claim all or part of a notice confidential. EPA will disclose information that is covered by a claim of confidentiality only to the extent permitted by, and in accordance with, the procedures described in TSCA section 14 and 40 CFR part 2.

Burden statement: The annual per-response public reporting and recordkeeping burden for this collection of information is estimated to average 126.44 hours per year for the average multi-chemical submission of 7.5 chemicals per site with 22% of reports consisting of partial reports. Additionally, for CDX electronic reporting activities, the average per response burden is estimated at .53 hours per registration for those respondents not already registered in CDX. Burden is defined in 5 CFR 1320.3(b).

The ICR Supporting Statement, which is available in the docket along with other related materials, provides a detailed explanation of the collection activities and the burden estimate that is only briefly summarized here:

Respondents/Affected Entities: Entities potentially affected by this ICR are companies that manufacture (including import) or process chemical substances, mixtures or categories into the United States.

Estimated total number of potential respondents: 5,662.

Frequency of response: Every four years (estimates below are on an annual basis).

Estimated total average number of responses for each respondent: 1.

Estimated total annual burden hours: 716,024 hours.

Estimated total annual costs: $56,959,323. This includes an estimated burden cost of $59,959,323 and an estimated cost of $0 for capital investment or maintenance and operational costs.

III. Are there changes in the estimates from the last approval?

There is a decrease of 73,179 hours in the total estimated respondent burden compared with that identified in the ICR currently approved by OMB. This decrease reflects a combination of program changes and adjustments. Program changes involving updated CBI substantiation requirements as a result of the Lautenberg Act are estimated at 4,877 hours. Agency adjustments include changes due to methodology corrections at—184,158 hours, and changes due to increased counts of sites at 106,102 hours. The ICR supporting statement provides a detailed analysis of the change in burden estimate. This change is an adjustment and the result of a program change.

IV. What is the next step in the process for this ICR?

EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval pursuant to 5 CFR 1320.12. EPA will issue another **Federal Register** document pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB. If you have any questions about this ICR or the approval process, please contact the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: July 16, 2018.

Charlotte Bertrand,

Acting Principal Deputy Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2018–16369 Filed 7–30–18; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0952]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before October 1, 2018. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *Nicole.Ongele@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele at (202) 418–2991.

SUPPLEMENTARY INFORMATION: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

OMB Control Number: 3060–0952.

Title: Proposed Demographic Information and Notifications, Second Further Notice of Proposed Rulemaking (FNPRM), CC Docket No. 98–147 and Fifth NPRM (NPRM), CC Docket No. 96–98.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 750 respondents; 1,500 responses.

Frequency of Response: On occasion reporting requirements and third-party disclosure requirement.

Estimated Time per Response: 2 hours.

Total Annual Burden: 3,000 hours.

Total Annual Cost: No cost.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 151–154, 201, 202, 251–254, 256, 271, and 303(r) of the Communications Act of 1934, as amended.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: The Commission is not requesting respondents to submit confidential information to the FCC. If the applicants wish to submit information which they believe is confidential, they may request confidential treatment of such information under 47 CFR 0.459 of the Commission's rules.

Needs and Uses: The Commission asked whether physical collocation in remote terminals presents technical or security concerns, and if so, whether these concerns warrant modification of its collocation rules. The Commission asked whether incumbent LECs should be required to provide requesting carriers with demographic and other information regarding particular remote terminals similar to the information available regarding incumbent LEC central offices. Requesting carriers use demographic and other information obtained from incumbent LECs to determine whether they wish to collocate at particular remote terminals. This proposed information collection in the Second Further Notice of Proposed Rulemaking, FCC 98–147, will be used by the Commission, state commissions, and competitive carriers to facilitate the deployment of advanced services and other telecommunications services in implementation of section 251(c)(6) of the Communications Act of 1934, as amended. The number of respondents, annual responses, and annual burden has not changed.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2018–16301 Filed 7–30–18; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0741]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before October 1, 2018. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *Nicole.Ongele@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele at (202) 418–2991.

SUPPLEMENTARY INFORMATION: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

OMB Control Number: 3060–0741.

Title: Accelerating Wireline Broadband Deployment by Removing Barriers to Infrastructure Investment, GN Docket No. 17–84.

Form Number(s): N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 5,357 respondents; 573,928 responses.

Estimated Time per Response: 0.5–4.5 hours.

Frequency of Response: On occasion reporting requirements; recordkeeping and third-party disclosure requirements.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 222 and 251.

Total Annual Burden: 575,448 hours.

Total Annual Cost: No cost.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: The Commission is not requesting that the respondents submit confidential information to the FCC. Respondents may, however, request confidential treatment for information they believe to be confidential under 47 CFR 0.459 of the Commission's rules.

Needs and Uses: Section 251 of the Communications Act of 1934, as amended, 47 U.S.C. 251, is designed to accelerate private sector development and deployment of telecommunications technologies and services by spurring competition. Section 222(e) is also designed to spur competition by prescribing requirements for the sharing of subscriber list information. These information collection requirements are designed to help implement certain provisions of sections 222(e) and 251, and to eliminate operational barriers to competition in the telecommunications services market. Specifically, these information collection requirements will be used to implement (1) local exchange carriers' (''LECs'') obligations to provide their competitors with dialing parity and non-discriminatory access to certain services and functionalities; (2) incumbent local exchange carriers' (''ILECs'') duty to make network information disclosures; and (3) numbering administration. The revisions to this collection relate to changes in one of many components of the currently approved collection—specifically, certain reporting, recordkeeping and/or third-party disclosure requirements under section 251(c)(5). In November 2017, the Commission adopted new rules concerning certain information collection requirements implemented under section 251(c)(5) of the Act, pertaining to network change disclosures. Most of the changes to those rules applied specifically to a certain subset of network change disclosures, namely notices of planned copper retirements. In addition, the changes removed a rule that prohibits incumbent LECs from engaging in useful advanced coordination with entities affected by network changes. In June 2018, the Commission revised its network change disclosure rules to (1) revise the types of network changes that trigger an incumbent LEC's public notice obligation, and (2) extend the *force majeure* provisions applicable to copper retirements to all types of network changes. The changes are aimed at removing unnecessary regulatory barriers to the deployment of high-speed broadband networks. The Commission estimates that these revisions do not result in any change to the total annual burden hours or any additional outlays of funds for hiring outside contractors or procuring equipment as the changes eliminate notices that are subsumed by notice obligations that remain in force or simply codify procedures available to a small number of incumbent LECs by waiver orders.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2018–16300 Filed 7–30–18; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL HOUSING FINANCE AGENCY

[No. 2018–N–08]

Proposed Collection; Comment Request

AGENCY: Federal Housing Finance Agency.

ACTION: 30-Day notice of submission of information collection for approval from Office of Management and Budget.

SUMMARY: In accordance with the requirements of the Paperwork Reduction Act of 1995 (PRA), the Federal Housing Finance Agency (FHFA or the Agency) is seeking public comments concerning an information collection known as ''Minimum Requirements for Appraisal Management Companies,'' which has been assigned control number 2590–0013 by the Office of Management and Budget (OMB). FHFA intends to submit the information collection to OMB for review and approval of a three-year extension of the control number, which is due to expire on July 31, 2018.

DATES: Interested persons may submit comments on or before August 30, 2018.

ADDRESSES: Submit comments to the Office of Information and Regulatory Affairs of the Office of Management and Budget, Attention: Desk Officer for the Federal Housing Finance Agency, Washington, DC 20503, Fax: (202) 395–3047, Email: *OIRA_submission@omb.eop.gov.* Please also submit comments to FHFA, identified by ''Proposed Collection; Comment Request: 'Minimum Requirements for Appraisal Management Companies, (No. 2018–N–08)''' by any of the following methods:

- *Agency Website: www.fhfa.gov/open-for-comment-or-input.*
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. If you submit your comment to the *Federal eRulemaking Portal,* please also send it by *email* to FHFA at *RegComments@fhfa.gov* to ensure timely receipt by the Agency.
- *Mail/Hand Delivery:* Federal Housing Finance Agency, Eighth Floor, 400 Seventh Street SW, Washington, DC 20219, ATTENTION: Proposed Collection; Comment Request: ''Minimum Requirements for Appraisal Management Companies, (No. 2018–N–08).''

We will post all public comments we receive without change, including any personal information you provide, such as your name and address, email address, and telephone number, on the FHFA website at *http://www.fhfa.gov.* In addition, copies of all comments received will be available for examination by the public through the electronic comment docket for this PRA Notice also located on the FHFA website.

FOR FURTHER INFORMATION CONTACT: Robert Witt. Senior Policy Analyst, Office of Housing and Regulatory Policy, by email at *Robert.Witt@fhfa.gov* or by telephone at (202) 649–3128; or Eric Raudenbush, Associate General Counsel, *Eric.Raudenbush@fhfa.gov,* (202) 649–3084 (these are not toll-free numbers); Federal Housing Finance Agency, 400 Seventh Street SW, Washington, DC 20219. The Telecommunications Device for the Hearing Impaired is (800) 877–8339.

SUPPLEMENTARY INFORMATION: FHFA is seeking comments on its upcoming request to OMB to renew the PRA clearance for the following collection of information:

Title: Minimum requirements for appraisal management companies.

OMB Number: 2590–0013.

Affected Public: Participating States and State-registered Appraisal Management Companies.

A. Need for and Use of the Information Collection

In 2015, the Federal Deposit Insurance Corporation (FDIC), the Office of the Comptroller of the Currency (OCC), the Board of Governors of the Federal Reserve System (Board), the Bureau of Consumer Financial Protection (Bureau), and FHFA (collectively, the Agencies) jointly issued regulations [1] to implement provisions of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act) relating to the eligibility of appraisal management companies (AMCs) to provide appraisal management services for real estate related financial transactions that are engaged in, contracted for, or regulated by a ''federal financial institutions regulatory agency'' or the Resolution Trust Corporation (''Federally related transactions'').[2] Generally, these statutory provisions provide that an AMC either be registered with a state's appraiser certifying and licensing agency or be subject to oversight by a federal financial institutions regulatory agency in order to participate in a Federally related transaction.[3]

As required by the Dodd-Frank Act provisions, the Agencies' joint AMC regulations establish minimum requirements for the registration and supervision of AMCs to be applied by states that have elected to establish an appraiser certifying and licensing agency with authority to register and supervise AMCs (participating states).[4] The joint regulations also implement the statutory requirement that states report to the Appraisal Subcommittee (ASC) of the Federal Financial Institutions Examination Council (FFIEC) the information required by the ASC to administer a national registry of AMCs (AMC National Registry or Registry).[5] When fully established, the AMC National Registry will include AMCs that are either: (1) Subsidiaries owned and controlled by an insured depository institution (as defined in 12 U.S.C. 1813) and regulated by either the FDIC, OCC, or Board (federally regulated AMCs) ;[6] or (2) registered with, and subject to supervision of, a state appraiser certifying and licensing agency. FHFA's AMC regulation, located at Subpart B of 12 CFR part 1222, is substantively identical to the AMC regulations of the FDIC, OCC, and Board and contains the recordkeeping and reporting requirements described below.[7]

1. State Reporting Requirements (IC #1)

The regulation requires that each state electing to register AMCs for purposes of permitting AMCs to provide appraisal management services relating to covered transactions in the state submit to the ASC the information regarding such AMCs required to be submitted by ASC regulations or guidance concerning AMCs that operate in the state.[8]

2. State Recordkeeping Requirements (IC #2)

States seeking to register AMCs must have an AMC registration and supervision program. The regulation requires each participating state to establish and maintain within its appraiser certifying and licensing agency a registration and supervision program with the legal authority and mechanisms to: (i) Review and approve or deny an application for initial registration; (ii) periodically review and renew, or deny renewal of, an AMC's registration; (iii) examine an AMC's books and records and require the submission of reports, information, and documents; (iv) verify an AMC's panel members' certifications or licenses; (v) investigate and assess potential violations of laws, regulations, or orders; (vi) discipline, suspend, terminate, or deny registration renewals of AMCs that violate laws, regulations, or orders; and (vii) report violations of laws, regulations, or orders, and disciplinary and enforcement actions to the ASC.[9]

The regulation requires each participating state to impose requirements on AMCs that are not federally regulated (non-federally regulated AMCs) to: (i) Register with and be subject to supervision by a state appraiser certifying and licensing agency in each state in which the AMC operates; (ii) use only state-certified or state-licensed appraisers for federally regulated transactions in conformity with any federally regulated transaction regulations; (iii) establish and comply with processes and controls reasonably designed to ensure that the AMC, in engaging an appraiser, selects an appraiser who is independent of the transaction and who has the requisite education, expertise, and experience necessary to competently complete the appraisal assignment for the particular market and property type; (iv) direct the appraiser to perform the assignment in accordance with the Uniform Standards of Professional Appraisal Practice; and (v) establish and comply with processes and controls reasonably designed to ensure that the AMC conducts its appraisal management services in accordance with sections 129E(a) through (i) of the Truth-in-Lending Act.[10]

3. AMC Reporting Requirements (IC #3)

The regulation provides that an AMC may not be registered by a state or included on the AMC National Registry if the company is owned, directly or indirectly, by any person who has had an appraiser license or certificate refused, denied, cancelled, surrendered in lieu of revocation, or revoked in any state for a substantive cause.[11] The regulation also provides that an AMC may not be registered by a state if any person that owns 10 percent or more of the AMC fails to submit to a background investigation carried out by the state appraiser certifying and licensing agency.[12] Thus, each AMC registering with a state must provide information to the state on compliance with those ownership restrictions. Further, the regulation requires that a federally regulated AMC report to the state or states in which it operates the information required to be submitted by the state pursuant to the ASC's policies, including policies regarding the determination of the AMC National

[1] *See* 80 FR 32658 (June 9, 2015). By agreement, the responsibility for clearance under the PRA of information collections contained in the joint regulations is shared only by the FDIC, OCC, Board, and FHFA.

[2] *See* 12 U.S.C. 3350(4), (5). ''Federal financial institutions regulatory agency'' includes the FDIC, OCC, Board, and National Credit Union Administration. *See* 12 U.S.C. 3350(6).

[3] Section 1117 of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989 (FIRREA), 12 U.S.C. 3346, permits states to establish an appraiser certifying and licensing agency ''to assure the availability of State certified and licensed appraisers for the performance in a State of appraisals in federally related transactions and to assure effective supervision of the activities of certified and licensed appraisers.'' The Dodd-Frank Act amended section 1117 to provide that the duties of a state appraiser certifying and licensing agency may also include the registration and supervision of AMCs. Although states are not required by federal law to register and supervise AMCs, or even to establish an appraiser certifying and licensing agency, an AMC that is not registered with such a state agency (except for those regulated by a federal financial institutions regulatory agency) may not participate in a federally-related transaction in that state. *See* 12 U.S.C. 3353(f)(1).

[4] See 12 CFR 1222.23.

[5] *See* 12 U.S.C. 3353(e).

[6] *See* 12 CFR 1222.21(k) (defining ''Federally regulated AMC'').

[7] *See* 12 CFR 1222.20 through 1222.26. For clarity, the regulatory citations in this notice are to FHFA's version of the joint regulations only.

[8] *See* 12 CFR 1222.26.

[9] *See* 12 CFR 1222.23(a).

[10] *See* 12 CFR 1222.23(b). Sections 129E(a) through (i) of the Truth-in-Lending Act are located at 15 U.S.C. 1639e(a) through (i).

[11] *See* 12 CFR 1222.24(a) and 1222.25(b).

[12] *See* 12 CFR 1222.24(b).

Registry fee, and information regarding compliance with the ownership restrictions described above.[13]

4. AMC Recordkeeping Requirements (IC #4)

An entity meets the definition of an AMC that is subject to the requirements of the AMC regulation if, among other things, it oversees an appraiser panel of more than 15 state-certified or state-licensed appraisers in a state, or 25 or more state-certified or state-licensed appraisers in two or more states, within a given 12-month period.[14] For purposes of determining whether a company qualifies as an AMC under that definition, the regulation provides that an appraiser in an AMC's network or panel is deemed to remain on the network or panel until: (i) The AMC sends a written notice to the appraiser removing the appraiser with an explanation; or (ii) receives a written notice from the appraiser asking to be removed or a notice of the death or incapacity of the appraiser.[15] The AMC would retain these notices in its files.

B. Burden Estimate

FHFA's burden estimates for the information collections described above appear below. The estimates below remain the same as those set forth in the 60-day notice, despite one commenter's assertion that some of the assumptions underlying those burden estimates are incorrect. Those assertions and FHFA's responses are addressed below in section C of the notice.

There is no change in the existing methodology or substance of this information collection. For the information collections described above, the general methodology is to compute the industry wide burden hours for participating states and AMCs and then assign a share of the burden hours to each of the Agencies for each information collection.

As noted above, each of the Agencies' AMC regulations contains reporting and recordkeeping requirements applying to participating states and to both federally regulated and non-federally regulated AMCs. The Agencies have estimated that approximately 200 entities meet the regulatory definition of an ''appraisal management company'' [16] and that, of those 200 AMCs, approximately 120 are federally regulated and approximately 80 are non-federally regulated.[17] Unlike the insured depository institutions regulated by the OCC, FDIC, and Board, none of FHFA's regulated entities owns or controls an AMC or, by law, could ever own or control an AMC. Accordingly, the Agencies have agreed that responsibility for the burdens arising from reporting and recordkeeping requirements imposed upon federally regulated AMCs are to be split evenly among the OCC, FDIC, and Board (*i.e.,* the equivalent of 40 federally regulated AMCs for each agency) and that FHFA will not include those burdens in its totals. The four Agencies have agreed to split the total burdens imposed upon participating states and upon non-federally regulated AMCs evenly between them (*i.e.,* by taking responsibility for 25 percent of the burden per agency or, in the case of non-federally regulated AMCs, the equivalent of 20 such AMCs for each agency).

Thus, for ICs #1 and #2, which relate to reporting and recordkeeping requirements imposed upon participating states, each agency is responsible for 25 percent of the total estimated burden. For ICs #3 and #4, which relate to reporting and recordkeeping requirements imposed upon both federally regulated AMCs and non-federally regulated AMCs, the OCC, FDIC, and Board are each responsible for the burden imposed upon a total of 60 AMCs (40 federally regulated plus 20 non-federally regulated), or 30 percent of the total burden, while FHFA is responsible only for the burden imposed upon 20 non-federally regulated AMCs, or 10 percent of the total burden.

The Agencies estimate the total annualized hour burden placed on respondents by the information collection in the joint AMC regulations to be 1,445 hours. FHFA estimates its share of the hour burden to be 183 hours. The calculations on which those estimates are based are described below.

1. State Reporting Requirements (IC #1)

The total estimated burden hours for states reporting to the ASC are calculated by multiplying the number of states by the hour burden per state. The burden hours are then divided equally among the FDIC, OCC, Board, and FHFA, with each agency responsible for 25 percent of the total. For purposes of this calculation, the number of states is set at 55 which, in conformity with the regulatory definition of ''state,'' includes all 50 U.S. states as well as the Commonwealth of the Northern Mariana Islands, the District of Columbia, Guam, Puerto Rico, and the U.S. Virgin Islands.[18] The burden estimate of 1 hour per report is unchanged from the estimate provided for the currently-approved ICR. Therefore, the estimated total state reporting burden attributable to all of the Agencies is: 55 states × 1 hour/state = 55 hours. The estimated burden hours attributable to FHFA are 55 hours × 25 percent = 14 hours (rounded to the nearest whole number).

2. State Recordkeeping Requirements (IC #2)

The estimated burden hours on participating states for developing and maintaining an AMC licensing program is calculated by multiplying the number of states without a registration and licensing program by the hour burden to develop the system. The total burden hours are then equally divided among the FDIC, OCC, Board, and FHFA. According to the Appraisal Institute, as of July 26, 2017, there were 5 states that had not developed a system to register and oversee AMCs.[19] The burden estimate of 40 hours per state without a registration system is unchanged from the estimate provided for the currently-approved ICR. Therefore, the total estimated burden attributable to all of the Agencies is: 5 states × 40 hours/state = 200 hours. The estimated burden hours attributable to FHFA are 200 hours × 25 percent = 50 hours.

3. AMC Reporting Requirements (IC #3)

The burden for AMC reporting requirements for information needed to determine the AMC National Registry fee and information regarding compliance with the AMC ownership restrictions is calculated by multiplying the number of AMCs by the frequency of response and then by the burden per response. As described above, 30 percent of the burden hours are then assigned to each of the FDIC, OCC, and Board, while 10 percent are assigned to FHFA.

The frequency of response is estimated as the number of states that do not have an AMC registration program in which the average AMC operates.[20] As discussed above, 5 states do not have AMC registration or

[13] *See* 12 CFR 1222.25(c).

[14] *See* 12 CFR 1222.21(c)(iii).

[15] *See* 12 CFR 1222.22(b).

[16] In FHFA's regulations, this definition is set forth at 12 CFR 1222.21(c).

[17] FHFA anticipates that definitive information on the total number of AMCs and on the relative number of federally regulated and non-federally regulated AMCs will become available after the AMC National Registry becomes fully operational in 2020.

[18] *See* 12 CFR 1222.21(o).

[19] Appraisal Institute ''Enacted State AMC Laws,'' *https://www.appraisalinstitute.org/advocacy/enacted-state-amc-laws1/.*

[20] The number of states includes all U.S. states, territories, and districts to include: The Commonwealth of the Northern Mariana Islands; the District of Columbia; Guam; Puerto Rico; and the U.S. Virgin Islands.

oversight programs. According to the Consumer Financial Protection Bureau (CFPB), the average AMC operates in 19.56 states.[21] Therefore, the average AMC operates in approximately 2 states that do not have AMC registration systems: (5 states/55 states) × 19.56 states = 1.778 states, rounded to 2 states. The burden estimate of one hour per response is unchanged from the estimate provided for the currently-approved ICR. Therefore, the total estimated hour burden is: 200 AMCs × 2 states × 1 hour = 400 hours. The estimated burden hours attributable to FHFA are 400 hours × 10 percent = 40 hours.

4. AMC Recordkeeping Requirements (IC #4)

The burden for recordkeeping by AMCs of written notices of appraiser removal from a network or panel is estimated to be equal to the number of appraisers who leave the profession per year multiplied by the estimated percentage of appraisers who work for AMCs, then multiplied by burden hours per notice. As described above, 30 percent of the burden hours are then assigned to each of the FDIC, OCC, and Board, while 10 percent are assigned to FHFA.

The number of appraisers who leave an AMC annually, either by resigning, being laid off, or having their licenses revoked or surrendered, is estimated to be 9,881. The burden estimate of 0.08 hours per notice is unchanged from the estimate provided for the currently-approved ICR. Therefore, the estimated total hour burden is: 9,881 notices × 0.08 hours = 790 hours (rounded to the nearest whole number). The estimated burden hours attributable to FHFA are 790 hours × 10 percent = 79 hours.

C. Response to Comments Received

In accordance with the requirements of 5 CFR 1320.8(d), FHFA published an initial notice and request for comments regarding the renewal of the PRA clearance for this information collection in the **Federal Register** on May 16, 2018 (''60-day notice'').[22] The 60-day comment period closed on July 16, 2018. FHFA received two comments.

One comment letter, from an individual, asserted that this collection of information is not necessary for the proper performance of FHFA functions because ''there is currently too much oversight which cost excessive amounts of money'' and that those costs are ''passed down to the consumers through the AMCs to cover costs to maintain regulatory compliance.'' Because these comments relate to regulatory burden generally and not to the collection of information under the joint AMC regulation, FHFA has not addressed them in this notice.

The second comment letter, from a trade association representing AMCs, addressed a number of issues relating to the collection of information under the joint AMC regulation. First, the commenter stated that the collection of information is ''necessary'' and has ''practical utility,'' but ''only to the extent that the information collected serves the proper purpose to promote appraiser independence while ensuring a healthy real estate valuation market.'' FHFA disagrees with the commenter's implication that the ''proper purpose'' of the collection of information under the joint AMC regulations is limited to the promotion of appraiser independence. In fact, as required by statute, the AMC regulations address all issues on which the Agencies were required to promulgate regulations—including minimum requirements for registration of AMCs in participating states,[23] registration limitations for AMCs,[24] and the reporting of information by AMCs to the ASC[25]—and not merely the promotion of appraiser independence. The collection of information is necessary for implementation of those requirements. To the extent that the commenter disagrees with the scope and requirements of the joint AMC regulations, FHFA notes that those regulations may not be rescinded or revised through the PRA renewal process.

The second comment letter also questioned the accuracy of FHFA's estimates of the burdens of the collection of information. Asserting that the Agencies' estimate that there are 200 AMCs currently operating in the U.S. is too low, the commenter stated, without providing any further information or support, that ''industry estimates'' as to the number of AMCs ''are closer to 400.'' As stated in the 60-day notice, because the actual number of AMCs is not currently known and will not be known until the AMC National Registry is fully operational in 2020, the Agencies made a best guess that 200 entities currently qualify as an AMC, as that term is defined under the joint AMC regulations.[26] Because the commenter has provided no support for its assertion regarding the current number of AMCs subject to the joint regulations, FHFA's estimate as to that number remains unchanged.

The commenter further asserted that, contrary to the Agencies' estimates that 60 percent of existing AMCs (or 120 out of 200) are federally regulated, it knows of only one federally regulated AMC in existence. As with respect to the total number of AMCs, the Agencies made a best guess estimate as to the relative number of federally regulated and non-federally-regulated AMCs in the absence of any available empirical data on this issue pending completion of the AMC National Registry. As explained above, that estimate has no bearing on the Agencies' estimates as to the total amount of burden imposed by the collections of information under the joint AMC regulations, but relates only to the appropriate distribution among the rulemaking Agencies of responsibility (under the PRA) for a portion of the total estimated burden. Given this, and the lack of support provided by the commenter for its estimate as to the actual number of federally regulated AMCs, FHFA's estimate as to the relative number remains unchanged from that reflected in the 60-day notice.

Other issues addressed in the second comment letter, including recommendations that the ASC issue additional guidance to states and AMCs concerning the AMC minimum requirements, find opportunities to develop reporting efficiencies in the state licensing system, and be more aggressive in supporting modernization of the outdated National Appraiser Registry do not relate to the collection of information under the joint AMC regulation. The Agencies, however, will forward these suggestions to the ASC for consideration.

D. Comments Request

In accordance with the requirements of 5 CFR 1320.10(a), FHFA is publishing

[21] The CFPB conducted a survey of 9 AMCs in 2013 regarding the provisions in the regulation and the related PRA burden.

[22] *See* 83 FR 22681 (May 16, 2018).

[23] *See* 12 U.S.C. 3353(a).

[24] *See* 12 U.S.C. 3353(d).

[25] *See* 12 U.S.C. 3353(e).

[26] The joint regulations define ''appraisal management company'' generally to mean an entity that: (1) Provides appraisal management services (for example, maintaining a panel of certified and licensed appraisers to perform appraisals, managing the process of having an appraisal performed, collecting fees, and paying appraisers) to creditors or to secondary mortgage market participants; (2) provides such services in connection with valuing a consumer's primary dwelling as security for a consumer credit transaction or incorporating such transactions into securitizations; and (3) oversees an appraiser panel of more than 15 State-certified or State-licensed appraisers in a State or 25 or more State-certified or State-licensed appraisers in two or more States within a 12-month period. *See* 12 CFR 1222.21(c)(1).

this second notice to request comments regarding the following: (1) Whether the collection of information is necessary for the proper performance of FHFA functions, including whether the information has practical utility; (2) the accuracy of FHFA's estimates of the burdens of the collection of information; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) 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.

Dated: July 26, 2018.

Kevin Winkler,

Chief Information Officer, Federal Housing Finance Agency.

[FR Doc. 2018–16350 Filed 7–30–18; 8:45 am]

BILLING CODE 8070–01–P

FEDERAL MARITIME COMMISSION

Notice of Agreement Filed

The Commission hereby gives notice of the filing of the following agreement under the Shipping Act of 1984. Interested parties may submit comments on the agreement to the Secretary by email at *Secretary@fmc.gov,* or by mail, Federal Maritime Commission, Washington, DC 20573, within twelve days of the date this notice appears in the **Federal Register**. Copies of the agreement are available through the Commission's website (*www.fmc.gov*) or by contacting the Office of Agreements at (202)-523–5793 or *tradeanalysis@fmc.gov.*

Agreement No.: 201263.

Agreement Name: Maersk/MSC/Zim Cooperative Working Agreement.

Parties: Maersk Line A/S; Mediterranean Shipping Company S.A.; and Zim Integrated Shipping Services Ltd.

Filing Party: Wayne Rohde, Cozen O'Connor.

Synopsis: The Agreement authorizes the parties to share space and cooperate on the provision of service strings in the trade between Asia and the U.S. East Coast.

Proposed Effective Date: 9/8/2018.

Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/14256.

Dated: July 25, 2018.

Rachel Dickon,

Secretary.

[FR Doc. 2018–16280 Filed 7–30–18; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than August 23, 2018.

A. Federal Reserve Bank of Minneapolis (Mark A. Rauzi, Vice President), 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *Mackinac Financial Corporation, Manistique, Michigan;* to acquire 100 percent of the voting shares of Lincoln Community Bank, Merrill, Wisconsin.

Board of Governors of the Federal Reserve System, July 26, 2018.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2018–16337 Filed 7–30–18; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than August 24, 2018.

A. Federal Reserve Bank of Minneapolis (Mark A. Rauzi, Vice President), 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *Citizens Community Bancorp, Inc., Eau Claire, Wisconsin;* to acquire 100 percent of United Bank, Osseo, Wisconsin.

B. Federal Reserve Bank of St. Louis (David L. Hubbard, Senior Manager), P.O. Box 442, St. Louis, Missouri 63166–2034. Comments can also be sent electronically to *Comments.applications@stls.frb.org:*

1. *Old National Bancorp, Evansville, Indiana;* to merge with Klein Financial, Inc., Chaska, Minnesota, and thereby indirectly acquire KleinBank, also of Chaska, Minnesota.

Board of Governors of the Federal Reserve System, July 25, 2018.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2018–16377 Filed 7–30–18; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities; Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to extend for three years, with revision, the Financial Statements for Holding Companies (FR Y–9 family of reports) (OMB No. 7100–0128).

FOR FURTHER INFORMATION CONTACT:

Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829. Telecommunications Device for the Deaf (TDD) users may contact (202) 263–4869, Board of Governors of the Federal Reserve System, Washington, DC 20551.

OMB Desk Officer—Shagufta Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–6974.

SUPPLEMENTARY INFORMATION: On June 15, 1984, the Office of Management and Budget (OMB) delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collection of information requests and requirements conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. Copies of the Paperwork Reduction Act Submission, supporting statements and approved collection of information instrument(s) are placed into OMB's public docket files. The Federal Reserve may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Final approval under OMB delegated authority the extension for three years, with revision, of the following reports:

Report title: Financial Statements for Holding Companies.

Agency form number: FR Y–9C, FR Y–9LP, FR Y–9SP, FR Y–9ES, and FR Y–9CS.

OMB control number: 7100–0128.

Effective Date: June 30, 2018.

Frequency: Quarterly and semiannually.

Respondents: Bank holding companies, savings and loan holding companies, securities holding companies, and U.S. intermediate holding companies (collectively, holding companies (HCs)).

Estimated number of respondents: FR Y–9C (non-advanced approaches holding companies): 638; FR Y–9C (advanced approaches holding companies): 18; FR Y–9LP: 775; FR Y–9SP: 3,837 FR Y–9ES: 82; FR Y–9CS: 236.

Estimated average hours per response: FR Y–9C (non-advanced approaches holding companies): 46.29 hours; FR Y–9C (advanced approaches holding companies HCs): 47.54 hours; FR Y–9LP: 5.27 hours; FR Y–9SP: 5.40 hours; FR Y–9ES: 0.50 hours; FR Y–9CS: 0.50 hours.

Estimated annual burden hours: FR Y–9C (non-advanced approaches holding companies): 118,132 hours; FR Y–9C (advanced approaches holding companies): 3,423 hours; FR Y–9LP: 16,337 hours; FR Y–9SP:41,440 hours; FR Y–9ES: 41 hours; FR Y–9CS: 472 hours.

General description of report: The FR Y–9C, FR Y–9LP, and FR Y 9SP serve as standardized financial statements for the consolidated holding company. The FR Y–9ES is a financial statement for HCs that are Employee Stock Ownership Plans. The Board uses the FR Y–9CS (a free-form supplement) to collect additional information deemed to be critical and needed in an expedited manner. The FR Y–9 family of reporting forms continues to be the primary source of financial data on HCs that examiners rely on between on-site inspections. Financial data from these reporting forms is used to detect emerging financial problems, review performance, conduct pre-inspection analysis, monitor and evaluate capital adequacy, evaluate HC mergers and acquisitions, and analyze an HC's overall financial condition to ensure the safety and soundness of its operations. The Board requires HCs to provide standardized financial statements to fulfill the Board's statutory obligation to supervise these organizations. HCs file the FRY–9C on a quarterly basis, the FR Y–9LP quarterly, the FR Y–9SP semiannually, the FR Y–9ES annually, and the FR Y–9CS on a schedule that is determined when this supplement is used.

Legal authorization and confidentiality: The FR Y–9 family of reports is authorized by section 5(c) of the Bank Holding Company Act (12 U.S.C. 1844(c)), section 10 of Home Owners' Loan Act (12 U.S.C. 1467a(b)), section 618 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (''Dodd-Frank Act'') (12 U.S.C. 1850a(c)(1)), and section 165 of the Dodd-Frank Act (12 U.S.C. 5365). The obligation of covered institutions to report this information is mandatory. With respect to the FR Y–9LP, FR Y–9SP, FR Y–9ES, and FR Y–9CS, as well as most items on the FR Y–9C, the information collected would generally not be accorded confidential treatment. If confidential treatment is requested by a respondent, the Board will review the request to determine if confidential treatment is appropriate. With respect to the FR Y–9C, Schedule HI's item 7(g) ''FDIC deposit insurance assessments,'' Schedule HC–P's item 7(a) ''Representation and warranty reserves for 1–4 family residential mortgage loans sold to U.S. government agencies and government sponsored agencies,'' and Schedule HC–P's item 7(b) ''Representation and warranty reserves for 1–4 family residential mortgage loans sold to other parties'' are considered confidential. Such treatment is appropriate because the data is not publicly available and could cause substantial harm to the competitive position of the respondent. The public release of this confidential data may impair the Board's future ability to collect similarly confidential data. Thus, this information may be kept confidential under exemptions (b)(4) of the Freedom of Information Act, which exempts from disclosure ''trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential'' (5 U.S.C. 552(b)(4)), and (b)(8) of the Freedom of Information Act, which exempts from disclosure information related to examination, operating, or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions (5 U.S.C. 552(b)(8)). If confidential treatment is requested by a respondent for other items in the FR Y–9C, the Board will review the request to determine if confidential treatment is appropriate.

Current Actions: On April 30, 2018, the Board published a notice in the **Federal Register** (83 FR 18843) requesting public comment for 60 days on the extension, with revision, of the FR Y–9C report, and the extension, without revision, of the FR Y–9LP, FR Y–9SP, FR Y–9ES, and FR Y–9CS report. The Board proposed to implement a number of revisions to the FR Y–9C requirements, most of which were consistent with changes now implemented on the Federal Financial Institutions Examination Council (FFIEC) Consolidated Reports of Condition and Income (Call Reports) (FFIEC 031, FFIEC 041, and FFIEC 051; OMB No. 7100–0036). The proposed revisions included deleting certain data items and consolidating existing data items into new data items, as well as adding new or raising existing reporting

thresholds for certain data items to reduce reporting burden. The comment period expired June 29, 2018.

Detailed Discussion of Public Comments

The Federal Reserve received one comment from a banking association. The commenter noted several inconsistencies on the FR Y–9C report form and one inconsistency on the instructions when compared to the Call Report pertaining to Schedule HC–Q Memoranda items 4.b and 4.d, column A and Schedule HC–S Column G instructions and requested clarification on the proper reporting. The draft report form was inadvertently updated to reflect the removal of items 4.b and 4.d and a line item reference on the instructions for Schedule HC–S Column G was also inadvertently struck through. The Board has revised these items so that both the report form and instructions align with the Call Report. Additionally, the commenter noted an inconsistency between the caption on the report form and the caption on the instructions pertaining to *Equity investments without readily determinable fair values* on Schedule HC–F line item 4 on the FR Y–9C report. The Board has updated the instructions so that the report form and instructions align.

The revisions will be implemented as proposed, with the modifications described above, effective for the June 30, 2018, report date.

Board of Governors of the Federal Reserve System, July 25, 2018.

Michele Taylor Fennell,

Assistant Secretary of the Board.

[FR Doc. 2018–16265 Filed 7–30–18; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Patient Safety Organizations: Voluntary Relinquishment From Diagnostic Quality Assurance

AGENCY: Agency for Healthcare Research and Quality (AHRQ), Department of Health and Human Services (HHS).

ACTION: Notice of delisting.

SUMMARY: The Patient Safety Rule authorizes AHRQ, on behalf of the Secretary of HHS, to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be ''delisted'' by the Secretary if it is found to no longer meet the requirements of the Patient Safety Act and Patient Safety Rule, when a PSO chooses to voluntarily relinquish its status as a PSO for any reason, or when a PSO's listing expires. AHRQ has accepted a notification of voluntary relinquishment from Diagnostic Quality Assurance of its status as a PSO, and has delisted the PSO accordingly. Diagnostic Quality Assurance, PSO number P0170, submitted this request for voluntary relinquishment after receiving a Notice of Preliminary Finding of Deficiency.

DATES: The directories for both listed and delisted PSOs are ongoing and reviewed weekly by AHRQ. The delisting was effective at 12:00 Midnight ET (2400) on July 1, 2018.

ADDRESSES: Both directories can be accessed electronically at the following HHS website: *http://www.pso.ahrq.gov/listed.*

FOR FURTHER INFORMATION CONTACT: Eileen Hogan, Center for Quality Improvement and Patient Safety, AHRQ, 5600 Fishers Lane, Room 06N94B, Rockville, MD 20857; Telephone (toll free): (866) 403–3697; Telephone (local): (301) 427–1111; TTY (toll free): (866) 438–7231; TTY (local): (301) 427–1130; Email: *pso@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b–21 to b–26, (Patient Safety Act) and the related Patient Safety and Quality Improvement Final Rule, 42 CFR part 3 (Patient Safety Rule), published in the **Federal Register** on November 21, 2008, 73 FR 70732–70814, establish a framework by which hospitals, doctors, and other health care providers may voluntarily report information to Patient Safety Organizations (PSOs), on a privileged and confidential basis, for the aggregation and analysis of patient safety events.

The Patient Safety Act authorizes the listing of PSOs, which are entities or component organizations whose mission and primary activity are to conduct activities to improve patient safety and the quality of health care delivery.

HHS issued the Patient Safety Rule to implement the Patient Safety Act. AHRQ administers the provisions of the Patient Safety Act and Patient Safety Rule relating to the listing and operation of PSOs. The Patient Safety Rule authorizes AHRQ to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be ''delisted'' if it is found to no longer meet the requirements of the Patient Safety Act and Patient Safety Rule, when a PSO chooses to voluntarily relinquish its status as a PSO for any reason, or when a PSO's listing expires. Section 3.108(d) of the Patient Safety Rule requires AHRQ to provide public notice when it removes an organization from the list of federally approved PSOs.

AHRQ has accepted a notification from Diagnostic Quality Assurance, a component entity of Quality Star, LLC, to voluntarily relinquish its status as a PSO. Accordingly, Diagnostic Quality Assurance was delisted effective at 12:00 Midnight ET (2400) on July 1, 2018. AHRQ notes that that Diagnostic Quality Assurance submitted this request for voluntary relinquishment following receipt of the Notice of Preliminary Finding of Deficiency sent on April 10, 2018.

More information on PSOs can be obtained through AHRQ's PSO website at *http://www.pso.ahrq.gov.*

Francis D. Chesley, Jr.,

Acting Deputy Director.

[FR Doc. 2018–16327 Filed 7–30–18; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0007]

Biosimilar User Fee Rates for Fiscal Year 2019

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates for biosimilar user fees for fiscal year (FY) 2019. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Biosimilar User Fee Amendments of 2017 (BsUFA II), authorizes FDA to assess and collect user fees for certain activities in connection with biosimilar biological product development; review of certain applications for approval of biosimilar biological products; and each biosimilar biological product approved in a biosimilar biological product application.

BsUFA II directs FDA to establish, before the beginning of each fiscal year, the amount of initial and annual biosimilar biological product development (BPD) fees, the reactivation fee, and the biosimilar biological product application and

program fees for such year. These fees apply to the period from October 1, 2018, through September 30, 2019.

FOR FURTHER INFORMATION CONTACT: David Haas, Office of Financial Management, Food and Drug Administration, 8455 Colesville Rd., COLE–14202I, Silver Spring, MD 20993–0002, 240–402–9845.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 744G, 744H, and 744I of the FD&C Act (21 U.S.C. 379j–51, 379j–52, and 379j–53), as amended by BsUFA II (title IV of the FDA Reauthorization Act of 2017, Pub. L. 115–52), authorize the collection of fees for biosimilar biological products. Under section 744H(a)(1)(A) of the FD&C Act, the initial BPD fee for a product is due when the sponsor submits an investigational new drug (IND) application that FDA determines is intended to support a biosimilar biological product application or within 5 calendar days after FDA grants the first BPD meeting, whichever occurs first. A sponsor who has paid the initial BPD fee is considered to be participating in FDA's BPD program for that product.

Under section 744H(a)(1)(B) of the FD&C Act, once a sponsor has paid the initial BPD fee for a product, the annual BPD fee is assessed beginning with the next fiscal year. The annual BPD fee is assessed for the product each fiscal year until the sponsor submits a marketing application for the product that is accepted for filing or discontinues participation in FDA's BPD program.

Under section 744H(a)(1)(D) of the FD&C Act, if a sponsor has discontinued participation in FDA's BPD program and wants to re-engage with FDA on development of the product, the sponsor must pay a reactivation fee to resume participation in the program. The sponsor must pay the reactivation fee by the earlier of the following dates: No later than 5 calendar days after FDA grants the sponsor's request for a BPD meeting for that product or upon the date of submission by the sponsor of an IND describing an investigation that FDA determines is intended to support a biosimilar biological product application for that product. The sponsor will be assessed an annual BPD fee beginning with the first fiscal year after payment of the reactivation fee.

BsUFA II also authorizes fees for certain biosimilar biological product applications and for each biosimilar biological product identified in an approved biosimilar biological product application (section 744H(a)(2) and (3) of the FD&C Act). Under certain conditions, FDA will grant a small business a waiver from its first biosimilar biological product application fee (section 744H(d)(1) of the FD&C Act).

For FY 2018 through FY 2022, the base revenue amounts for the total revenues from all BsUFA fees are established by BsUFA II. For FY 2019, the base revenue amount is the FY 2018 inflation adjusted fee revenue amount of $40,214,000. The FY 2019 base revenue amount is to be adjusted for inflation and may be reduced, as appropriate, for long-term financial planning purposes.

This document provides fee rates for FY 2019 for the initial and annual BPD fee ($185,409), for the reactivation fee ($370,818), for an application requiring clinical data ($1,746,745), for an application not requiring clinical data ($873,373), and for the program fee ($304,162). These fees are effective on October 1, 2018, and will remain in effect through September 30, 2019. For applications that are submitted on or after October 1, 2018, the new fee schedule must be used.

II. Fee Revenue Amount for FY 2019

The base revenue amount for FY 2019 is $40,214,000 prior to adjustments for inflation and operating reserves (see section 744H(c)(1) and (3) of the FD&C Act).

A. FY 2019 Statutory Fee Revenue Adjustments for Inflation

BsUFA II specifies that the $40,214,000 is to be adjusted for inflation increases for FY 2019 using two separate adjustments—one for personnel compensation and benefits (PC&B) and one for non-PC&B costs (see section 744H(c)(1) of the FD&C Act).

The component of the inflation adjustment for payroll costs shall be one plus the average annual percent change in the cost of all PC&B paid per full-time equivalent (FTE) positions at FDA for the first 3 of the preceding 4 FYs, multiplied by the proportion of PC&B costs to total FDA costs of the process for the review of biosimilar biological product applications for the first 3 of the preceding 4 FYs (see section 744H(c)(1)(B) of the FD&C Act).

Table 1 summarizes the actual cost and FTE data for the specified FYs and provides the percent changes from the previous FYs and the average percent changes over the first 3 of the 4 FYs preceding FY 2019. The 3-year average is 2.4152 percent.

TABLE 1—FDA PC&B EACH YEAR AND PERCENT CHANGES

Fiscal year	2015	2016	2017	3-year average
Total PC&B	$2,232,304,000	$2,414,728,159	$2,581,551,000	.....
Total FTE	15,484	16,381	17,022	.....
PC&B per FTE	144,168	147,408	151,660	.....
Percent Change From Previous Year	2.1136	2.2474	2.8845	2.4152

The statute specifies that this 2.4152 percent be multiplied by the proportion of PC&B costs to the total FDA costs of the process for the review of biosimilar biological product applications. Table 2 shows the PC&B and the total obligations for the process for the review of biosimilar biological product applications for the first 3 of the preceding 4 FYs.

TABLE 2—PC&B AS A PERCENT OF TOTAL COST OF THE PROCESS FOR THE REVIEW OF BIOSIMILAR BIOLOGICAL PRODUCT APPLICATIONS

Fiscal year	2015	2016	2017	3-year average
Total PC&B	$23,265,434	$26,775,674	$30,707,050	.....
Total Costs	34,817,217	45,569,430	55,814,043	.....

TABLE 2—PC&B AS A PERCENT OF TOTAL COST OF THE PROCESS FOR THE REVIEW OF BIOSIMILAR BIOLOGICAL PRODUCT APPLICATIONS—Continued

Fiscal year	2015	2016	2017	3-year average
PC&B Percent	66.8216	58.7580	55.0167	60.1988

The payroll adjustment is 2.4152 percent from table 1 multiplied by 60.1988 percent (or 1.4539 percent).

The statute specifies that the portion of the inflation adjustment for non-payroll costs is the average annual percent change that occurred in the Consumer Price Index (CPI) for urban consumers (Washington-Baltimore, DC–MD–VA–WV; not seasonally adjusted; all items; annual index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than PC&B costs to total costs of the process for the review of biosimilar biological product applications for the first 3 years of the preceding 4 FYs (see section 744H(c)(1)(B) of the FD&C Act). Table 3 provides the summary data for the percent changes in the specified CPI for the Washington-Baltimore area. The data are published by the Bureau of Labor Statistics and can be found on its website at: *https://data.bls.gov/pdq/SurveyOutputServlet?data_tool=dropmap&series_id=CUURA311SA0, CUUSA311SA0.*

TABLE 3—ANNUAL AND THREE-YEAR AVERAGE PERCENT CHANGE IN CPI FOR WASHINGTON-BALTIMORE AREA

Year	2015	2016	2017	3-year average
Annual CPI	155.353	157.180	159.202	.....
Annual Percent Change	0.3268	1.1760	1.2864	0.9297

The statute specifies that this 0.9297 percent be multiplied by the proportion of all costs other than PC&B to total costs of the process for the review of biosimilar biological product applications obligated. Since 60.1988 percent was obligated for PC&B (as shown in table 2), 39.8012 percent is the portion of costs other than PC&B (100 percent minus 60.1988 percent equals 39.8012 percent). The non-payroll adjustment is 0.9297 percent times 39.8012 percent, 0.3700 percent.

Next, we add the payroll adjustment (1.4539 percent) to the non-payroll adjustment (0.3700 percent), for a total inflation adjustment of 1.8239 percent (rounded) for FY 2019.

We then multiply the base revenue amount for FY 2019 ($40,214,000) by one plus the inflation adjustment percentage (1.018239), yielding an inflation-adjusted amount of $40,947,463.

B. FY 2019 Statutory Fee Revenue Adjustments for Operating Reserve

BsUFA II provides for an operating reserve adjustment to allow FDA to adjust the fee revenue and fees for any given fiscal year during BsUFA II, after FY 2018, to maintain an appropriate operating reserve of carryover user fees. Beginning in FY 2019, FDA may reduce the fee revenue and fees for long-term financial planning purposes. Once the capacity planning adjustment is effective (see section 744H(c)(2) of the FD&C Act), which FDA expects to occur in FY 2021, FDA also may, if necessary, increase the fee revenue and fees to maintain not more than 21 weeks of operating reserve of carryover user fees.

As described in the BsUFA II commitment letter, *Biosimilar Biological Product Reauthorization Goals and Procedures Fiscal Years 2018 Through 2022,* FDA is committed to reducing the BsUFA carryover reserve to an amount no greater than 21 weeks of operating reserve of carryover user fees by the end of FY 2022. In support of this commitment, FDA has determined that it shall apply an operating reserve adjustment to lower the FY 2019 target revenue amount by $2,100,000. This would establish an adjusted FY 2019 BsUFA fee revenue amount of $38,847,000 (rounded to the nearest thousand dollars).

III. Fee Amounts for FY 2019

Under section 744H(b)(3)(A) of the FD&C Act, FDA must determine the percentage of the total revenue amount for a fiscal year to be derived from: (1) Initial and annual BPD fees and reactivation fees; (2) biosimilar biological product application fees; and (3) biosimilar biological product program fees. In establishing the fee amounts for the second year of BsUFA II, FDA considered how best to balance the fee allocation to provide stable funding and reasonable fee amounts. In future years, FDA will consider the most appropriate means of allocating the fee amounts to collect the adjusted target revenue amount, subject to the relevant statutory provisions.

A. Application Fees

In establishing the biosimilar biological product application fee amount for FY 2019, FDA considered historical program information as well as input from an annual industry survey. Based on the available information, FDA estimates it will receive nine biosimilar biological product applications requiring clinical data for approval in FY 2019.

FDA will maintain the biosimilar biological product application fee for FY 2019 at the same level as FY 2018, which is $1,746,745. This is estimated to provide a total of $15,720,705 representing 40 percent (rounded to the nearest whole number) of the FY 2019 target revenue amount.

B. Biosimilar Biological Product Program Fee

Under BsUFA II, FDA assesses biosimilar biological product program fees (''program fees''). An applicant in a biosimilar biological product application shall not be assessed more than five program fees for a fiscal year for biosimilar biological products identified in a single biosimilar biological product application (see FD&C Act section 744H(a)(3)(D)). Applicants are assessed a program fee for a fiscal year only for biosimilar biological products identified in a biosimilar biological product application approved as of October 1 of such fiscal year.

Based on available information, FDA estimates that 23 program fees will be

invoiced for FY 2019, including currently approved products and products with the potential to be approved in pending applications with goal dates in FY 2018. For products invoiced in the FY 2019 regular billing cycle, FDA anticipates that zero program fees will be refunded. This is based on observations dating to 2015, when the first biosimilar product was approved.

FDA will maintain the biosimilar biological product program fee for FY 2019 at the same level as FY 2018, which is $304,162. This is estimated to provide a total of $6,995,726, representing 18 percent (rounded to the nearest whole number) of the FY 2019 target revenue amount.

C. Initial and Annual BPD Fees, Reactivation Fees

To estimate the number of participants in the BPD program in FY 2019, FDA must consider the number of new participants in the BPD program (initial BPD), the number of current participants (annual BPD), and the number of participants who will re-enter the BPD program (reactivation).

FDA uses internal data and a survey of BPD sponsors to estimate the total number of participants in the BPD program. In FY 2019, FDA estimates 24 participants entering the BPD program, zero reactivations, and 63 participants to be invoiced for the annual BPD fee for a total of 87 participants in the BPD program in FY 2019.

The remainder of the target revenue of $16,130,569, or 42 percent (rounded to the nearest whole number), is to be collected from the BPD fees. Dividing this amount by the estimated 87 BPD fees to be paid equals a BPD fee amount of $185,409. The reactivation fee is set at twice the initial/annual BPD amount at $370,818. This represents a reduction of the BPD fee from the FY 2018 levels.

IV. Fee Schedule for FY 2019

The fee rates for FY 2019 are displayed in table 4.

TABLE 4—FEE SCHEDULE FOR FY 2019

Fee category	Fee rates for FY 2019
Initial BPD	$185,409
Annual BPD	185,409
Reactivation	370,818
Applications:	
Requiring clinical data	1,746,745
Not requiring clinical data	873,373
Program	304,162

V. Fee Payment Options and Procedures

A. Initial BPD, Reactivation, and Application Fees

The fees established in the new fee schedule apply to FY 2019, *i.e.,* the period from October 1, 2018, through September 30, 2019. The initial BPD fee for a product is due when the sponsor submits an IND that FDA determines is intended to support a biosimilar biological product application for the product or within 5 calendar days after FDA grants the first BPD meeting for the product, whichever occurs first. Sponsors who have discontinued participation in the BPD program for a product and seek to resume participation in such program must pay the reactivation fee by the earlier of the following dates: No later than 5 calendar days after FDA grants the sponsor's request for a BPD meeting for that product or upon the date of submission by the sponsor of an IND describing an investigation that FDA determines is intended to support a biosimilar biological product application for that product.

The application fee for a biosimilar biological product is due upon submission of the application (see section 744H(a)(2)(C) of the FD&C Act).

To make a payment of the initial BPD, reactivation, or application fee, complete the Biosimilar User Fee Cover Sheet, available on FDA's website (*https://www.fda.gov/bsufa*) and generate a user fee identification (ID) number. Payment must be made in U.S. currency by electronic check, check, bank draft, U.S. postal money order, or wire transfer. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay* (*Note:* only full payments are accepted. No partial payments can be made online). Once you search for your invoice, click ''Pay Now'' to be redirected to *Pay.gov*. Electronic payment options are based on the balance due. Payment by credit card is available for balances that are less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S bank accounts as well as U.S. credit cards.

FDA has partnered with the U.S. Department of the Treasury to use *Pay.gov*, a web-based payment application, for online electronic payment. The *Pay.gov* feature is available on the FDA website after the user fee ID number is generated.

Please include the user fee ID number on your check, bank draft, or postal money order. Mail your payment to: Food and Drug Administration, P.O. Box 979108, St. Louis, MO 63197–9000. If a check, bank draft, or money order is to be sent by a courier that requests a street address, the courier should deliver your payment to: U.S. Bank, Attention: Government Lockbox 979108, 1005 Convention Plaza, St. Louis, MO 63101. (*Note:* This U.S. Bank address is for courier delivery only. If you have any questions concerning courier delivery, contact U.S. Bank at 314–418–4013. This telephone number is only for questions about courier delivery.) Please make sure that the FDA post office box number (P.O. Box 979108) is written on the check, bank draft, or postal money order.

If paying by wire transfer, please reference your unique user fee ID number when completing the transfer. The originating financial institution may charge a wire transfer fee. Please ask your financial institution about the fee and include it with your payment to ensure that your fee is fully paid. The account information for wire transfers is as follows: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No.: 75060099, Routing No.: 021030004, SWIFT: FRNYUS33. If needed, FDA's tax identification number is 53–0196965.

B. Annual BPD and Program Fees

FDA will issue invoices with payment instructions for FY 2019 annual BPD and program fees under the new fee schedule in August 2018. Payment will be due on October 1, 2018. If sponsors join the BPD program after the annual BPD invoices have been issued in August 2018, FDA will issue invoices in December 2018 to firms subject to fees for FY 2019 that qualify for the annual BPD fee after the August 2018 billing. FDA will issue invoices in December 2018 for any annual program fees for FY 2019 that qualify for fee assessments and were not issued in August 2018.

Dated: July 26, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–16312 Filed 7–30–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS), Full Committee Meeting.

Date and Times: Thursday, September 13, 2018: 9:00 a.m.–5:00 p.m. (EDT); Friday, September 14, 2018: 8:30 a.m.–3:00 p.m. (EDT).

Place: Melrose Georgetown Hotel, 2430 Pennsylvania Avenue NW, Washington, DC 20037.

Status: Open.

Purpose: At the September 13–14, 2018 meeting, the Committee will hear presentations, hold discussions on several health data policy topics and continue work on projects outlined in the NCVHS 2018 workplan. Anticipated action items during this meeting include an Environmental Scan Report on Health Terminologies and Vocabularies (T/V); and a summary report of the health T/V expert roundtable meeting held July 17–18, 2018. The NCVHS Population Health Subcommittee will hold a session with panelists to provide input to the Committee regarding strategies and resources/tools to increase access to small area data, and in general, the challenges in making relevant sub-national level health data more readily available. Subcommittee activities for discussion include the Predictability Roadmap as part of the Standards Subcommittee's project to identify possible approaches to improve predictability and improvements in the adoption and processes related to updating standards and operating rules for electronic administrative transactions (*e.g.,* claims, eligibility, electronic funds transfer). The Privacy, Confidentiality & Security Subcommittee will continue its focus on use cases that highlight the intersection of the regulated and unregulated domains for its ''Health Information Privacy and Security Beyond HIPAA'' project, and will propose a model that depicts the opportunities to address risks to individually identifiable information through improved stewardship for consideration by the full Committee.

The Committee will initiate discussion regarding plans for the NCVHS Thirteenth Report to Congress. The agenda times and topics are subject to change. There will be a public comment period on both meeting days. Please refer to the posted agenda for any updates.

Contact Persons for More Information: Substantive program information may be obtained from Rebecca Hines, MHS, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Hyattsville, Maryland 20782, telephone (301) 458–4715. Summaries of meetings and a roster of Committee members are available on the home page of the NCVHS website: *www.ncvhs.hhs.gov,* where further information including an agenda and instructions to access the audio broadcast of the meetings will be posted.

Should you require reasonable accommodation, please contact the CDC Office of Equal Employment Opportunity on (770) 488–3210 as soon as possible.

Dated: July 25, 2018.

Laina Bush,

Deputy Assistant Secretary for Planning and Evaluation, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 2018–16361 Filed 7–30–18; 8:45 am]

BILLING CODE 4151–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Emergency Use of Treatment for Uncontrolled Hemorrhage Due to Agents of Military Combat; Correction

AGENCY: Office of the Secretary, Department of Health and Human Services.

ACTION: Notice, correction.

SUMMARY: The Department of Health and Human Services is correcting a notice that appeared in the **Federal Register** on July 16, 2018. The notice announced the Secretary's Declaration Regarding Emergency Use of Treatment for Uncontrolled Hemorrhage During an Emergency Involving Agents of Military Combat pursuant to section 564 of the Federal Food, Drug & Cosmetic (FD&C) Act. On July 9, 2018, the Secretary declared that circumstances exist justifying the authorization of emergency use of freeze dried plasma (FDP) for the treatment of hemorrhage or coagulopathy during an emergency involving agents of military combat (*e.g.,* firearms, projectiles, and explosive devices) when plasma is not available for use or when the use of plasma is not practical, pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section. This notice is correcting the July 16, 2018 notice to correctly state the Secretary's declaration.

FOR FURTHER INFORMATION CONTACT: Robert P. Kadlec, MD, MTM&H, MS, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201, Telephone (202) 205–2882 (this is not a toll free number).

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 16, 2018 (83 FR 32884) appearing on page 32884 in FR Doc. 2018–15152 the following corrections are made:

1. Title, change the title of the notice to ''Declaration Regarding Emergency Use of Treatment for Hemorrhage or Coagulopathy During an Emergency Involving Agents of Military Combat.''

2. Summary section, change the second paragraph to: '' On the basis of this determination, on July 9, 2018, the Secretary declared that circumstances exist justifying the authorization of emergency use of freeze dried plasma (FDP) for the treatment of hemorrhage or coagulopathy during an emergency involving agents of military combat (*e.g.,* firearms, projectiles, and explosive devices) when plasma is not available for use or when the use of plasma is not practical, pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.''

3. **SUPPLEMENTARY INFORMATION** section, subpart I, Background, second paragraph second sentence, delete ''French'' before ''FDP.''

4. **SUPPLEMENTARY INFORMATION** section, subpart III, Determination of the Secretary of Health and Human Services, change paragraph 1 to: ''On July 9, 2018, on the basis of the Deputy Secretary of Defense's determination that there is a military emergency or significant potential for a military emergency involving a heightened risk to U.S. military forces of an attack with an agent or agents that may cause, or are otherwise associated with an imminently life-threatening and specific risk to those forces, I declared that circumstances exist justifying the authorization of emergency use of FDP for the treatment of hemorrhage or coagulopathy during an emergency involving agents of military combat (*e.g.,* firearms, projectiles, and explosive devices) when plasma is not available for use or when the use of plasma is not practical, pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.''

Dated: July 25, 2018.

Ann Agnew,

Executive Secretary to the Department, U.S. Department of Health and Human Services.

[FR Doc. 2018–16331 Filed 7–30–18; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Council on Aging.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council on Aging.

Date: September 13–14, 2018.

Closed: September 13, 2018, 3:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, C Wing 6th Floor Conference Room 10, 9000 Rockville Pike, Bethesda, MD 20892.

Open: September 14, 2018, 8:00 a.m. to 12:45 p.m.

Agenda: Call to order and report from the Director; Discussion of future meeting dates; Consideration of minutes of last meeting; Reports from Task Force on Minority Aging Research, Working Group on Program; Council Speaker; Program Highlights.

Place: National Institutes of Health, Building 31, C Wing 6th Floor Conference Room 10, 9000 Rockville Pike, Bethesda, MD 20892.

Contact Person: Robin Barr, Director, National Institute on Aging, Office of Extramural Activities, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20814, (301) 496–9322, *barrr@nia.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit. Information is also available on the Institute's/Center's home page:*www.nia.nih.gov/about/naca,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: July 25, 2018.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–16294 Filed 7–30–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Microbiology, Infectious Diseases and AIDS Initial Review Group Acquired Immunodeficiency Syndrome Research Review Committee.

Date: August 30–31, 2018.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: San Diego Marriott Mission Valley, 8757 Rio Diego Drive, San Diego, CA 92108.

Contact Person: Robert C. Unfer, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3F40A, National Institutes of Health, NIAID, 5601 Fishers Lane, MSC 9834, Bethesda, MD 20892–9834, (240) 669–5035, *robert.unfer@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: July 25, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–16296 Filed 7–30–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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 grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; Quantitative Imaging Tools and Methods for Cancer Therapy Response Assessment (UG3/UH3 & U01).

Date: September 7, 2018.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute, Shady Grove, 9609 Medical Center Drive, Room 7W640, Rockville, MD 20850 (Telephone Conference Call).

Contact Person: Saejeong J. Kim, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W640, Bethesda, MD 20892–9750, 240–276–5179, *saejeong.kim@nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Program Project II.

Date: September 20–21, 2018.

Time: 3:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, North Bethesda, MD 20852.

Contact Person: Anita T. Tandle, Ph.D., Scientific Review Officer, Research Program

Review Branch, Division of Extramural Activities, National Cancer Institute, NIH 9609, Medical Center Drive, Room 7W248, Bethesda, MD 20892–9750, 240–276–5007 *tandlea@mail.nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Program Project III (P01).

Date: September 24–25, 2018.

Time: 8:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville Hotel, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Majed M. Hamawy, Ph.D., Scientific Review Officer, Research Program Review Branch, Division of Extramural Activities, National Cancer Institute, NIH 9609, Medical Center Drive, Room 7W120, Bethesda, MD 20892–9750, 240–276–6457, *mh101v@nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Program Project V (P01).

Date: September 24–25, 2018.

Time: 4:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Boulevard, Gaithersburg, MD 20878.

Contact Person: Adriana Stoica, Ph.D., Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, NIH 9609, Medical Center Drive, Room 7W234, Bethesda, MD 20892–9750, 240–276–6368, *Stoicaa2@mail.nih.gov*.

Name of Committee: National Cancer Institute Initial Review Group, Subcommittee F—Institutional Training and Education.

Date: October 15–16, 2018.

Time: 7:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard Bethesda, MD 20817.

Contact Person: Timothy C. Meeker, M.D., Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, NIH 9609, Medical Center Drive, Room 7W624, Bethesda, MD 20892–9750, 240–276–6464, *meekert@mail.nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; Informatics Technologies for Cancer Research.

Date: October 24–25, 2018.

Time: 5:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, North Bethesda, MD 20852.

Contact Person: Nadeem Khan, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH 9609, Medical Center Drive, Room 7W260, Bethesda, MD 20892–9750, 240–276–5856, *nadeem.khan@nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; Innovative Molecular Analysis Technologies.

Date: November 7, 2018.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute, Shady Grove, 9609 Medical Center Drive, Room 7W246, Rockville, MD 20850 (Telephone Conference Call).

Contact Person: Jun Fang, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH 9609, Medical Center Drive, Room 7W246, Bethesda, MD 20892–9750, 240–276–5460, *jfang@mail.nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; IMAT Biospecimen Research.

Date: November 14, 2018.

Time: 10:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute, Shady Grove, 9609 Medical Center Drive, Room 7W246, Rockville, MD 20850 (Telephone Conference Call).

Contact Person: Jun Fang, Ph.D. Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH 9609, Medical Center Drive, Room 7W246, Bethesda, MD 20892–9750, 240–276–5460 *jfang@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: July 25, 2018.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–16291 Filed 7–30–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Fogarty International Center; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Fogarty International Center Advisory Board.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Fogarty International Center Advisory Board.

Date: September 6–7, 2018.

Closed: September 6, 2018, 3:00 p.m. to 5:00 p.m.

Agenda: Second level review of grant applications.

Place: National Institutes of Health, Lawton L. Chiles International House Building 16, Conference Room, 16 Center Drive, Bethesda, MD 20892.

Open: September 7, 2018, 9:00 a.m. to 3:00 p.m.

Agenda: Update and discussion of current and planned FIC activities.

Place: National Institutes of Health, Lawton L. Chiles International House, Building 16, Conference Room, 16 Center Drive, Bethesda, MD 20892.

Contact Person: Kristen Weymouth, Executive Secretary, Fogarty International Center, National Institutes of Health, 31 Center Drive, Room B2C02, Bethesda, MD 20892, (301) 496–1415, *weymouthk@mail.nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *http://www.fic.nih.gov/About/Advisory/Pages/default.aspx,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.106, Minority International Research Training Grant in the Biomedical and Behavioral Sciences; 93.154, Special International Postdoctoral Research Program in Acquired Immunodeficiency Syndrome; 93.168, International Cooperative Biodiversity Groups Program; 93.934, Fogarty International Research Collaboration Award; 93.989, Senior International Fellowship

Awards Program, National Institutes of Health, HHS)

Dated: July 25, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–16299 Filed 7–30–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Heart, Lung, and Blood Advisory Council.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Advisory Council.

Date: August 28, 2018.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Room 9100, Bethesda, MD 20892 (Teleconference).

Contact Person: Laura K. Moen, Ph.D., Director, Division of Extramural Research Activities, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Room 7100, Bethesda, MD 20892, 301–435–0260, *moenl@mail.nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *www.nhlbi.nih.gov/meetings/nhlbac/index.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: July 25, 2018.

David D. Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–16293 Filed 7–30–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Child Health and Human Development Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. A portion of this meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended for the review and discussion of grant applications. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the contact person listed below in advance of the meeting.

Name of Committee: National Advisory Child Health and Human Development Council.

Date: September 13, 2018–September 14, 2018.

Open: September 13, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: The agenda will include opening remarks, administrative matters, Director's Report, Division of Extramural Research Report and other business of the Council.

Place: National Institutes of Health, 6710B Bethesda Drive, Rm. 1425, Bethesda, MD 20892.

Closed: September 14, 2018.

Time: 8:00 a.m. to Adjournment.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6710B Bethesda Drive, Rm. 1425, Bethesda, MD 20892.

Contact Person: Della Hann, Ph.D., Director, Division of Extramural Research, *Eunice Kenney Shriver* National Institute of Child Health, and Human Development, NIH, 6710 Rockledge Blvd., MSC 7002, Bethesda, MD 20892, 301–496–8535.

Any interested person may file written comments with the committee by forwarding the statement to the contact person listed on this notice. The statement should include the name, address, telephone number, and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxis, hotel, and airport shuttles, will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit. In order to facilitate public attendance at the open session of Council in the main meeting room, Conference Room 1425, please contact Ms. Lisa Kaeser, Office of Legislation and Public Policy, NICHD, at 301–496–0536 to make your reservation, additional seating will be available in the meeting overflow rooms, Conference Rooms 1417 and 1411. Individuals will also be able to view the meeting via NIH Videocast. Select the following link for Videocast access instructions: *http://www.nichd.nih.gov/about/advisory/nachhd/Pages/virtual-meeting.aspx*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment program, National Institutes of Health, HHS)

Dated: July 25, 2018.

David D. Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–16295 Filed 7–30–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The purpose of this meeting is to evaluate requests for preclinical development resources for potential new therapeutics for the treatment of cancer. The outcome of the evaluation will provide information to internal NCI committees that will decide whether NCI should support requests and make available contract resources for development of the potential therapeutic to improve the treatment of various forms of cancer. The research proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the

proposed research projects, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; JUN2018 Cycle 29 NExT SEP Committee Meeting.

Date: August 30, 2018.

Time: 8:00 a.m. to 4:30 p.m.

Agenda: To evaluate the NCI Experimental Therapeutics Program Portfolio.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, Wing C, 6th Floor, Conference Room 6, Bethesda, MD 20892.

Contact Persons: Barbara Mroczkowski, Ph.D., Executive Secretary, Discovery Experimental Therapeutics Program, National Cancer Institute, NIH, 31 Center Drive, Room 3A44, Bethesda, MD 20817, (301) 496–4291, *mroczkoskib@mail.nih.gov.* Toby Hecht, Ph.D., Executive Secretary, Development Experimental Therapeutics Program, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 3W110, Rockville, MD 20850, (240) 276–5683, *toby.hecht2@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: July 25, 2018.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–16292 Filed 7–30–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Mentored Clinical Scientist Research Career Development Award (Parent K08).

Date: August 21, 2018.

Time: 10:00 a.m. to 11:30 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Frank S. De Silva, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room #3E72A, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9823, Rockville, MD 20892–9823, (240) 669–5023, *fdesilva@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: July 25, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–16297 Filed 7–30–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2018–0492]

Great Lakes Pilotage Advisory Committee; Vacancy

AGENCY: U.S. Coast Guard, Department of Homeland Security.

ACTION: Request for applications; extension of application.

SUMMARY: The U.S. Coast Guard seeks applications for membership on the Great Lakes Pilotage Advisory Committee. The Great Lakes Pilotage Advisory Committee provides advice and makes recommendations to the Secretary of Homeland Security through the U.S. Coast Guard Commandant on matters relating to Great Lakes pilotage, including review of proposed Great Lakes pilotage regulations and policies.

DATES: Open until the vacancy is filled.

ADDRESSES: Applicants should send a cover letter expressing interest in an appointment to the Great Lakes Pilotage Advisory Committee that also identifies which membership category the applicant is applying under, along with a resume detailing the applicant's experience via one of the following methods:

- *By Email: Rajiv.Khandpur@uscg.mil.*
- *By Fax:* (202) 372–8387 ATTN: Mr. Rajiv Khandpur.
- *By Mail:* Commandant (CG–WWM–2), U.S. Coast Guard.

Attention: Mr. Rajiv Khandpur, Designated Federal Officer, Great Lakes Pilotage Advisory Committee, 2703 Martin Luther King Jr. Ave. SE, Stop 7509, Washington, DC 20593–7509.

FOR FURTHER INFORMATION CONTACT: Mr. Rajiv Khandpur, Designated Federal Officer, Great Lakes Pilotage Advisory Committee, 2703 Martin Luther King Jr. Ave. SE, Stop 7509, Washington, DC 20593–7509; telephone 202–372–1525, fax 202–372–8387, or email at *Rajiv.Khandpur@uscg.mil.*

SUPPLEMENTARY INFORMATION: On March 28, 2018, the U.S. Coast Guard published a request in the **Federal Register** Volume 83, Number 60, for applications for membership in the Great Lakes Pilotage Advisory Committee. The application in the notice is being extended until the vacancy is filled. Applicants who responded to the initial notice do not need to reapply.

The Great Lakes Pilotage Advisory Committee is a federal advisory committee established in accordance with the provisions of the Federal Advisory Committee Act (5 U.S.C., Appendix). The Great Lakes Pilotage Advisory Committee operates under the authority of 46 U.S.C. 9307, and makes recommendations to the Secretary and the U.S. Coast Guard on matters relating to the Great Lakes.

Meetings of the Great Lakes Pilotage Advisory Committee will be held with the approval of the Designated Federal Officer. The Committee is required to meet at least once per year. Additional meetings may be held at the request of a majority of the Committee or at the discretion of the Designated Federal Officer.

Each Great Lakes Pilotage Advisory Committee member serves a term of office of up to 3 years. Members may serve a maximum of six consecutive years. All members serve without compensation from the Federal Government; however, they may receive travel reimbursement and per diem.

We will consider applicants for one position that will become vacant on September 30, 2018.

- One member with a background in finance or accounting, who—

a. Must have been recommended to the Secretary of the Department of Homeland Security by a unanimous vote of the other members of the Committee, and

b. May be appointed without regard to the requirement that each member have five years of practical experience in maritime operations.

To be eligible, applicants should have particular expertise, knowledge, and experience regarding the regulations and policies on the pilotage vessels on the Great Lakes, and at least five years of practical experience in maritime operations.

If you are selected as a member you will be appointed and serve as a Special Government Employee as defined in 202(a) of Title 18, U.S.C. Applicants for appointment as a Special Government Employee are required to complete a Confidential Financial Disclosure Report (OGE Form 450). The U.S. Coast Guard may not release the reports or the information in them to the public except under an order issued by a Federal Court or as otherwise provided under the Privacy Act (5 U.S.C. 552a). Only the Designated U.S. Coast Guard Ethics Official or his or her designee may release a Confidential Financial Disclosure Report. Applicants can obtain this form by going to the website of the Office of Government Ethics (*www.oge.gov*) or by contacting the individual listed above in **FOR FURTHER INFORMATION CONTACT**.

Registered lobbyists are not eligible to serve on Federal Advisory Committees in an individual capacity. See ''Revised Guidance on Appointment of Lobbyists to federal advisory committees, Boards and Commissions'' (79 FR 47482, August 13, 2014). Registered lobbyists are lobbyists as defined in Title 2 U.S.C. 1602 who are required by Title 2 U.S.C. 1603 to register with the Secretary of the Senate and the Clerk of the House Representatives.

The Department of Homeland Security does not discriminate in selection of Committee members on the basis of race, color, religion, sex, national origin, political affiliation, sexual orientation, gender identity, marital status, disability and genetic information, age, membership in an employee organization, or other non-merit factor. The Department of Homeland Security strives to achieve a widely diverse candidate pool for all of its recruitment actions.

If you are interested in applying to become a member of the Committee, send your cover letter and resume to Mr. Rajiv Khandpur, Designated Federal Officer, Great Lakes Pilotage Advisory Committee, via one of the transmittal methods in the **ADDRESSES** section by the deadline in the **DATES** section of this notice. Email submittals will receive email receipt confirmation.

Dated: July 26, 2018.

Michael D. Emerson,

Director, Marine Transportation Systems.

[FR Doc. 2018–16335 Filed 7–30–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2018–0704]

Great Lakes Pilotage Advisory Committee

AGENCY: U.S. Coast Guard, Department of Homeland Security.

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: The Great Lakes Pilotage Advisory Committee will meet in Cape Vincent, New York, to discuss Committee matters relating to Great Lakes pilotage, including review of proposed Great Lakes pilotage regulations and policies. The meeting will be open to the public.

DATES:

Meeting: The Great Lakes Pilotage Advisory Committee will meet on Monday, September 10, 2018, from 8 a.m. to 5:30 p.m. EDT. Please note that this meeting may adjourn early if the Committee has completed its business.

Comments and supporting documents: To ensure your comments are received by Committee members before the meeting, submit your written comments no later than September 4, 2018.

ADDRESSES: The meeting will be held at a location owned and operated by Saint Lawrence Seaway Pilots Association, 230 N Point Street, Cape Vincent, New York 13618. *https://seawaypilots.com/.*

Pre-registration Information: Pre-registration is not required for access.

All attendees will be required to provide a government-issued picture identification card in order to gain admittance to the building.

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

Instructions: You are free to submit comments at any time, including orally at the meetings, but if you want Committee members to review your comment before the meetings, please submit your comments no later than September 4, 2018. We are particularly interested in comments on the issues in the ''Agenda'' section below. You must include the words ''Department of Homeland Security'' and the docket number USCG–0704. Written comments may also be submitted using the Federal e-Rulemaking Portal at *http://www.regulations.gov.* If you encounter technical difficulties with comment submission, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section below. Comments received will be posted without alteration at *http://www.regulations.gov,* including any personal information provided. You may review the Privacy and Security Notice for the Federal Docket Management System at *https://www.regulations.gov/privacyNotice.*

Docket Search: For access to the docket or to read documents or comments related to this notice, go to *http://www.regulations.gov,* and use ''USCG–2018–0704'' in the ''Search'' box, press Enter, and then click on the item you wish to view.

FOR FURTHER INFORMATION CONTACT: Mr. Vincent Berg, Alternate Designated Federal Officer of the Great Lakes Pilotage Advisory Committee, telephone (202) 906–0835, or email *Vincent.F.Berg@uscg.mil.*

SUPPLEMENTARY INFORMATION: Notice of this meeting is in compliance with the Federal Advisory Committee Act, Title 5, U.S.C. Appendix. The Great Lakes Pilotage Advisory Committee is established under the authority of 46 U.S.C. 9307, and makes recommendations to the Secretary of Homeland Security and the Coast Guard on matters relating to Great Lakes pilotage, including review of proposed Great Lakes pilotage regulations and policies.

Agenda: The Great Lakes Pilotage Advisory Committee will meet on Monday, September 10, 2018 to review, discuss, deliberate and formulate recommendations, as appropriate, on the following topics:

1. Annual rulemakings and financial reports—uniform system of accounts and uniform auditing practices;
2. Target pilot compensation study;
3. Use of the 10-year rolling average of traffic;
4. Weighting factors application to charges;
5. Itemized source form;
6. Working capital fund;
7. Pilot association projects;
8. Pilot association compensation practices;
9. Pilot association training for applicants and partners;
10. Labor disputes/6-hour rule;
11. Temporary registration;
12. Billing disputes/process;
13. Tug usage;

14. Competitive pilotage;
15. Recuperative rest for pilots;
16. Legislative changes;
17. Lake Ontario/Saint Lawrence River Traffic Challenges;
18. Public comment period.

A copy of all meeting documentation will be available at *https://dco.uscg.afpims.mil/Our-Organization/Assistant-Commandant-for-Prevention-Policy-CG-5P/Marine-Transportation-Systems-CG-5PW/Office-of-Waterways-and-Ocean-Policy/Office-of-Waterways-and-Ocean-Policy-Great-Laskes-Pilotage-Div/* by September 4, 2018. Alternatively, you may contact Mr. Vincent Berg as noted in the **FOR FURTHER INFORMATION CONTACT** section above.

Public comments or questions will be taken throughout the meeting as the Committee discusses the issues and prior to deliberations and voting. There will also be a public comment period at the end of the meeting. Speakers are requested to limit their comments to 5 minutes. Please note that the public comment period will end following the last call for comments. Contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section above, to register as a speaker.

Dated: July 26, 2018.

Michael D. Emerson,

Director, Marine Transportation Systems.

[FR Doc. 2018–16365 Filed 7–30–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Notice of Availability of Updated Privacy Impact Assessment for the Southwest Border Pedestrian Exit Field Test

AGENCY: U.S. Customs and Border Protection, DHS.

ACTION: Notice of availability.

SUMMARY: U.S. Customs and Border Protection (CBP) has made available an updated Privacy Impact Assessment (PIA) for the Southwest Border Pedestrian Exit Field Test. This updated PIA, which changes the retention period for certain biometric data gathered during the test, was published on the Department of Homeland Security (DHS) Privacy Office's website on March 5, 2018.

FOR FURTHER INFORMATION CONTACT: Debra Danisek, Privacy Officer, U.S. Customs and Border Protection, at *debra.danisek@cbp.dhs.gov* or (202) 344–1191.

SUPPLEMENTARY INFORMATION: U.S. Customs and Border Protection (CBP) conducted a test to collect certain biometric information at the Otay Mesa port of entry from December 2015 through June 2016 (''Southwest Border Pedestrian Exit Field Test''). This test was announced in a notice published in the **Federal Register** on November 13, 2015 (''2015 Notice'').[1] CBP published a Privacy Impact Assessment (PIA) for this test on the Department of Homeland Security (DHS) Privacy Office's website on November 6, 2015.[2] The purpose of the test was to determine if collecting biometrics in conjunction with biographic data upon exit from the United States would assist CBP in matching subsequent border crossing information records with previously collected entry records. The biometrics collected provide CBP with a baseline of images collected in a live environment that can be compared with existing images. CBP stated in the 2015 Notice and in the PIA that it would retain data collected during the test for one year.

Since the conclusion of the Southwest Border Pedestrian Exit Field Test, CBP has continued to explore the best collection methods and modalities for a biometric entry-exit program. CBP has found that the data collected in the Southwest Border Pedestrian Exit Field Test continues to have value because it provides CBP with a rich source of data for ongoing analysis in its efforts to implement an effective biometric entry-exit program. CBP and its vendors are able to use this data for analysis prior to expending additional time and resources to test various systems in the field. Therefore, CBP revised its retention policy for this data and published an updated PIA on the DHS Privacy Office's website on March 5, 2018. The updated PIA provides that CBP is retaining the biometric data gathered under the Southwest Border Pedestrian Exit Field Test until April 2020. It further provides that CBP is not storing the associated biographic information.

The updated PIA is available at: *https://www.dhs.gov/publication/dhscbppia-027-southwest-border-pedestrian-exit-field-test.*

[1] 80 FR 70241. In the 2015 Notice, the test was referred to as the ''Test to Collect Biometric Information at the Otay Mesa Port of Entry.''

[2] This PIA is available at: *https://www.dhs.gov/publication/dhscbppia-027-southwest-border-pedestrian-exit-field-test.*

Dated: July 26, 2018.

Debra Danisek,

CBP Privacy Officer, Privacy and Diversity Office, Office of the Commissioner.

[FR Doc. 2018–16351 Filed 7–30–18; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Notice of Issuance of Final Determination Concerning Subdermal Needle Electrodes

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of final determination.

SUMMARY: This document provides notice that U.S. Customs and Border Protection (''CBP'') has issued a final determination concerning the country of origin of Rhythmlink International, LLC's Subdermal Needle Electrode. Based upon the facts presented, CBP has concluded that the country of origin of the Subdermal Needle Electrode is the United States or Japan, depending on the country of origin of the needle electrode used in the assembly of the Subdermal Needle Electrode, for purposes of U.S. Government procurement.

DATES: The final determination was issued on July 13, 2018. A copy of the final determination is attached. Any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of this final determination no later than August 30, 2018.

FOR FURTHER INFORMATION CONTACT: James Kim, Valuation and Special Programs Branch, Regulations and Rulings, Office of Trade (202) 325–0158.

SUPPLEMENTARY INFORMATION: Notice is hereby given that on July 13, 2018, pursuant to subpart B of Part 177, U.S. Customs and Border Protection Regulations (19 CFR part 177, subpart B), CBP issued a final determination concerning the country of origin of Rhythmlink International, LLC's Subdermal Needle Electrode, which may be offered to the U.S. Government under an undesignated government procurement contract. This final determination, HQ H296072, was issued under procedures set forth at 19 CFR part 177, subpart B, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. 2511–18). In the final determination, CBP concluded that the assembly and processing in China does not result in a substantial transformation. Therefore,

the country of origin of Rhythmlink International, LLC's Subdermal Needle Electrode is the United States or Japan, depending on the country of origin of the needle electrode used in the assembly of the Subdermal Needle Electrode, for purposes of U.S. Government procurement.

Section 177.29, CBP Regulations (19 CFR 177.29), provides that a notice of final determination shall be published in the **Federal Register** within 60 days of the date the final determination is issued. Section 177.30, CBP Regulations (19 CFR 177.30), provides that any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of a final determination within 30 days of publication of such determination in the **Federal Register**.

Dated: July 13, 2018.

Alice A. Kipel,

Executive Director, Regulations and Rulings, Office of Trade.

HQ H296072

July 13, 2018

OT:RR:CTF:VS H296072 JK

CATEGORY: Origin

David S. Robinson
Nexsen Pruet, PLLC
4141 Parklake Avenue
Suite 200
Raleigh, NC 27612

RE: U.S. Government Procurement; Title III, Trade Agreements Act of 1979 (19 U.S.C. § 2511); Subpart B, Part 177, CBP Regulations; Subdermal Needle Electrode; Substantial Transformation

Dear Mr. Robinson:

This is in response to your correspondence of March 29, 2018, requesting a final determination on behalf of Rhythmlink International, LLC (''Rhythmlink''), pursuant to subpart B of Part 177, U.S. Customs and Border Protection (''CBP'') Regulations (19 C.F.R. § 177.21 *et seq.*).

This final determination concerns the country of origin of the Subdermal Needle Electrode. We note that Rhythmlink is a party-at-interest within the meaning of 19 C.F.R. § 177.22(d)(1) and is entitled to request this final determination.

FACTS:

Rhythmlink is headquartered in Columbia, North Carolina and manufactures and distributes medical devices and provides custom packaging, private labeling, custom products, and contract manufacturing to its customers.

The subject merchandise is a Subdermal Needle Electrode (''Product''), a high-tensile strength stainless steel wire cleared by the U.S. Food & Drug Administration (''FDA'') for performing both stimulating and recording electrical conductor functions. The Product serves as a physical connection between a patient and medical diagnostic equipment that records and/or elicits neurophysical biopotentials. The FDA classifies and designates the Product as a ''needle electrode,'' defined in FDA regulations as ''a device which is placed subcutaneously to stimulate or to record electrical signals.'' *See* 21 C.F.R. § 882.1350.

Rhythmlink's fully assembled, packaged Product consists of the following six component parts: the needle electrode, the leadwire, a miniscule amount of solder, a heat shrink tube, a protective cover for the needle, and packaging. Rhythmlink sells the Product in varying lengths and styles, and end users can customize the color of the connecting leadwire. The leadwire acts as an electrical conductor that transfers low voltage electrical signals from the needle electrode to medical diagnostic equipment. You state that the functionality of the Product is common to all lengths and is unchanged by the color of the pre-connected leadwire. You also state that other varieties of needle electrodes are available in the market that are not pre-connected to a leadwire. Such needle electrodes may connect to a leadwire without soldering by using alligator clips and other removable connectors. Other varieties of needle electrodes may utilize wireless transmission, eliminating the need for a leadwire altogether.

You state that Rhythmlink conducts all of the engineering and design of the Product in the United States. The engineering and design of the Subdermal Needle Electrode include the following steps: research and development; design control; IP generation; regulatory clearances; specifications; engineering drawings; work instructions; tooling, fixtures, and equipment designs; functional verification testing; sterilization validation; packaging, sterile barrier and shelf life validation; and process validations.

Rhythmlink outsources the actual manufacturing and production of the FDA-compliant needle electrodes (prior to being attached to other components) to a contract manufacturer of medical devices. The contract manufacturer manufactures the needle electrode entirely in either the United States or Japan using either U.S. or Japanese stainless steel material. You state that its production processes are largely proprietary and that the manufacturing costs are unknown. Under the manufacturing process of the needle electrode, a stainless steel wire is cut to precise lengths, and the cut wire undergoes precise facet grinding, passivation, and electropolishing. The needle electrode is manufactured to Rhythmlink's precise specifications, with three facets ground onto the front end to meet sharpness and insertion force requirements. Finally, it is packaged and shipped. The country of origin of the needle electrode is marked as either the United States or Japan, depending on the country in which it was manufactured.

The Korean-origin leadwire is a commercially available 26-gauge twisted copper wire comprising 19 strands of 38-gauge copper wire with medical grade PVC covering. The leadwire is available in a total of 35 color options. The Korean supplier of this wire cuts the wire, crimps a socket pin, attaches a connector to one end of the wire, and ships the wire to China.

The needle electrodes from the United States or Japan are exported to China for additional assembly and processing. The 'naked' end of the Korean leadwire is soldered to the needle electrode using Chinese-origin solder, which is a mix of tin and copper and represents a quarter of a percent of the Product's cost. You state that the soldering process takes roughly a second, substantiated by a video you provided of the process, and that six operators can professionally solder 30,000 Products in a day. The soldered Product undergoes ultrasonic cleaning and drying (spin and convention drying) in bulk. A Japanese-origin heat shrink tube, available in almost 40 different diameters, is added to protect the solder joint. A U.S.-origin protective needle cover is placed over the needle electrode to prevent accidents. Finally, the product is packaged in a Tyvek pouch and cardboard packaging of Chinese-origin and re-exported to the United States.

In the United States, the Product is subject to sterilization and a randomized sampling and testing protocol prior to sale.

You provided a catalog of Rhythmlink's products, which includes the Subdermal Needle Electrode. You also provided a detailed process map depicting the various processing steps involved in the engineering, manufacture, and sale of the Product, along with information on the country in which each step occurs and the skill and technology level required for each step. In addition, you provided component specifications for the Product.

ISSUE:

What is the country of origin of the Subdermal Needle Electrode for purposes of U.S. Government procurement?

LAW AND ANALYSIS:

CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers of certain ''Buy American'' restrictions in U.S. law or practice for products offered for sale to the U.S. Government, pursuant to subpart B of Part 177, 19 C.F.R. § 177.21 *et seq.,* which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. § 2511 *et seq.*) (''TAA'').

Under the rule of origin set forth under 19 U.S.C. § 2518(4)(B):

> An article is a product of a country or instrumentality only if (i) it is wholly the growth, product, or manufacture of that country or instrumentality, or (ii) in the case of an article which consists in whole or in part of materials from another country or instrumentality, it has been substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed.

See also 19 C.F.R. § 177.22(a).

In rendering advisory rulings and final determinations for purposes of U.S. Government procurement, CBP applies the provisions of subpart B of Part 177 consistent with Federal Acquisition Regulations. *See* 19 C.F.R. § 177.21. In this regard, CBP recognizes that the Federal Acquisition Regulations restrict the U.S. Government's purchase of products to U.S.-made or designated country end products for acquisitions subject to the TAA. *See* 48 C.F.R. § 25.403(c)(1). The Federal Acquisition Regulations define ''U.S.-made end product'' as:

> . . . an article that is mined, produced, or manufactured in the United States or that is substantially transformed in the United States into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed.

48 C.F.R. § 25.003.

A substantial transformation occurs when an article emerges from a process with a new name, character or use different from that possessed by the article prior to processing. A substantial transformation will not result from a minor manufacturing or combining process that leaves the identity of the article intact. *See United States* v. *Gibson-Thomsen Co.,* 27 C.C.P.A. 267 (1940); *National Juice Products Association* v. *United States,* 628 F. Supp. 978 (Ct. Int'l Trade 1986).

Courts have held that when the properties and uses of a product are predetermined by the material from which it was made, no substantial transformation occurs. For example, in *Superior Wire* v. *United States,* 669 F. Supp. 472 (Ct. Int'l Trade 1987), *aff'd,* 867 F.2d 1409 (Fed. Cir. 1989), wire rod in coils was shipped to Canada where it was drawn into wire. The tensile strength of the final product was increased by approximately 30 to 40 percent as the rod was reduced in cross-sectional area by about 30 percent and was elongated. The court determined that the drawing operation did not result in a substantial transformation, pointing out that the properties of the wire rod and its uses were determined by the chemical content of the rod and the cooling processes used in its manufacture, and that the wire rod dictated the final form of the finished wire.

For purposes of this ruling, we assume that the country of origin of the stainless steel wire used to manufacture the needle electrode is the United States or Japan. You assert that the assembly and processing that occurs in China, a non-designated country, does not substantially transform the U.S. or Japanese-origin needle electrode, claimed to be the essential character of the Product, into a new and different article of commerce.

In HQ 555774, dated December 10, 1990, Customs, a predecessor of CBP, ruled that Japanese-origin wire cut to varying length and electrical connectors crimped onto the ends of the wire in the United States did not constitute substantial transformation. Customs found that the essential character and use of the wire before and after the processing was the same, *i.e.,* to conduct electrical current.

In HQ H248851, dated July 8, 2014, CBP held that an Israeli-origin CO2 tube was not substantially transformed in China when cut to length and attached to four other components from Israel and China. CBP found that the CO2 tube performed the essential function of the finished product, which was the delivery of breath for monitoring the CO2 level in a patient's breath. By way of the assembly process in China, the CO2 tube was attached to other components that facilitated its function and did not lose its individual identity in the process.

Like the operations described in HQ 555774 and HQ H248851, the assembly and processing that occur in China are simple and minor processes that leave the identity of the needle electrode intact. The soldering of the leadwire to the needle electrode occurs in roughly one second. The remaining processing of the Product, consisting of cleaning and drying, adding a heat shrink and protective cover, and packaging, are likewise simple and minor operations involving highly repetitive, low-skill functions.

As in *Superior Wire,* the properties and uses of the Product are predetermined by the qualities of the needle electrode itself, which do not change as a result of the Chinese assembly and processing operations. The Product's main function is to penetrate the skin or other membrane to allow medical diagnostic equipment to record or stimulate neurophysical biopotentials. While the presence of a pre-connected leadwire does provide convenience for the end user, by eliminating the need to use removable connectors for attaching a leadwire, the needle electrode is nonetheless capable of performing its main function without a pre-connected leadwire. Prior to any Chinese assembly or processing, the needle electrode already meets the definition of the FDA regulated ''needle electrode.'' As in HQ H248851, the attachment of the leadwire and other components to the needle electrode may facilitate its function, but the needle electrode does not lose its individual identity in the process. As a result, we find that the U.S. or Japanese-origin needle electrode, rather than the Korean-origin leadwire, determines the essential character of the Product.

We find that the name, character, and use of the needle electrode remain unchanged after the attachment of the leadwire and other components. Accordingly, we find that the needle electrode is not substantially transformed as a result of the Chinese assembly and processing operations.

HOLDING:

The country of origin of the Subdermal Needle Electrode for U.S. Government procurement purposes is the United States or Japan, depending on the country of origin of the needle electrode.

Notice of this final determination will be given in the **Federal Register**, as required by 19 C.F.R. § 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 C.F.R. § 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 C.F.R. § 177.30, any party-at-interest may, within 30 days after publication of the **Federal Register** notice referenced above, seek judicial review of this final

determination before the Court of International Trade.

Sincerely,

Alice A. Kipel

Executive Director
Regulations and Rulings
Office of Trade

[FR Doc. 2018–16281 Filed 7–30–18; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2018–0003]

Privacy Act of 1974; System of Records

AGENCY: Department of Homeland Security.

ACTION: Notice of a new system of records.

SUMMARY: In accordance with the Privacy Act of 1974, the Department of Homeland Security (DHS) proposes to consolidate two legacy systems of record, Department of Homeland Security/U.S. Citizenship and Immigration Services-002 Background Check Service and Department of Homeland Security/U.S. Citizenship and Immigration Services-003 Biometric Storage System into the new DHS system of records titled, ''Department of Homeland Security/U.S. Citizenship and Immigration Services-018 Immigration Biometric and Background Check System of Records.'' This system of records notice (SORN) allows the DHS U.S. Citizenship and Immigration Services (USCIS) to collect and maintain biographic, biometric, and background check records on applicants, petitioners, sponsors, beneficiaries, or other individuals in connection with a benefit request. USCIS uses biometric and associated biographic information to verify identity, conduct criminal and national security background checks against internal and external government systems, and to support domestic and foreign data sharing agreements. The categories of individuals, categories of records, and the routine uses of these legacy systems of records notices have been consolidated and updated to better reflect the Department's biometric and biographic criminal background checks; identity enrollment, verification, and resolution; document production record systems; and data sharing efforts.

Additionally, DHS is issuing a Notice of Proposed Rulemaking (NPRM) to exempt this system of records from certain provisions of the Privacy Act, elsewhere in the **Federal Register**. This new system will be included in DHS's inventory of record systems.

DATES: Submit comments on or before August 30, 2018. This system will be effective upon publication. Routine uses will become effective August 30, 2018.

ADDRESSES: You may submit comments, identified by docket number DHS–2018–0003 by one of the following methods:

- *Federal e-Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–343–4010.
- *Mail:* Philip S. Kaplan, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528–0655.

Instructions: All submissions received must include the agency name and docket number DHS–2018–0003 for this notice. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For general questions, please contact: Donald K. Hawkins, (202) 272–8030, *USCIS.PrivacyCompliance@uscis.dhs.gov,* Privacy Officer, U.S. Citizenship and Immigration Services, 20 Massachusetts Avenue NW, Washington, DC 20529. For privacy questions, please contact: Philip S. Kaplan, (202) 343–1717, *Privacy@hq.dhs.gov,* Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528–0655.

SUPPLEMENTARY INFORMATION:

I. Background

DHS USCIS has relied on two preexisting DHS/USCIS Privacy Act SORNs for the maintenance of USCIS biometric and background check records: ''DHS/USCIS 002 Background Check Service,'' 72 FR 31082 (June 5, 2007), and ''DHS/USCIS–003 Biometric Storage System,'' 72 FR 17172 (April 6, 2007). Such records will be covered by one new system of records named ''DHS/USCIS–018 Immigration Biometric and Background Check (IBBC) System of Records.'' USCIS processes and adjudicates most immigration benefit requests and other immigration request forms (*e.g.,* applications and petitions) for DHS. This new system of records notice consolidates and covers all of USCIS's biometric and associated biographic information it collects pursuant to that mission. The purpose of this system is to verify identity and conduct criminal and national security background checks in order to establish an individual's eligibility for an immigration benefit or other request, and support domestic and international data sharing efforts. USCIS determines eligibility by capturing biometric and associated biographic data from benefit requestors, beneficiaries, and other categories of individuals to facilitate three key operational functions: (1) Verify an individual's identity; (2) conduct criminal and national security background checks; and (3) produce benefit cards and documents as a proof of benefit.

Most individuals who file benefit requests for themselves or on the behalf of others (*i.e.,* petitioner, applicants, beneficiaries, and requestors) are subject to background, identity, and security checks to ensure eligibility for the requested benefit. Other individuals in connection with immigration benefit requests or other requests (*i.e.,* household members, sponsors) may also be subject to certain background, identity, and security checks. The biometric collection process begins with the capture of biometric data at an authorized biometric capture site, including USCIS offices, Application Support Centers, or U.S. consular offices and military installations abroad. USCIS requires applicants, petitioners, sponsors, beneficiaries, or other individuals in connection of a benefit request to submit their biometrics along with associated biographic information to USCIS for background, identity, and security checks. The types of background checks USCIS conducts vary by the benefit or request type. Standard background checks may include, but are not limited to:

Biometric based checks:

- Federal Bureau of Investigation (FBI) Next Generation Identification (NGI) Biometric Check;
- DHS Office of Biometric and Identity Management (OBIM) Automated Biometric Identification System (IDENT) Biometric Check;
- Department of Defense (DoD) Automated Biometric Identification System (ABIS) Biometric Check;

Biographic name-based checks:

- FBI Central Records System (CRS) and Universal Index (UNI) Name Check;
- U.S. Customs and Border Protection (CBP) TECS Name Checks;
- Department of State (DOS) Consular Lookout and Support System (CLASS); and
- DOS Security Advisory Opinion (SAO).

USCIS may also perform interagency checks with intelligence community partners for certain benefits. The results of these checks are used to inform

eligibility determinations, which will result in the approval or denial of a benefit. If fraudulent activity, criminal activity, or potential threats to public safety or national security are detected as a result of the biometric or name check, information may be referred to the USCIS Fraud Detection and National Security Directorate (FDNS) or appropriate law enforcement agencies for further review. These law enforcement agencies include U.S. Immigration and Customs Enforcement (ICE), CBP, FBI, or other federal, state, local, tribal, foreign, or international law enforcement agencies. USCIS may also conduct additional background and security checks against other federal, international, state, and local systems to verify the identity of the individual as part of the eligibility determination for a benefit or request, as appropriate.

USCIS sends biometric, associated biographic, and encounter-related data to IDENT to conduct biometric searches against the system. IDENT is the central DHS-wide information technology system for enrollment, storage, and processing of biometric and associated biographic information. IDENT is maintained for the purposes of national security, law enforcement, immigration and border management, intelligence, and credentialing (*e.g.,* background investigations for national security positions and certain positions of public trust), as well as for other administrative uses (*e.g.,* providing associated testing, training, management reporting, or planning and analysis). When an authorized request is received by OBIM, the program management office for IDENT, analysts search IDENT for biometric matches and assign matches as new encounters into IDENT on behalf of USCIS. Consistent with this SORN and other SORNs governing different biometric data sets in IDENT, USCIS biographic and biometric information from IDENT may be shared with federal, state, local, tribal, foreign, and international agencies for national security, law enforcement, criminal justice, immigration and border management, and intelligence purposes. In addition, information from IDENT may also be shared for background investigations for national security positions and certain positions of public trust in accordance with statutory and regulatory restrictions on disclosure.

International Biometric Sharing Initiatives

This system of records supports the biometric vetting capability outlined in data sharing agreements between DHS and certain foreign partners. USCIS may send and receive biometric requests to and from certain foreign partners through IDENT in support of its immigration mission and applicable laws. The purpose of these data sharing initiatives is to enhance the cooperation between the United States and foreign partners to prevent terrorism, including terrorist travel; prevent serious crime and other threats to national security and public safety; assist in the administration and enforcement of immigration laws; and provide the foreign partner with appropriate information for its consideration when adjudicating requests for immigration benefits including, but not limited to, asylum or refugee status. Through international sharing agreements, USCIS may share biometric and associated biographic information stored in IDENT, which it collected in determining suitability for an immigration benefit, with foreign partners. DHS does not permit third party disclosure without prior approval.

Document Production

Once the adjudication of certain immigration benefits are complete, USCIS creates official, personalized and secure identity documents to certify the grant of the requested benefit. The secure identification documents USCIS produces and issues are high-quality and state-of-the-art, incorporating tamper-resistant, machine-readable, and biometrically-enabled technologies designed to withstand document counterfeiting efforts, alteration, or efforts employed to commit fraud.

Information stored in the DHS/USCIS–018 IBBC System of Records may be shared with other DHS Components that have a need to know the information to carry out their national security, law enforcement, immigration, intelligence, or other homeland security functions. In addition, DHS/USCIS may share information with appropriate federal, state, local, tribal, territorial, foreign, or international government agencies consistent with the routine uses set forth in this system of records notice.

Additionally, DHS is issuing an NPRM to exempt this system of records from certain provisions of the Privacy Act elsewhere in the **Federal Register**. This new system of records will be included in DHS's inventory of record systems.

II. Privacy Act

The Privacy Act embodies fair information practice principles in a statutory framework under which Federal Government agencies collect, maintain, use, and disseminate individuals' records. The Privacy Act applies to information that is maintained in a ''system of records.'' A ''system of records'' is a group of any records under the control of an agency from which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. In the Privacy Act, an individual is defined to encompass U.S. citizens and lawful permanent residents. Additionally, the Judicial Redress Act (JRA) provides statutory rights to covered persons to request access and amendment to covered records, as defined by the JRA, along with judicial review for denials of such requests. In addition, the JRA prohibits disclosures of covered records, except as otherwise permitted by the Privacy Act.

Below is the description of the DHS/USCIS–018-Immigration Biometric and Background Check (IBBC) System of Records.

In accordance with 5 U.S.C. 552a(r), DHS has provided a report of this system of records to the Office of Management and Budget and to Congress.

SYSTEM NAME AND NUMBER:

DHS/USCIS–018 Immigration Biometric and Background Check (IBBC) System of Records.

SECURITY CLASSIFICATION:

Unclassified and classified. The data may be retained on classified networks but this does not change the nature and character of the data until it is combined with classified information.

SYSTEM LOCATION:

DHS/USCIS maintains records in DHS-approved data centers in the Washington, DC, metropolitan area. Backups are maintained offsite. IBBC will be accessible world-wide from all USCIS field offices, service centers, and Application Service Centers that are part of the DHS Network. Paper files are located at USCIS Headquarters in Washington, DC and in DHS/USCIS service centers, domestic and international field offices, and other USCIS facilities. USCIS stores biometric records in the DHS biometrics repository, OBIM IDENT.

DHS/USCIS replicates records from the operational IT systems and maintains them in other IT systems connected on the DHS unclassified and classified networks.

SYSTEM MANAGER(S):

Associate Director, Immigration Records and Identity Services, *BD.systems@uscis.dhs.gov,* U.S. Citizenship and Immigration Services,

Department of Homeland Security, 111 Massachusetts Avenue NW, Washington, DC 20529.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

8 U.S.C. 1101 and 1103; 8 CFR 103.16(a); and 8 CFR 103.2(b)(9).

PURPOSE(S) OF THE SYSTEM:

The purpose of this system is to assist USCIS with determining an individual's eligibility for an immigration benefit request or other USCIS requests. USCIS captures biographic and biometric data from applicants, petitioners, sponsors, beneficiaries, or other individuals to facilitate three key operational functions: (1) Enroll, verify, and manage an individual's identity; (2) conduct criminal and national security background checks; and (3) produce benefit cards/documents as a proof of benefit. Also, the purpose of this system is to (4) support data sharing initiatives between DHS components, other U.S. Government agencies and foreign partners in order to prevent terrorism, including terrorist travel; prevent serious crime and other threats to national security and public safety; and assist in the administration and enforcement of immigration laws.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Categories of individuals covered by this system include:

- Persons who have filed on their own behalf, or on the behalf of others, applications or petitions for immigration benefits or other requests under the Immigration and Nationality Act (INA) (*i.e.,* applicants, petitioners, and beneficiaries), as amended;
- Current, former, and potential derivative family members of benefit requestors;
- Affiliated persons who have a clearly articulated rational connection to the request, applicant, petitioner, or beneficiary, that may have an impact on the adjudication process of a request;
- Associates whose information is voluntarily provided by the applicant as part of the family tree, and which include points of contact in the United States and other individuals with whom the applicant associates (*i.e.,* household members, sponsors);
- Attorneys and representatives recognized by USCIS and/or accredited by the Board of Immigration Appeals (Representatives); and
- All individuals who meet the definition of an adult member of the household, 8 CFR 204.3(b) or 8 CFR 204.301; and/or any other individual whose presence in the applicant's or petitioner's residence is relevant to the prospective adoptive parent(s)'s suitability to adopt overseas.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system covers biographic, biometric, unique machine-generated identifiers, encounter-related data, criminal and national security background check results, and card production information.

Biographic information may include:

- Full name;
- Aliases;
- Other names;
- Date of birth;
- Place of birth;
- Country of Citizenship/Nationality;
- Current and previous immigration status;
- Mailing and physical address;
- Phone number;
- Employment status;
- Travel Document Numbers (*i.e.,* passport numbers, I–94 number);
- Travel Document Information (*i.e.,* country of issuance, nationality, date of issuance, expiration date);
- Case Type (*i.e.,* refugee claimant, identity investigation, absconder, visa applicant);
- Filing date;
- Filing determination;
- Reason for filing determination;
- Gender;
- Height;
- Weight;
- Eye color;
- Hair color;
- Race/Ethnicity; and
- Unique Identifying Numbers, including, but not limited to, Alien Registration Number (Alien Number), Receipt Number, Social Security number (SSN), and USCIS Online Account Number.

Biometric information may include:

- Biometric images (including, but not limited to: Photographs/facial images, fingerprint images, iris images, voice samples, and signatures); and
- Details about images (*i.e.,* capture date, reason fingerprinted, and location).

Encounter information may include:

- Scan of marked travel document page;
- Foreign partner point of contact information;
- Watchlist indicator, indicator of derogatory information, or reason for alert;
- Arrival, Departure, and/or Removal information (date and location);
- Transaction Control Numbers Associated with FBI fingerprint checks;
- Date/time of submission;
- Type of immigration form or non-biometric encounter;
- Date of immigration form or non-biometric encounter;
- Query results (match or no match);
- Error code; and
- Transaction Identifier Data (*i.e.,* sending organization; timestamp; date; transaction type; case type; priority level; message origin; message destination; reference numbers (requesting participants subject specific reference number; or requesting participants event specific reference number); workstation; reason fingerprinted, such as entry, visa application, credentialing application, or apprehension; and any available encounter information, including an IDENT-generated encounter identification number (EID)).

BACKGROUND CHECK INFORMATION MAY INCLUDE:

- Results of criminal and national security background checks (*i.e.,* positive or negative response; and positive responses are generally accompanied with the individual's criminal history and additional information explaining the results of the response); Unique Biometric Identifier (*i.e.,* Fingerprint Identification Number (FIN) and Universal Control Number (formerly known as FBI Number)); and
- Logs associated with the requests of background checks, which may include requesting location and requesting person.

Document Production information may include:

- Identifying Transactional Information (*i.e.,* transaction control number, book number);
- Biographical Information used for Document Production;
- Document Production Status;
- Benefit Card/Document Type;
- Class of Admission;
- Document Serial Number;
- Radio Frequency Identification (RFID) with USCIS Issued Document;
- Machine-readable Barcode;
- Production Site;
- Production Status; and
- Document Issuance Time/Date and Expiration Date.

RECORD SOURCE CATEGORIES:

Records are obtained from the categories of individuals included in this SORN. Information contained in this system may also be supplied by DHS, other U.S. Federal, state, tribal, or local government agencies, foreign government agencies, and international organizations. USCIS personnel may input information as they process a case, including information from internal and external sources, and to verify whether a benefit requestor or family is eligible for the benefit requested. Records covered by other

systems of records (or their successor systems) that are ingested and covered by this SORN include the following:

1. DHS/USCIS/ICE/CBP–001 Alien File, Index, and National File Tracking System of Records, 82 FR 43556 (Sept. 18, 2017);

2. DHS/USCIS–005 Intercountry Adoptions Security, 81 FR 78614 (Nov. 8, 2016);

3. DHS/USCIS–006 Fraud Detection and National Security Records (FDNS), 77 FR 47411 (Aug. 8, 2012);

4. DHS/USCIS–007 Benefit Information System, 81 FR 72069 (Oct. 19, 2016);

5. DHS/USCIS–010 Asylum Information and Pre-Screening, 80 FR 74781 (Nov. 30, 2015);

6. DHS/USCIS–017 Refugee Case Processing and Security Screening Information, 81 FR 72075 (Oct. 19, 2016);

7. DHS/CBP–011 U.S. Customs and Border Protection TECS, 73 FR 77778 (Dec. 19, 2008);

8. DHS/ICE–011-Criminal Arrest Records and Immigration Enforcement Records (CARIER) System of Records, 81 FR 72080 (Oct. 19, 2016);

9. DHS/US–VISIT–001 DHS Automated Biometric Identification System (IDENT), 72 FR 31080 (June 5, 2007);

10. DHS/ALL–041 External Biometric Records (EBR) System of Records, 83 FR 17829 (April 24, 2018);

11. JUSTICE/FBI–002 The FBI Central Records System, 82 FR 24147 (May 25, 2017), and prior history (*https://www.justice.gov/opcl/doj-systems-records*);

12. JUSTICE/FBI–009 The Next Generation Identification (NGI) System, 81 FR 27283 (May 5, 2016), and 82 FR 24151 (May 25, 2017);

13. STATE–05 Overseas Citizens Services Records and Other Overseas Records, 81 FR 62235 (Sept. 8, 2016);

14. STATE–26 Passport Records, 80 FR 15653 (March 24, 2015);

15. STATE–39 Visa Records, 77 FR 65245 (Oct. 25, 2012);

16. STATE–59 Refugee Case Records, 77 FR 5865 (Feb. 6, 2012);

17. ODNI/NCTC–008 National Counterterrorism Center Terrorism Analysis Records, 72 FR 73895 (Dec. 28, 2007);

18. DoD/A0025–2 Defense Biometric Services, 74 FR 48237 (Sept. 22, 2009);

19. DoD/A0025–2 PMG (DFBA) Defense Biometric Identification Records System, 80 FR 8292 (Feb. 17, 2015); and

20. DoD/A0025–2a Defense Biometric Identification Records System, 74 FR 17840 (April 17, 2009).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

Information in this system of records contains information relating to certain persons who have pending or approved benefit requests for special protected class status and should not be disclosed pursuant to a routine use unless disclosure is otherwise permissible under the confidentiality statutes, regulations, or policies applicable to that information. For example, information relating to persons who have applied for asylum or refugee status, have pending or approved benefit requests for protection under the Violence Against Women Act, Seasonal Agricultural Worker or Legalization claims, the Temporary Protected Status of an individual, and information relating to certain nonimmigrant visas. These confidentiality provisions do not prevent DHS from disclosing information to the Department of Justice (DOJ) and Offices of the United States Attorneys as part of an ongoing criminal or civil investigation.

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside DHS as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

A. To the DOJ, including Offices of the U.S. Attorneys, or other federal agency conducting litigation or in proceedings before any court, adjudicative, or administrative body, when it is relevant or necessary to the litigation and one of the following is a party to the litigation or has an interest in such litigation:

1. DHS or any component thereof;

2. Any employee or former employee of DHS in his/her official capacity;

3. Any employee or former employee of DHS in his/her individual capacity when DOJ or DHS has agreed to represent the employee; or

4. The United States or any agency thereof.

B. To a congressional office from the record of an individual in response to an inquiry from that congressional office made at the request of the individual to whom the record pertains.

C. To the National Archives and Records Administration (NARA) or General Services Administration pursuant to records management inspections being conducted under the authority of 44 U.S.C. 2904 and 2906.

D. To an agency or organization for the purpose of performing audit or oversight operations as authorized by law, but only such information as is necessary and relevant to such audit or oversight function.

E. To appropriate agencies, entities, and persons when (1) DHS suspects or has confirmed that there has been a breach of the system of records; (2) DHS has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, DHS (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with DHS's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

F. To another Federal agency or Federal entity, when DHS determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

G. To contractors and their agents, grantees, experts, consultants, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for DHS, when necessary to accomplish an agency function related to this system of records. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to DHS officers and employees.

H. To an appropriate Federal, state, tribal, local, international, or foreign law enforcement agency or other appropriate authority charged with investigating or prosecuting a violation or enforcing or implementing a law, rule, regulation, or order, when a record, either on its face or in conjunction with other information, indicates a violation or potential violation of law, which includes criminal, civil, or regulatory violations and such disclosure is proper and consistent with the official duties of the person making the disclosure.

I. To appropriate Federal, state, local, tribal, territorial, or foreign governments, as well as to other individuals and organizations during the course of an investigation by DHS or the processing of a matter under DHS's jurisdiction, or during a proceeding within the purview of the immigration and nationality laws, when DHS deems

that such disclosure is necessary to carry out its functions and statutory mandates.

J. To a former employee of DHS, in accordance with applicable regulations, for purposes of: Responding to an official inquiry by a Federal, state, or local government entity or professional licensing authority; or facilitating communications with a former employee that may be necessary for personnel-related or other official purposes when DHS requires information or consultation assistance from the former employee regarding a matter within that person's former area of responsibility.

K. To a coroner, in accordance with applicable law and regulations, for purposes of affirmatively identifying a deceased individual (whether or not such individual is deceased as a result of a crime).

L. To a Federal, state, or local government agency seeking to verify or ascertain the citizenship or immigration status of any individual within the jurisdiction of the agency for any purpose authorized by law

M. To an appropriate domestic government agency or other appropriate authority for the purpose of providing information about an individual who has been or is about to be released from DHS custody who, due to a condition such as mental illness, may pose a health or safety risk to himself/herself or to the community. DHS will only disclose information about the individual that is relevant to the health or safety risk they may pose and/or the means to mitigate that risk (*e.g.,* the individuals need to remain on certain medication for a serious mental health condition).

N. To foreign governments for the purpose of coordinating and conducting the removal of individuals to other nations under the INA; and to international, foreign, and intergovernmental agencies, authorities, and organizations in accordance with law and formal or informal international arrangements.

O. To DOJ FBI for the purpose of conducting name and fingerprint background checks in order to verify the identity of an individual and generate information used to grant or deny an immigration benefit request or other request.

P. To U.S. Department of State for the purpose of conducting biographic and biometric based searches for identity verification in order to process requests for benefits under the INA, and all other immigration and nationality laws including treaties and reciprocal agreements; or when DOS requires information to consider and/or provide an informed response to a request for information from a foreign, international, or intergovernmental agency, authority, or organization about an alien or an enforcement operation with transnational implications.

Q. To U.S. Department of Defense for the purpose of biometric background checks to verify the identity of an individual and generate information used to grant or deny an immigration benefit request or other request.

R. To the Office of the Director of National Intelligence National Counterterrorism Center (ODNI/NCTC) and other Federal and foreign government intelligence or counterterrorism agencies when USCIS becomes aware of an indication of a threat or potential threat to national or international security, or when such use is to assist in anti-terrorism efforts and disclosure is appropriate to the proper performance of the official duties of the person making the disclosure.

S. To an individual's prospective or current employer to the extent necessary to determine employment eligibility (for example, pursuant to the Form I–140, *Immigrant Petition for Alien Worker*).

T. To the news media and the public, with the approval of the Chief Privacy Officer in consultation with counsel, when there exists a legitimate public interest in the disclosure of the information, when disclosure is necessary to preserve confidence in the integrity of DHS, or when disclosure is necessary to demonstrate the accountability of DHS's officers, employees, or individuals covered by the system, except to the extent the Chief Privacy Officer determines that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

DHS/USCIS stores records in this system electronically or on paper in secure facilities in a locked drawer behind a locked door. The records may be stored on magnetic disc, tape, and digital media.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records may be retrieved by any of the data elements listed above or a combination thereof. This may include, but is not limited to, name, date of birth, Alien Number, SSN, USCIS Online Account Number, and Receipt Number.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

USCIS retains the records 100 years from the date of birth of the individual in accordance with NARA Disposition Authority Number DAA–0563–2013–0001–0005. USCIS collects and uses the information to verify the identity of the individual and support the background check process. The 100-year retention rate comes from the length of time USCIS may interact with a customer. Further, retaining the data for this period of time will enable USCIS to fight identity fraud and misappropriation of benefits.

USCIS generates secure identification documents to communicate adjudication decisions to the mailing address on file for the benefit requestor or his or her legal representative. USCIS systems that generate cards and documents retain data 10 years from the date of record creation in accordance with NARA Disposition Authority Number DAA–0566–2016–0014. Proof of benefits sent to the benefit requestor and returned to USCIS are retained by USCIS for up to one year in accordance with NARA Disposition Authority Number DAA–0566–2014–0005.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

DHS/USCIS safeguards records in this system according to applicable rules and policies, including all applicable DHS automated systems security and access policies. USCIS has imposed strict controls to minimize the risk of compromising the information that is being stored. Access to the computer system containing the records in this system is limited to those individuals who have a need to know the information for the performance of their official duties and who have appropriate clearances or permissions.

RECORD ACCESS PROCEDURES:

The Secretary of Homeland Security has exempted this system from the notification, access, and amendment procedures of the Privacy Act, and consequently the JRA if applicable, because it may interfere with ongoing investigations and law enforcement activities. However, DHS will consider individual requests to determine whether or not information may be released. Thus, individuals seeking access to and notification of any record contained in this system of records, or seeking to contest its content, may submit a request in writing to the Chief Privacy Officer and Headquarters or component's FOIA Officer, whose contact information can be found at *http://www.dhs.gov/foia* under

''Contacts Information.'' If an individual believes more than one component maintains Privacy Act records concerning him or her, the individual may submit the request to the Chief Privacy Officer and Chief FOIA Officer, Department of Homeland Security, Washington, DC 20528–0655. Even if neither the Privacy Act nor the Judicial Redress Act provide a right of access, certain records about the individual may be available under the Freedom of Information Act.

When an individual is seeking records about himself or herself from this system of records or any other Departmental system of records, the individual's request must conform with the Privacy Act regulations set forth in 6 CFR part 5. The individual must first verify his or her identity, meaning that the individual must provide his or her full name, current address, and date and place of birth. The individual must sign the request, and the individual's signature must either be notarized or submitted under 28 U.S.C. 1746, a law that permits statements to be made under penalty of perjury as a substitute for notarization. While no specific form is required, an individual may obtain forms for this purpose from the Chief Privacy Officer and Chief FOIA Officer, *http://www.dhs.gov/foia* or 1–866–431–0486. In addition, the individual should:

- Explain why the individual believe the Department would have information on him or her;
- Identify which component(s) of the Department the individual believes may have the information about him or her;
- Specify when the individual believes the records would have been created; and
- Provide any other information that will help the FOIA staff determine which DHS component agency may have responsive records;

If an individual's request is seeking records pertaining to another living individual, the first individual must include a statement from that individual certifying his/her agreement for the first individual to access his/her records.

Without the above information, the component(s) may not be able to conduct an effective search, and the individual's request may be denied due to lack of specificity or lack of compliance with applicable regulations.

CONTESTING RECORD PROCEDURES:

For records covered by the Privacy Act or covered JRA records, see ''Records Access Procedures'' above. Any individual, regardless of immigration status, may file a request to access his or her information under the FOIA. Throughout the benefit determination process, and prior to USCIS making a determination to deny a benefit request, USCIS provides individuals with the opportunity to address and correct the information.

NOTIFICATION PROCEDURES:

See ''Record Access Procedures.''

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

The Secretary of Homeland Security, pursuant to Secretary's delegation number 15002 to the Director of USCIS to conduct certain law enforcement activities, when necessary to protect the national security and public safety, pursuant to 5 U.S.C. 552a(j)(2), is proposing to exempt this system from the following provisions of the Privacy Act: 5 U.S.C. 552a(c)(3), (c)(4); (d); (e)(1), (e)(2), (e)(3), (e)(4)(G), (e)(4)(H), (e)(4)(I), (e)(5), (e)(8); (f); and (g). Additionally, the Secretary of Homeland Security, pursuant to 5 U.S.C. 552a(k)(2), has exempted this system from the following provisions of the Privacy Act: 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (e)(4)(H), (e)(4)(I), and (f). When a record received from another system has been exempted in that source system under 5 U.S.C. 552a(j)(2), DHS will claim the same exemptions for those records that are claimed for the original primary systems of records from which they originated and claims any additional exemptions set forth here.

HISTORY:

DHS/USCIS–002 Background Check Service, 72 FR 31082 (June 5, 2007); DHS/USCIS–003 Biometric Storage System, 72 FR 17172 (April 6, 2007).

Philip S. Kaplan,

Chief Privacy Officer, Department of Homeland Security.

[FR Doc. 2018–16138 Filed 7–30–18; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6083–N–02]

Notice of a Federal Advisory Committee Meeting: Manufactured Housing Consensus Committee

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, Department of Housing and Urban Development (HUD).

ACTION: Notice of a Federal Advisory Committee Meeting: Manufactured Housing Consensus Committee (MHCC).

SUMMARY: This notice sets forth the schedule and proposed agenda for a meeting of the MHCC. The meeting is open to the public and the site is accessible to individuals with disabilities. The agenda provides an opportunity for citizens to comment on the business before the MHCC.

DATES: The meeting will be held on September 11 through September 13, 2018, 9:00 a.m. to 5:00 p.m. Eastern Standard Time (EST) daily.

ADDRESSES: The meeting will be held at the Holiday Inn Washington—Capitol, 550 C Street SW, Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Teresa B. Payne, Acting Administrator, Office of Manufactured Housing Programs, Department of Housing and Urban Development, 451 7th Street SW, Room 9166, Washington, DC 20410, telephone (202) 708–6423 (this is not a toll-free number). Persons who have difficulty hearing or speaking may access this number via TTY by calling the toll-free Federal Information Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Background

Notice of this meeting is provided in accordance with the Federal Advisory Committee Act, 5. U.S.C. App. 10(a)(2) through implementing regulations at 41 CFR 102–3.150. The MHCC was established by the National Manufactured Housing Construction and Safety Standards Act of 1974, 42 U.S.C. 5403(a)(3), as amended by the Manufactured Housing Improvement Act of 2000, (Pub. L. 106–569). According to 42 U.S.C. 5403, as amended, the purposes of the MHCC are to:

- Provide periodic recommendations to the Secretary to adopt, revise, and interpret the Federal manufactured housing construction and safety standards in accordance with this subsection;
- Provide periodic recommendations to the Secretary to adopt, revise, and interpret the procedural and enforcement regulations, including regulations specifying the permissible scope and conduct of monitoring in accordance with subsection (b);
- Be organized and carry out its business in a manner that guarantees a fair opportunity for the expression and consideration of various positions and for public participation.

The MHCC is deemed an advisory committee not composed of Federal employees.

Public Comment

Citizens wishing to make comments on the business of the MHCC are

encouraged to register by or before Tuesday, August 28, 2018, by contacting Home Innovation Research Labs; *Attention:* Kevin Kauffman, 400 Prince Georges Blvd., Upper Marlboro, MD 20774, or email to *mhcc@homeinnovation.com* or call 1–888–602–4663. Written comments are encouraged. The MHCC strives to accommodate citizen comments to the extent possible within the time constraints of the meeting agenda. Advance registration is strongly encouraged. The MHCC will also provide an opportunity for public comment on specific matters before the MHCC.

Tentative Agenda

Tuesday, September 11, 2018

I. Call to Order—Chair & Designated Federal Officer (DFO)
II. Opening Remarks—Chair & HUD
A. Roll Call—Administering Organization (AO)
B. Introductions
i. HUD Staff
ii. Guests
C. Administrative Announcements—DFO & AO
III. Approve draft minutes from December 12, 2016, MHCC meeting
IV. Update on the Regulatory Process
V. Update on Approved Proposals—HUD OGC
VI. Review of Current Log & Action Items
VII. Break
VIII. Continue Review of Current Log & Action Items
IX. Public Comment Period
X. Lunch
XI. Continue Review of Current Log & Action Items
XII. Break
XIII. Continue Review of Current Log & Action Items
XIV. Daily Wrap Up—DFO & AO
XV. Adjourn

Wednesday, September 12, 2018

I. Reconvene Meeting—Chair & Designated Federal Officer (DFO)
II. Opening Remarks—Chair
A. Roll Call—Administering Organization (AO)
III. Continue Review of Current Log & Action Items
IV. Break
V. Continue Review of Current Log & Action Items
VI. Public Comment
VII. Lunch
VIII. Continue Review of Current Log & Action Items or Subcommittee/Task Group Meetings
IX. Break
X. Continue Review of Current Log & Action Items or Subcommittee/Task Group Meetings
XI. Daily Wrap Up—DFO
XII. Adjourn

Thursday, September 13, 2018

I. Reconvene Meeting—Chair & Designated Federal Officer (DFO)
II. Opening Remarks—Chair & FHA Commissioner
A. Roll Call—Administering Organization (AO)
III. Continue Review of Current Log & Action Items or Subcommittee/Task Group Meetings
IV. Break
V. Continue Review of Current Log & Action Items or Subcommittee/Task Group Meetings
VI. Public Comment
VII. Daily Wrap Up—DFO & AO
VIII. Adjourn

Dated: July 25, 2018.

Vance Morris,

Special Assistant to Assistant Secretary for Housing—Federal Housing Commissioner.

[FR Doc. 2018–16346 Filed 7–30–18; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R3–ES–2018–N085; FXES11130300000–189–FF03E00000]

Endangered and Threatened Species; Receipt of Recovery Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit applications; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, have received applications for permits to conduct activities intended to enhance the propagation or survival of endangered or threatened species under the Endangered Species Act of 1973, as amended. We invite the public and local, State, Tribal, and Federal agencies to comment on these applications. Before issuing any of the requested permits, we will take into consideration any information that we receive during the public comment period.

DATES: We must receive your written comments on or before August 30, 2018.

ADDRESSES: *Document availability and comment submission:* You may, within 30 days of the date of publication of this notice (see **DATES**) submit requests for copies of the applications and related documents, and submit any comments by one of the following methods. All requests and comments should specify the applicant name(s) and application number(s) (*e.g.,* TEXXXXXX):

- *Email: permitsR3ES@fws.gov.* Please refer to the respective permit number (*e.g.,* Application No. TE*XXXXXX*) in the subject line of your email message.
- *U.S. Mail:* Regional Director, Attn: Carlita Payne, U.S. Fish and Wildlife Service, Ecological Services, 5600 American Blvd. West, Suite 990, Bloomington, MN 55437–1458.

FOR FURTHER INFORMATION CONTACT: Carlita Payne, 612–713–5343; *permitsR3ES@fws.gov.* Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance.

SUPPLEMENTARY INFORMATION: We, the U.S. Fish and Wildlife Service, invite the public to comment on applications for permits under section 10(a)(1)(A) of the Endangered Species Act, as amended (ESA; 16 U.S.C. 1531 *et seq.*). The requested permits would allow the applicants to conduct activities intended to promote recovery of species that are listed as endangered or threatened under the ESA.

Background

With some exceptions, the ESA prohibits activities that constitute take of listed species unless a Federal permit is issued that allows such activity. The ESA's definition of ''take'' includes such activities as pursuing, harassing, trapping, capturing, or collecting in addition to hunting, shooting, harming, wounding, or killing.

A recovery permit issued by us under section 10(a)(1)(A) of the ESA authorizes the permittee to conduct activities with endangered or threatened species for scientific purposes that promote recovery or for enhancement of propagation or survival of the species. These activities often include such prohibited actions as capture and collection. Our regulations implementing section 10(a)(1)(A) for these permits are found in the Code of Federal Regulations at 50 CFR 17.22 for endangered wildlife species, 50 CFR 17.32 for threatened wildlife species, 50 CFR 17.62 for endangered plant species, and 50 CFR 17.72 for threatened plant species.

Permit Applications Available for Review and Comment

Proposed activities in the following permit requests are for the recovery and enhancement of propagation or survival of the species in the wild. The ESA requires that we invite public comment before issuing these permits. Accordingly, we invite local, State, Tribal, and Federal agencies and the public to submit written data, views, or

arguments with respect to these applications. The comments and recommendations that will be most useful and likely to influence agency decisions are those supported by quantitative information or studies.

Application No.	Applicant	Species	Location	Activity	Type of take	Permit action
TE81001C	Katharine Zlonis, Cass Lake, MN.	Rusty patched bumble bee (*Bombus affinis*)	MN	Conduct presence/absence surveys, document habitat use, conduct population monitoring, evaluate impacts.	Capture, handle, hold, release.	New.
TE81122C	Three Rivers Park District, Plymouth, MN.	Rusty patched bumble bee (*Bombus affinis*)	MN	Conduct presence/absence surveys, document habitat use, conduct population monitoring, evaluate impacts.	Capture, handle, hold, release.	New.
TE86137B	The Nature Conservancy, Minneapolis, MN.	Dakota skipper (*Hesperia dacotae*)	MN, ND, SD	Monitoring, habitat management.	Add new activities— propagate and reintroduce—to existing authorized activities: prescribed burns.	Amend.
TE81137C	Luther College, Decorah, IA.	Rusty patched bumble bee (*Bombus affinis*)	IA	Conduct presence/absence surveys, document habitat use, conduct population monitoring, evaluate impacts.	Capture, handle, hold, release.	New.
TE84882C	U.S. Forest Service, Deer River, MN.	Rusty patched bumble bee (*Bombus affinis*)	MN	Conduct presence/absence surveys, document habitat use, conduct population monitoring, evaluate impacts.	Capture, handle, hold, release.	New.
TE85294C	Amy Wolf, Green Bay, WI.	Rusty patched bumble bee (*Bombus affinis*)	WI	Conduct presence/absence surveys, document habitat use, conduct population monitoring, evaluate impacts.	Capture, handle, hold, release.	New.
TE86600C	National Park Service Ashland, WI, and Bad River Band of Lake Superior Tribe of Chippewa, Odanah, WI.	Piping plover (*Charadrius melodus*)	WI	Conduct presence/absence surveys, document habitat use, conduct population monitoring, evaluate impacts.	Capture, handle, mist-net, band, collect feather and blood samples propagate, temporary hold, release.	New.
TE98032A	James Gardner, Jefferson City, MO.	Indiana bat (*Myotis sodalis*), gray bat (*M. grisescens*), northern long-eared bat (*M. septentrionalis*), Ozark big-eared bat (*Corynorhinus townsendii ingens*).	Add new location—WV—to existing authorized locations: AR, IL, IN, IA, KS, KY, MO, OK, TN.	Conduct presence/absence surveys, document habitat use, conduct population monitoring, evaluate impacts.	Capture, handle, mist-net, radio-tag, release.	Amend.
TE64073B	Ecological and GIS Services, Indianola, IA.	Dakota skipper (*Hesperia dacotae*), Poweshiek skipperling (*Oarisma poweshiek*).	IA, MN, ND, SD	Conduct presence/absence surveys, document habitat use, conduct population monitoring, evaluate impacts.	Capture, handle, hold, release.	Renew.

Application No.	Applicant	Species	Location	Activity	Type of take	Permit action
TE90420C	Jennifer Bonta, Melrose, MA.	Indiana bat (*Myotis sodalis*), northern long-eared bat (*M. septentrionalis*).	AL, AR, CT, DE, GA, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NH, NJ, NY, NC, ND, OH, OK, PA, RI, SC, SD, TN, VT, VA, WV, WI, WY.	Conduct presence/absence surveys, document habitat use, conduct population monitoring, evaluate impacts.	Capture, handle, mist-net, harp trap, release.	New.
TE64077B	Scott Krych, Minneapolis, MN.	Dakota skipper (*Hesperia dacotae*), Poweshiek skipperling (*Oarisma poweshiek*).	MN, MT, ND, SD	Conduct presence/absence surveys, document habitat use, conduct population monitoring, evaluate impacts.	Capture, handle, hold, release.	Renew.
TE90423C	Shaughn Barnett, Austin, TX.	Clubshell (*Pleurobema clava*), fanshell (*Cyprogenia stegaria*), fat pocketbook (*Potamilus capax*), Higgins eye (pearlymussel) (*Lampsilis higginsii*), pink mucket (pearlymussel) (*L. abrupta*), northern riffleshell (*Epioblasma torulosa rangiana*), purple cat's paw pearlymussel (*E. obliquata obliquata*), white catspaw (pearlymussel) (*E. o. perobliqua*), snuffbox mussel (*E. triquetra*), orangefoot pimpleback (pearlymussel) (*Plethobasus cooperianus*), sheepnose mussel (*P. cyphyus*), rayed bean (*Villosa fabalis*), scaleshell mussel (*Leptodea leptodon*), spectaclecase (mussel) (*Cumberlandia monodonta*).	IL, IN, OH	Conduct presence/absence surveys, document habitat use, conduct population monitoring, evaluate impacts.	Capture, handle, hold, release.	New.
TE64239B	Nathanael Light, Ozark, MO.	Add Ozark big-eared bat (*Corynorhinus towsendii ingens*) to existing permitted species: Indiana bat (*Myotis sodalis*), gray bat (*M. grisescens*), northern long-eared bat (*M. septentrionalis*).	AL, AR, CT, DE, D.C., FL, GA, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NH, NJ, NY, NC, ND, OH, OK, PA, RI, SC, SD, TN, VT, VA, WV, WI, WY.	Conduct presence/absence surveys, document habitat use, conduct population monitoring, evaluate impacts.	Capture, handle, mist-net, harp trap, band, radio-tag, release.	Amend.
TE90426C	Natalie Dingledine, Haslett, MI.	Hungerford's crawling water beetle (*Brychius hungerfordi*).	MI	Conduct presence/absence surveys, document habitat use, conduct population monitoring, evaluate impacts.	Capture, handle, hold, relocate, release.	New.
TE130900	EnviroScience, Inc., Stow, OH.	Add Texas hornshell (*Popenaias popeii*) and Yellow lance (*Elliptio lanceolata*) to existing permitted species: 70 freshwater mussel species, shortnose sturgeon (*Acipenser brevirostrum*), blue shiner (*Cyprinella caerulea*), Cherokee darter (*Etheostoma scotti*), Etowah darter (*E. etowahae*), amber darter (*Percina antesella*), goldline darter (*P. aurolineata*), Conasauga logperch (*P. jenkinsi*), snail darter (*P. tanasi*).	Add new locations—NC, TX, VA—to existing authorized locations: AR, FL, GA, IL, IN, IA, KY, MI, MN, MO, OH, TN, WI.	Conduct presence/absence surveys, document habitat use, conduct population monitoring, evaluate impacts.	Capture, handle, temporary hold, release, relocate.	Amend.

Public Availability of Comments

Written comments we receive become part of the administrative record associated with this action. 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 request in your comment that we withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

Next Steps

If we decide to issue permits to any of the applicants listed in this notice, we will publish a notice in the **Federal Register**.

Authority

Section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: June 15, 2018.

Lori H. Nordstrom,

Assistant Regional Director, Ecological Services, Midwest Region.

[FR Doc. 2018–16315 Filed 7–30–18; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R2–ES–2018–N045; FXES11130200000–189–FF02ENEH00]

U.S. Endangered Species; Recovery Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit applications; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, invite the public to comment on the following applications for a permit to conduct activities intended to recover and enhance endangered species survival. With some exceptions, the Endangered Species Act of 1973, as amended (ESA), prohibits certain activities that may impact endangered species unless a Federal permit allows such activity. The ESA also requires that we invite public comment before issuing these permits.

DATES: To ensure consideration, please send your written comments by August 30, 2018.

ADDRESSES: *Document availability:* Request documents by phone or email: Susan Jacobsen, 505–248–6641, *susan_jacobsen@fws.gov.*

Comment submission: Submit comments by U.S. mail to Susan Jacobsen, Classification and Recovery Division, U.S. Fish and Wildlife Service, P.O. Box 1306, Albuquerque, NM 87103. Please specify the permit you are interested in by number (*e.g.,* Permit No. TE–123456).

FOR FURTHER INFORMATION CONTACT: Susan Jacobsen, Chief, Classification and Restoration Division, 505–248–6641.

Background

With some exceptions, the ESA prohibits activities that constitute take of listed species unless a Federal permit is issued that allows such activity. The ESA's definition of ''take'' includes hunting, shooting, harming, wounding, or killing but also such activities as pursuing, harassing, trapping, capturing, or collecting.

The ESA and our implementing regulations in the Code of Federal Regulations (CFR) title 50, part 17, provide for issuing such permits and require that we invite public comment before issuing permits for activities involving endangered species.

A recovery permit we issue under the ESA, section 10(a)(1)(A), authorizes the permittee to conduct activities with endangered or threatened species for scientific purposes that promote recovery or enhance the species' propagation or survival. These activities often include such prohibited actions as capture and collection. Our regulations implementing section 10(a)(1)(A) for these permits are found at 50 CFR 17.22 for endangered wildlife species, 50 CFR 17.32 for threatened wildlife species, 50 CFR 17.62 for endangered plant species, and 50 CFR 17.72 for threatened plant species.

Permit Applications Available for Review and Comment

Documents and other information submitted with these applications are available for review by any party who submits a request as specified in **ADDRESSES**. Releasing documents is subject to the Privacy Act (5 U.S.C. 552a) and Freedom of Information Act (5 U.S.C. 552) requirements.

Proposed activities in the following permit requests are for the recovery and enhancement of propagation or survival of the species in the wild. We invite local, State, Tribal, and Federal agencies and the public to submit written data, views, or arguments with respect to these applications. The comments and recommendations that will be most useful and likely to influence agency decisions are those supported by quantitative information or studies. Please refer to the application number when submitting comments.

Application No.	Applicant	Species	Location	Activity	Type of take	Permit action
TE–72370C	Gonzales, Kelly; Houston, Texas.	Aplomado Falcon *(Falco femoralis septentrionalis),* Interior Least Tern *(Sterna antillarum),* Gulf Coast jaguarundi *(Herpailurus yagouaroundi cacomitli),* Ocelot *(Leopardus pardalis),* Piping Plover *(Charadrius melodus),* Red Knot *(Calidris canutus rufa).*	Alabama, Arizona, Arkansas, Florida, Georgia, Kentucky, Louisiana, Mississippi, New Mexico, North Carolina, Oklahoma, South Carolina, Tennessee, Texas.	Presence/absence surveys, Nest monitoring.	Harm and harass	New.

Application No.	Applicant	Species	Location	Activity	Type of take	Permit action
TE–79697C	Clark, Barrett; Kyle, Texas.	Coffin Cave mold beetle *(Batrisodes texanus),* Helotes mold beetle *(Batrisodes venyivi),* Robber Baron Cave meshweaver *(Cicurina baronia),* Madla Cave meshweaver *(Cicurina madla),* Bracken Bat Cave meshweaver *(Cicurina venii),* Government Canyon Bat Cave meshweaver *(Cicurina vespera),* Government Canyon Bat Cave spider *(Neoleptoneta microps),* Tooth Cave spider *(Neoleptoneta myopica),* Ground beetle *(Rhadine exilis),* Ground beetle *(Rhadine infernalis),* Tooth Cave ground beetle *(Rhadine persephone),* Tooth Cave pseudoscorpion *(Tartarocreagris texana),* Kretschmarr Cave mold beetle *(Texamaurops reddelli),* Cokendolpher cave harvestmen *(Texella cokendolpheri),* Bee Creek Cave harvestmen *(Texella reddilli),* Bone Cave harvestman *(Texella reyesi),* Diminutive amphipod *(Gammarus hyalleloides),* Pecos amphipod *(Gammarus pecos),* Comal Springs riffle beetle *(Heterelmis comalensis),* Peck's Cave amphipod *(Stygobromus pecki),* Comal Springs dryopid beetle *(Stygoparnus comalensis).*	Texas	Habitat assessments, presence/absence surveys, biological monitoring, biological inventories.	Capture, harm, and harass, injury, death, removal.	New.
TE–79170C	Ogle, Jennifer; Fayetteville, Arkansas.	American burying beetle (*Nicrophorus americanus*).	Arkansas, Kansas, Oklahoma, Texas.	Presence/absence surveys.	Capture, harm, harass.	New.
TE–43719A	Desert Botanical Garden; Phoenix, Arizona.	Acuna cactus *(Echinomastus erectrocentrus* var. *acunensis),* Kuenzler hedgehog cactus *(Echinocereus fendleri* var. *kuenzleri).*	Arizona, New Mexico.	Collection of tissue	Harm	Renew.
TE–168185	Cox/McClain Environmental Consulting; Austin, Texas.	Gray bat *(Myotis grisescens),* Northern long-eared bat *(Myotis septentrionalis),* Ozark big-eared bat *(Corynorhinus townsendii ingens).*	Oklahoma	Capture, handle, tag, and release, presence/absence surveys, habitat assessments, habitat use studies, population monitoring, collection of tissue.	Capture, harm, harass.	Amend.
TE–148363	Martin, Keith; Claremore, Oklahoma.	American burying beetle *(Nicrophorus americanus),* Northern long-eared bat *(Myotis septentrionalis),.* Gray bat *(Myotis grisescens),* Indiana bat *(Myotis sodalist),* Ozark big-eared bat *(Corynorhinus townsendii ingens).*	Arkansas, Kansas, Missouri, Oklahoma.	Presence/absence surveys, abundance inventories, presence/absence trapping, acoustic surveys, hibernacula monitoring, collection of tissue, exit surveys, banding, construction and repair internal grill/gate systems.	Capture, harm, harass.	Renew.
TE–009926–3	Gulf South Research Corporation; Baton Rouge, Louisiana.	Reticulated flatwoods salamander *(Ambystoma bishopi),* Chiricahua leopard frog (*Lithobates chiricahuensis),* Southwestern willow flycatcher *(Empidonax traillii extimus),* Sierra Nevada yellow-legged frog *(Lithobates sierrae),* Yosemite toad *(Anaxyrus canorus),* Arroyo toad *(Anaxyrus californicus),* Giant garter snake (*Thamnophis gigas),* Interior Least Tern *(Sterna antillarum).*	Arizona, Arkansas, California, Florida, New Mexico.	Presence/absence surveys, seining.	Capture, harm, harass.	Amend.
TE–77509C–0	Schuster, Sara; Saint Louis, Missouri.	Golden-cheeked Warbler *(Setophaga chrysoparia).*	Texas	Presence/absence surveys, nest monitoring.	Harm and harass	New.
TE–74409C	Kitchen, Matthew; San Antonio, Texas.	Golden-cheeked Warbler *(Setophaga chrysoparia).*	Texas	Presence/absence surveys, habitat surveys.	Harm and harass	New.
TE–72898C	Williams, David; Fayetteville, Arkansas.	American burying beetle *(Nicrophorus americanus).*	Arkansas, Kansas, Oklahoma, Texas.	Presence/absence surveys.	Capture, harm and harass.	New.
TE–71114C–0	Kainer, Patrick; Austin, Texas.	Houston toad *(Bufo houstonensis)*	Texas	Presence/absence surveys.	Harm and harass	New.
TE–73319B–0	Thompson, Brent; Los Alamos, New Mexico.	Jemez Mountains salamander (*Plethodon neomexicanus),* Southwestern willow flycatcher (*Empidonax traillii extimus).*	New Mexico	Presence/absence surveys.	Capture, harm, harass.	Amend.

Application No.	Applicant	Species	Location	Activity	Type of take	Permit action
TE–72371C	Boone, Aaron; San Antonio, Texas.	Golden-cheeked Warbler (*Setophaga chrysoparia*), Black-capped Vireo *(Vireo atricapilla).*	Oklahoma, Texas	Presence/absence surveys, nest monitoring, habitat suitability surveys.	Harm and harass	New.
TE–60111B	Robb, Natalie; Mesa, Arizona.	Razorback sucker *(Xyrauchen texanus),* Bonytail chub *(Gila elegans),* Colorado pikeminnow *(Ptychocheilus lucius),* Humpback chub (*Gila cypha),* Spikedace *(Meda fulgida).*	Arizona, California, Nevada.	Presence/absence surveys, electrofishing, minnow traps, hoop nets, seines, dip nets, snorkeling, angling and/or trammel or gill nets.	Capture, harm and harass.	Amend.
TE–72895C	Schatte, Joshua; Guthrie, Oklahoma.	American burying beetle *(Nicrophorus americanus).*	Arkansas, Kansas, Oklahoma, Texas.	Presence/absence surveys.	Capture, harm, and harass.	New.
TE–69480C	Haverland, Matthew; San Marcos, Texas.	Golden-cheeked Warbler (*Setophaga chrysoparia*).	Texas	Presence/absence surveys, territory mapping, nest monitoring.	Harm and harass	New.
TE–17880C	Garrett, Timothy; Houston, Texas.	American burying beetle *(Nicrophorus americanus).*	Oklahoma	Presence/absence surveys.	Capture, harm, and harass.	Amend.
TE–71101C–0	Ramirez, Abbey; Tahlequah, Oklahoma.	American burying beetle *(Nicrophorus americanus).*	Oklahoma	Presence/absence surveys.	Capture, harm, and harass.	New.
TE–71110C	Durish, Nevin; Austin, Texas.	Golden-cheeked Warbler (*Setophaga chrysoparia*), Black-capped Vireo *(Vireo atricapilla),* Houston toad (*Bufo houstonensis).*	Oklahoma, Texas	Presence/absence surveys.	Harm and harass	New.
TE40886B	Zahratka, Jennifer; Durango, Colorado.	Southwestern Willow Flycatcher *(Empidonax traillii extimus),* Black-footed ferret (*Mustela nigripes*).	Arizona, Colorado, New Mexico, Texas, Utah.	Presence/absence surveys.	Harm and harass	Amend.
TE82893C	Pina, Anna; El Paso, Texas.	Roswell springsnail (*Pyrgulopsis roswellensis*), Koster's springsnail (*Juturnia kosteri*), Pecos asseiminea snail (*Assiminea pecos*), Noel's amphipod (*Gammarus desperatus*).	New Mexico, Texas.	Sampling, collection.	Harm and harass	New.
TE30430B	University of Houston—Clear Lake; Houston, TX.	Leon Springs pupfish (*Cyprinodon bovinus*), Comanche Springs pupfish (*Cyprinodon elegans*), Big Bend gambusia (*Gambusia gaigei*), Pecos gambusia (*Gambusia nobilis*), Smalleye shiner (*Notropis buccula*), Sharpnose shiner (*Notropis oxyrhynchus*).	Texas	Sampling, collecting.	Harm and harass	Amend.

Public Availability of Comments

All comments and materials we receive in response to these requests will be available for public inspection, by appointment, during normal business hours at the address listed 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 review, 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.*).

Dated: March 30, 2018.

Amy L. Lueders.

Regional Director, Southwest Region, U.S. Fish and Wildlife Service.

[FR Doc. 2018–16306 Filed 7–30–18; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[189A2100DD/AAKC001030/A0A501010.999900 253G; OMB Control Number 1076–0104]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Documented Petitions for Federal Acknowledgment as an Indian Tribe

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Assistant Secretary-Indian Affairs (AS–IA) is proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before August 30, 2018.

ADDRESSES: Send written comments on this information collection request (ICR) to the Office of Management and Budget's Desk Officer for the Department of the Interior by email at *OIRA_Submission@omb.eop.gov*; or via facsimile to (202) 395–5806. Please provide a copy of your comments to R. Lee Fleming, Director, Office of Federal Acknowledgment, Assistant Secretary—Indian Affairs, 1849 C Street NW, MS–4071 MIB, Washington, DC 20240; facsimile: (202) 219–3008; email: *Lee.Fleming@bia.gov.* Please reference OMB Control Number 1076–0104 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact R. Lee Fleming, (202) 513–7650. You may also view the ICR at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the

impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provides the requested data in the desired format.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on April 9, 2018 (83 FR 15171). No comments were received.

We are again soliciting comments on the proposed ICR that is described below. We are especially interested in public comment addressing the following issues: (1) Is the collection necessary to the proper functions of the AS–IA; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the AS–IA enhance the quality, utility, and clarity of the information to be collected; and (5) how might the AS–IA minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. 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.

Abstract: Submission of this information allows the Office of Federal Acknowledgment (OFA), within the Office of the Assistant Secretary-Indian Affairs, to review groups' documented petitions for the Federal acknowledgment as an Indian tribe. The acknowledgment regulations at 25 CFR 83 contain seven criteria that unrecognized groups seeking Federal acknowledgment as Indian tribes must demonstrate that they meet. Information collected from petitioning groups under these regulations provide anthropological, genealogical and historical data used by the AS–IA to establish whether a petitioning group has the characteristics necessary to be acknowledged as a continuously existing Indian tribe. Federal acknowledgment establishes a government-to-government relationship with the United States. Respondents are not required to retain copies of the information submitted to OFA but will probably maintain copies for their own use; therefore, there is no recordkeeping requirement included in this information collection.

Title of Collection: Documented Petitions for Federal Acknowledgment as an Indian Tribe.

OMB Control Number: 1076–0104.

Form Number: BIA–8304, BIA–8305, and BIA–8306.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Groups petitioning for Federal acknowledgment as Indian Tribes.

Total Estimated Number of Annual Respondents: 10.

Total Estimated Number of Annual Responses: 10.

Estimated Completion Time per Response: 1,436 hours, on average.

Total Estimated Number of Annual Burden Hours: 14,360, on average.

Respondent's Obligation: Required to Obtain or Retain a Benefit.

Frequency of Collection: Once.

Total Estimated Annual Nonhour Burden Cost: $21,000,000.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq*).

Elizabeth K. Appel,

Director, Office of Regulatory Affairs and Collaborative Action—Indian Affairs.

[FR Doc. 2018–16344 Filed 7–30–18; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[189A2100DD/AAKC001030/A0A501010.999900 253G; OMB Control Number 1076–0180]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Leasing of Osage Reservation Lands for Oil and Gas Mining

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Bureau of Indian Affairs (BIA) is proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before August 30, 2018.

ADDRESSES: Send written comments on this information collection request (ICR) to the Office of Management and Budget's Desk Officer for the Department of the Interior by email at *OIRA_Submission@omb.eop.gov;* or via facsimile to (202) 395–5806. Please provide a copy of your comments to Robin M. Phillips, Superintendent, Osage Agency, P.O. Box 1539, Pawhuska, OK 74056 or by email to *Robin.Phillips@bia.gov.* Please reference OMB Control Number 1076–0180 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Richard Winlock, Deputy Superintendent by email at *Richard.Winlock@bia.gov,* or by telephone at (918) 287–5700. You may also view the ICR at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provides the requested data in the desired format.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on April 9, 2018 (83 FR 15173).

We are again soliciting comments on the proposed ICR that is described below. We are especially interested in public comment addressing the following issues: (1) Is the collection necessary to the proper functions of the BIA; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the BIA enhance the quality, utility, and clarity of the information to be collected; and (5) how might the BIA minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. 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.

Abstract: Congress passed legislation specifically addressing oil and gas leasing on Osage lands and requiring Secretarial approval of leases. *See* 34 Stat. 543, section 3, as amended. The regulations art 25 CFR 226 implement that statute by specifying what information a lessee must provide related to drilling, development, and production of oil and gas on Osage reservation land. The oil, gas, and land are assets that the United States holds in trust or restricted status for Indian beneficiaries. The information collections in 25 CFR 226 are necessary to ensure that the beneficial owners of the mineral rights are provided the royalties due them, ensure that the oil and gas trust assets are protected, and to ensure that the surface estate assets are protected.

Title of Collection: Leasing of Osage Reservation lands for Oil and Gas Mining.

OMB Control Number: 1076–0180.

Form Number:

- Form A—Mining Lease
- Form B—Oil Lease
- Form C—Oil & Gas Lease
- Form D—Mining Lease Bond
- Form F—Assignment of Lease
- Form G—Collective Bond
- Form H—Assignment Bond Form
- Monthly Accounting Forms (Forms 101, 101A, 133, 157,and 300)
- Form 139—Permit to Drill or Reenter
- Easement Form
- Modification of Oil/Gas Mining Lease
- List of Corporate Officers Form
- Tank Bottom Oil Report Form
- Assignment of Liability Form
- Waterflood Operating Report Form 229
- Lease Status Report Form
- Spill Reporting and Remediation Form
- Environmental Assessment Questionnaire
- Osage Mineral Reserve Trucking Permit

Type of Review: Revision of a currently approved collection.

Respondents/Affected Public: Individual Indians, businesses, and Tribal authorities.

Total Estimated Number of Annual Respondents: 1,397.

Total Estimated Number of Annual Responses: 48,113.

Estimated Completion Time per Response: Five minutes to 28 hours.

Total Estimated Number of Annual Burden Hours: 22,776.

Respondent's Obligation: Required to Obtain or Retain a Benefit.

Frequency of Collection: As needed.

Total Estimated Annual Nonhour Burden Cost: $4,535.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq*).

Elizabeth K. Appel,

Director, Office of Regulatory Affairs and Collaborative Action—Indian Affairs.

[FR Doc. 2018–16342 Filed 7–30–18; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–NERO–GATE–25583; PPNEGATEB0, PPMVSCS1Z.Y00000]

Request for Nominations for the Gateway National Recreation Area Fort Hancock 21st Century Advisory Committee

AGENCY: National Park Service, Interior.

ACTION: Request for nominations.

SUMMARY: The National Park Service (NPS), U.S. Department of the Interior is requesting nominations for qualified persons to serve as members of the Committee.

DATES: Written nominations must be received by August 30, 2018.

ADDRESSES: Nominations should be sent to Daphne Yun, U.S. Department of the Interior, National Park Service, Gateway National Recreation Area, Office of the Superintendent, 210 New York Avenue, Staten Island, New York 10305, or email *daphne_yun@nps.gov.*

FOR FURTHER INFORMATION CONTACT: Daphne Yun, U.S. Department of the Interior, National Park Service, Gateway National Recreation Area, Sandy Hook Unit, 26 Hudson Road, Highlands, New Jersey 07732, or email at *daphne_yun@nps.gov,* or via telephone at (732) 872–5908.

SUPPLEMENTARY INFORMATION: The Gateway National Recreation Area Fort Hancock 21st Century Advisory Committee was established by authority of the Secretary of the Interior under 54 U.S.C. 100906, and in accordance with the Federal Advisory Committee Act (5 U.S.C. Appendix 1–16). The purpose of the Committee is to advise the Secretary of the Interior, through the Director of the National Park Service, on the development of a reuse plan and on matters relating to future uses of certain buildings at the Fort Hancock Historic District, located within the Sandy Hook Unit of Gateway National Recreation Area in New Jersey.

The Committee consists of representatives from among, but not limited to, the following interest groups to represent a range of interests concerned with the management of Fort Hancock within the park and its impact on the local area: The natural resource community, the business community, the cultural resource community, the real estate community, the recreation community, the education community, the scientific community, and hospitality organizations. The Committee will also include representatives from the following municipalities: Borough of Highlands, Borough of Sea Bright, Borough of Rumson, Middletown Township, Monmouth County Freeholders, and Borough of Monmouth Beach.

We are currently seeking members to represent all categories.

Nominations should be typed and should include a resume providing an adequate description of the nominee's qualifications, including information that would enable the Department of the Interior to make an informed decision regarding meeting the membership requirements of the Committee and permit the Department to contact a potential member. All documentation, including letters of recommendation, must be compiled and submitted in one complete package. All those interested in membership, including current members whose terms are expiring, must follow the same nomination process. Members may not appoint deputies or alternates.

Members of the Committee serve without compensation. However, while away from their homes or regular places of business in the performance of services for the Committee as approved by the NPS, members may be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as persons employed intermittently in Government service are allowed such expenses under section 5703 of title 5 of the United States Code.

Public Disclosure of Information: Before including your address, phone number, email address, or other personal identifying information with your nomination, you should be aware that your entire nomination—including your personal identifying information—may be made publicly available at any time. While you can ask us in your nomination to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 54 U.S.C. 100906.

Shirley Sears,

Acting Chief, Office of Policy.

[FR Doc. 2018–16381 Filed 7–30–18; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–DTS#–26087; 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 July 14, 2018, for listing or related actions in the National Register of Historic Places.

DATES: Comments should be submitted by August 15, 2018.

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 July 14, 2018. 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:

IDAHO

Idaho County
Butts Point Creek Fire Lookout, Approx. 40 mi. NE of Salmon, ID Salmon vicinity, SG100002786

MARYLAND

Frederick County
Mason and Dixon West Line Milestone Markers 76 and 77, 716 Mason Dixon Rd., Harney vicinity, SG100002789

MASSACHUSETTS

Suffolk County
Benjamin Silverman Apartments, 50–52 Lorne & 4 Wilson Sts., Boston, SG100002790

MISSOURI

Clay County
Boarding House District (Excelsior Springs, Missouri MPS), 401–608 Benton, 339–436 E Broadway, 201–223 S Francis, 105 Haynes, 309–526 Isley, 101 Linden, 110–112 Perry, 103–305 Saratoga, 000–213 Temple Excelsior Springs, MP100002791
Jackson County
Crown Center Hotel, 1 E Pershing St., Kansas City, SG100002793
St. Louis Independent City
Jefferson—Cass Health Center, 1421 N Jefferson Ave., St. Louis, SG100002792

NORTH CAROLINA

Beaufort County
U.S. ARMY GUNBOAT PICKET (screw steamer) (Eastern North Carolina Civil War Shipwrecks, 1861–1865 MPS), Address Restricted, Washington vicinity, MP100002796
Bertie County
Broad Creek Block Ships (Eastern North Carolina Civil War Shipwrecks, 1861–1865 MPS), Address Restricted, Plymouth vicinity, MP100002797
U.S.S. BAZELY (tugboat) (Eastern North Carolina Civil War Shipwrecks, 1861–1865 MPS), Address Restricted, Jamesville vicinity, MP100002798
Camden County
C.S.S. BLACK WARRIOR (two-masted schooner) (Eastern North Carolina Civil War Shipwrecks, 1861–1865 MPS), Address Restricted, Elizabeth City, MP100002799
SCUPPERNONG (two-masted schooner) (Eastern North Carolina Civil War Shipwrecks, 1861–1865 MPS), Address Restricted, Shawboro vicinity, MP100002800
Craven County
U.S.S. UNDERWRITER (side-wheel steamer) (Eastern North Carolina Civil War Shipwrecks, 1861–1865 MPS), Address Restricted, New Bern vicinity, MP100002801
Dare County
C.S.S. CURLEW (side-wheel steamer) (Eastern North Carolina Civil War Shipwrecks, 1861–1865 MPS), Address Restricted, Mann's Harbor vicinity, MP100002802
Edgecombe County
C.S.S. COL. HILL (side-wheel steamer) (Eastern North Carolina Civil War Shipwrecks, 1861–1865 MPS), Address Restricted, Tarboro vicinity, MP100002803
Martin County
U.S.S. OTSEGO (side-wheel gunboat) (Eastern North Carolina Civil War Shipwrecks, 1861–1865 MPS), Address Restricted, Jamesville vicinity, MP100002804
Pitt County
Chicod Creek Wreck (Eastern North Carolina Civil War Shipwrecks, 1861–1865 MPS), Address Restricted, Grimesland, MP100002805
Washington County
U.S.S. SOUTHFIELD (side-wheel ferryboat) (Eastern North Carolina Civil War Shipwrecks, 1861–1865 MPS), Address Restricted, Plymouth, MP100002806

SOUTH DAKOTA

Buffalo County
Long View Stock Farm, 22182 361st Ave. Gann Valley vicinity, SG100002808
Hyde County
Hyde County Memorial Auditorium, 200 2nd St. SW, Highmore, SG100002809

WASHINGTON

Okanogan County
Fort Okanogan Interpretive Center, 14379 US 17, Brewster, SG100002814

WISCONSIN

Dane County
Hoyt, Frank W, Park, 3902 Regent St., 90 & 91 Owen Pkwy., Madison, SG100002815

A request for removal has been made for the following resources:

IOWA

Delaware County
Coffin's Grove Stagecoach House, 3 mi. W of Manchester, Manchester vicinity, OT75000681
Woodbury County
Florence Crittenton Home and Maternity Hospital, 1105–1111 28th St., Sioux City, OT00000306

Additional documentation has been received for the following resources:

NEW YORK

Albany County
St. Agnes Cemetery, 48 Cemetery Ave., Menands, AD08000095

TENNESSEE

Williamson County
Franklin Historic District, (Williamson County MRA (AD)), Centered around Main St. (TN 96) and 3rd Ave. (U.S. 31), Franklin, AD72001254

Authority: Section 60.13 of 36 CFR part 60.

Dated: July 19, 2018.

Christopher Hetzel,

Acting Chief, National Register of Historic Places/National Historic Landmarks Program.

[FR Doc. 2018–16268 Filed 7–30–18; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

Bureau of Safety and Environmental Enforcement

[Docket ID BSEE–2017–0006; 189E1700D2 ET1SF0000.PSB000.EEEE500000; OMB Control Number 1014–0021]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Operations in the Outer Continental Shelf for Minerals Other Than Oil, Gas, and Sulphur

AGENCY: Bureau of Safety and Environmental Enforcement, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Bureau of Safety and Environmental Enforcement (BSEE) proposes to renew an information collection.

DATES: Interested persons are invited to submit comments on or before August 30, 2018.

ADDRESSES: Send written comments on this information collection request (ICR) to the Office of Management and Budget's Desk Officer for the Department of the Interior by email at *OIRA_Submission@omb.eop.gov;* or via facsimile to (202) 395–5806. Please provide a copy of your comments to the Bureau of Safety and Environmental Enforcement; Regulations and Standards Branch; ATTN: Nicole Mason; 45600 Woodland Road, Sterling, VA 20166; or by email to *kye.mason@bsee.gov.* Please reference OMB Control Number 1014–0021 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Nicole Mason by email at *kye.mason@bsee.gov,* or by telephone at (703) 787–1607. You may also view the ICR at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on November 16, 2017 (82 FR 53519). The BSEE received two comments pertaining to this **Federal Register** notice, but neither were germane to the collection of information.

We are again soliciting comments on the proposed ICR that is described below. We are especially interested in public comments addressing the following issues: (1) Is the collection necessary to the proper functions of BSEE; (2) Will this information be processed and used in a timely manner; (3) Is the estimate of burden accurate; (4) How might BSEE enhance the quality, utility, and clarity of the information to be collected; and (5) How might BSEE minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. 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.

Abstract: BSEE will use the information required by 30 CFR part 282 to determine if lessees are complying with the regulations that implement the mining operations program for minerals other than oil, gas, and sulphur. Specifically, BSEE will use the information:

- To ensure that operations for the production of minerals other than oil, gas, and sulphur in the outer continental shelf (OCS) are conducted in a manner that will result in orderly resource recovery, development, and the protection of the human, marine, and coastal environments.
- To ensure that adequate measures will be taken during operations to prevent waste, conserve the natural resources of the OCS, and to protect the environment, human life, and correlative rights.
- To determine if suspensions of activities are in the national interest, to facilitate proper development of a lease including reasonable time to develop a mine and construct its supporting facilities, and to allow for the construction or negotiation for use of transportation facilities.
- To identify and evaluate the cause(s) of a hazard(s) generating a suspension, the potential damage from a hazard(s) and the measures available to mitigate the potential for damage.
- For technical evaluations that provide a basis for BSEE to make informed decisions to approve, disapprove, or require modification of the proposed activities.

Title of Collection: 30 CFR part 282, *Operations in the Outer Continental Shelf for Minerals Other than Oil, Gas, and Sulphur.*

OMB Control Number: 1014–0021.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Potential respondents comprise Federal OCS oil, gas, and sulphur lessees/operators and holders of pipeline rights-of-way.

Total Estimated Number of Annual Respondents: As there are no active respondents; we estimated the potential annual number of respondents to be one.

Total Estimated Number of Annual Responses: 16.

Estimated Completion Time per Response: Varies from 1 hour to 20 hours, depending on activity.

Total Estimated Number of Annual Burden Hours: 56.

Respondent's Obligation: Most responses are mandatory, while others are required to obtain or retain benefits, or are voluntary.

Frequency of Collection: On occasion and varies by section.

Total Estimated Annual Nonhour Burden Cost: We have identified one non-hour cost burden. Pursuant to § 282.13(e)(1), a site-specific study to determine and evaluate hazards that results in a suspension of operation would have a non-hour cost burden. Since this has not been done to date, we estimated that the cost of such a study for industry would be approximately $100,000 to comply with the requirement. We have not identified any other non-hour cost burdens associated with this collection of information.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq*).

Dated: July 11, 2018.

Doug Morris,

Chief, Office of Offshore Regulatory Programs.

[FR Doc. 2018–16319 Filed 7–30–18; 8:45 am]

BILLING CODE 4310–VH–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–582 and 731–TA–1377 (Final)]

Ripe Olives From Spain; Determinations

On the basis of the record [1] developed in the subject investigations, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that an industry in the United States is materially injured by reason of imports of ripe olives from Spain, provided for in subheadings 2005.70.02, 2005.70.04, 2005.70.50, 2005.70.60, 2005.70.70, and 2005.70.75 of the Harmonized Tariff Schedule of the United States, that have been found by the U.S. Department of Commerce (''Commerce'') to be sold in the United States at less than fair value (''LTFV'') and to be subsidized by the government of Spain.[2]

Background

The Commission, pursuant to sections 705(b) and 735(b) of the Act (19 U.S.C. 1671d(b) and 19 U.S.C. 1673d(b)), instituted these investigations effective June 22, 2017, following receipt of a petition filed with the Commission and Commerce by the Coalition of Fair Trade in Ripe Olives, consisting of Bell-Carter Foods, Walnut Creek, CA, and Musco Family Olive Company, Tracy, CA. The final phase of the investigations was scheduled by the Commission following notification of preliminary determinations by Commerce that imports of ripe olives from Spain were subsidized within the meaning of section 703(b) of the Act (19 U.S.C. 1671b(b)) and sold at LTFV within the meaning of 733(b) of the Act (19 U.S.C. 1673b(b)). Notice of the scheduling of the final phase of the Commission's investigations and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** on February 22, 2018 (83 FR 7774). The hearing was held in Washington, DC, on May 24, 2018, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission made these determinations pursuant to sections 705(b) and 735(b) of the Act (19 U.S.C. 1671d(b) and 19 U.S.C. 1673d(b)). It completed and filed its determinations in these investigations on July 25, 2018. The views of the Commission are contained in USITC Publication 4805 (July 2018), entitled *Ripe Olives from Spain: Investigation Nos. 701–TA–582 and 731–TA–1377 (Final).*

By order of the Commission.

Issued: July 25, 2018.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2018–16283 Filed 7–30–18; 8:45 am]

BILLING CODE 7020–02–P

[1] The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] Commissioner Meredith M. Broadbent dissenting. Commissioner Jason E. Kearns did not participate in these investigations.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Craig S. Morris, DDS; Dismissal of Proceeding

On November 13, 2017, the Acting Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Craig S. Morris, DDS (Respondent), of Texas. The Show Cause Order proposed the revocation of Respondent's Certificates of Registration FM5300582 and FM5293294 on the ground that he ''materially falsified [his] applications for [his] DEA Certificates of Registration.'' Order to Show Cause, Government Exhibit (GX) A–8 to Request for Final Agency Action (RFAA), at 1 (citing 21 U.S.C. 824(a)(1)).

With respect to the Agency's jurisdiction, the Show Cause Order alleged that Respondent was registered at that time in schedules II through V, pursuant to DEA Certificates of Registration Nos. FM5300582 and FM5293294 at the addresses of 19121 West Lake Houston Parkway, Humble, TX, and 25130 Grogans Park Drive, The Woodlands, TX, respectively.[1] *Id.* at 1–2. The Order also alleged that these registrations would each expire on January 31, 2018. *Id.*

As substantive grounds for the proceeding, the Show Cause Order alleged that on February 9, 2015, Respondent ''submitted applications to the DEA for the above-referenced Certificates of Registration'' but materially falsified the application when he ''provided a 'no' response to Liability Question 3, which asked, '[h]as the applicant *ever* surrendered (for cause) or had a state professional license or controlled substances registration revoked, *suspended,* denied, restricted or *placed on probation,* or is any such action pending?' '' *Id.* at 2. The Order further alleged that, when he ''submitted his applications to the DEA and provided a 'no' answer to Liability Question 3, [his] Nevada license to practice dentistry had been placed on probation and was currently suspended.'' *Id.* Based on Respondent's alleged ''material falsification of [his] applications to the DEA,'' the Order asserted that ''DEA must revoke'' his registrations. *Id.* at 3.

The Show Cause Order notified Respondent of his right to request a hearing on the allegations or to submit a written statement in lieu of a hearing, the procedure for electing either option, and the consequence of failing to elect either option. *Id.* (citing 21 CFR 1301.43). The Show Cause Order also notified Respondent of his right to submit a corrective action plan. *Id.* at 3–4 (citing 21 U.S.C. 824(c)(2)(C)).

The Government represents that on November 20, 2017, a DEA Diversion Investigator (DI) served a copy of the Show Cause Order on Respondent by electronic mail to an email address that the DI had previously used to correspond with Respondent in April 2017 and that Respondent had provided to DEA as a ''contact email'' in connection with his DEA Certificates of Registration. RFAA, at 3–4 (citing Declaration of DI, attached as GX A to RFAA, at 3). There is no dispute that timely service occurred because the Government states that DEA's Diversion Control Division received Respondent's written submissions in connection with the Show Cause Order on December 19, 2017. RFAA, at 4 (citing the Diversion Control Division's Acting Assistant Administrator's December 20, 2017 letter to Respondent, attached as GX C to RFAA, at 1).

Although Respondent's submissions included a letter (dated December 12, 2017) entitled ''*Corrective Action Plan,*'' the letter stated that it was ''being submitted in response to the Order to Show Cause levied against me by your office'' and attached an affidavit in support signed by Respondent and notarized on December 15, 2017. Respondent's Written Submissions (hereinafter ''Respondent's Statement'' or ''Resp. Stat.''), attached as GX B to RFAA, at 1. Respondent did not, however, request a hearing. *See generally id.* Based on Respondent's submission, I find that he waived his right to a hearing on the allegations. 21 CFR 1301.43(c). However, pursuant to 21 CFR 1301.43(c), I deem Respondent's submission to be his ''written statement

[1] The record establishes that Respondent was registered as a ''practitioner'' with respect to each of the above DEA registrations. Certifications of Registration History for FM5300582 and FM5293294, GXs A–1 at 1, 3; A–2, at 1, 3.

[of] position on the matters of fact and law involved'' in the proceeding. *See Arthur H. Bell, D.O.,* 80 FR 50035, 50036 (2015) (deeming Respondent's letter to be a written statement pursuant to 21 CFR 1301.43(c) because the letter ''responded to each of the Government's allegations'' without requesting a hearing).[2] On March 16, 2018, the Government forwarded its Request for Final Agency Action and the evidentiary record to my Office.

Having reviewed the record, I find that this proceeding is now moot. The evidence in the record establishes that each of Respondent's registrations at issue were due to expire on January 31, 2018, and according to the Agency's registration record for Respondent, of which I take official notice,[3] Respondent has not submitted an application to renew his registrations. DEA has long held that '' 'if a registrant has not submitted a timely renewal application prior to the expiration date, then the registration expires and there is nothing to revoke.' '' *Donald Brooks Reece II, M.D.,* 77 FR 35054, 35055 (2012) (quoting *Ronald J. Riegel,* 63 FR 67312, 67133 (1998)). ''Moreover, in the absence of an application (whether timely filed or not), there is nothing to act upon.'' *Id.* at 35055.

Although the Government acknowledges that Respondent's DEA registrations expired on January 31, 2018 and prior to its March 16, 2018 Request for Final Agency Action, RFAA, at 1, the Government nonetheless argues that the ''matter is not moot.'' *Id.* at 5. Specifically, the Government claims that, prior to the issuance of the Show Cause Order, Respondent requested ''to modify his DEA Certificates of Registration and change his registered address to an address in California, where [he] holds an active dental license. That request for modification is pending.'' *Id.* at 5–6. The Government's argument that the case is not moot based on this purported modification request is unavailing for at least two reasons.

First, as a threshold matter, the record does not establish by a preponderance of the evidence that Respondent does, in fact, have a pending request to modify the address of his DEA registrations to an address in California. In its Request, the Government relies exclusively on the DI's statement in her Declaration that, ''[o]n February 17, 2017, Dr. Morris submitted a request for modification of his DEA Certificates of Registration [FM5300582 and FM5293294], seeking to change his address to 19121 Allingham Avenue, Cerritos, California.'' GX A, at 3. The DI does not cite in her Declaration to any evidence in support of this statement. *See id.* Furthermore, the Government submitted a Certification of Registration History for each of these registrations (both dated March 12, 2018), and neither certification references this modification request. GX A–1; GX A–2. In addition, the Agency's registration record for Respondent reflects no reference to these specific modification requests.[4] Indeed, not even the Show Cause Order references the modification request. *See* GX A–8. Thus, because the Government's argument against mootness relies entirely on a pending modification request not established in the record, I reject the Government's argument on this basis alone. *See* RFAA, at 3.

Second, even if the purported modification requests were made, my finding that this case is moot would not change. The Government argues that the Show Cause Order to revoke Respondent's registrations is not moot when a request to modify such registrations remains pending (even after the expiration of the very registration that Respondent seeks to modify) because DEA regulations state that ''a request for modification shall be handled in the same manner as an application for registration.'' *Id.* at 5–6 (citing 21 CFR 1301.51(c)). I disagree.

The fact that DEA handles a modification request ''in the same manner as an application for registration'' pursuant to 21 CFR 1301.51(c) does not mean that a modification request is the same as an application for a new registration in every respect. For example, although a registrant must pay a fee when he or she applies for a new registration, *see* 21 CFR 1301.14(a), ''[n]o fee shall be required for modification.'' *Id.* 1301.51(c). Most importantly, even if a modification request is approved and a new certificate of registration is issued, DEA regulations state that the new (as modified) registration expires when the original registration certificate expires. *Id.* (''If the modification of registration is approved, the Administrator shall issue a new certificate of registration . . . to the registrant, who shall maintain it with the old certificate of registration *until expiration*.'') (emphasis added). Thus, unlike a timely renewal application, a request to modify the registration address of an existing registration (whether pending or granted) does not remain pending after that registration expires, nor does it operate to extend when that registration expires. *See* 21 CFR 1301.51(c).[5]

Accordingly, because Respondent has allowed his registrations to expire and did not file an application to renew his registrations, this case is now moot and will be dismissed.

Order

Pursuant to the authority vested in me by 21 U.S.C. 824(a), as well as 28 CFR 0.100(b), I order that the Order to Show Cause issued to Craig S. Morris, DDS, be, and it hereby is, dismissed. This Order is effective immediately.

Dated: July 18, 2018.

Uttam Dhillon,

Acting Administrator.

[FR Doc. 2018–16313 Filed 7–30–18; 8:45 am]

BILLING CODE 4410–09–P

[2] In its Request for Final Agency Action, the Government properly treated Respondent's written submissions as a ''written statement'' pursuant to 21 CFR 1301.43. RFAA, at 6–8. However, because I am dismissing the Government's Show Cause Order as moot, I decline to reach the question of whether Respondent's submissions could also be deemed to have included a Corrective Action Plan pursuant to 21 U.S.C. 824(c)(2)(C).

[3] Under the Administrative Procedure Act (APA), an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' U.S. Dept. of Justice, *Attorney General's Manual on the Administrative Procedure Act* 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). In accordance with the APA and DEA's regulations, Respondent is ''entitled on timely request to an opportunity to show to the contrary.'' 5 U.S.C. 556(e); *see also* 21 CFR 1316.59(e). To allow Respondent the opportunity to refute the facts of which I take official notice, Respondent may file a motion for reconsideration within 15 calendar days of service of this order which shall commence on the date this order is mailed.

[4] I take official notice of this fact pursuant to the authority set forth *supra* in footnote 3.

[5] Neither of the cases that the Government relies upon supports its position. RFAA, at 5–6 (citing *Michael G. Dolin, M.D.,* 65 FR 5661, 5661 (2000); *Daniel Koller, D.V.M.,* 71 FR 66975 (2006)). *Michael G. Dolin* focused on whether Respondent lacked state authorization to handle controlled substances and does not address the issue of mootness. 65 FR at 5661. The Government's other case, *Daniel Koller,* actually cuts against its position. In that case, the registrant had separately submitted an application for a new DEA registration at a new location—in addition to prior submissions for modifications of the existing registration for the new location. 71 FR at 66979–81. Ultimately, the Agency found that ''Respondent's Registration . . . [had] expired . . . , and that Respondent did not file a renewal application, let alone a timely one, for this registration.'' *Id.* at 66981. As a result, the Agency did not revoke the expired registration nor consider the pending requests to modify that registration, as the Government requests in this case. *See id.* Instead, the Agency held, as I do here, that ''the revocation portion of this proceeding is moot.'' *Id.* The Agency properly concluded in *Koller* that only the application for a new registration ''remain[ed] a live controversy.'' *Id.*

DEPARTMENT OF JUSTICE

Foreign Claims Settlement Commission

[F.C.S.C. Meeting and Hearing Notice No. 7–18]

Sunshine Act Meeting

The Foreign Claims Settlement Commission, pursuant to its regulations (45 CFR 503.25) and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice in regard to the scheduling of open meetings as follows:

Thursday, August 9, 2018: 10:00 a.m.—Issuance of Proposed Decisions in claims against Iraq.

11:00 a.m.—Issuance of Proposed Decisions under the Guam World War II Loyalty Recognition Act, Title XVII, Public Law 114–328.

Status: Open.

All meetings are held at the Foreign Claims Settlement Commission, 601 D Street NW, Suite 10300, Washington, DC. Requests for information, or advance notices of intention to observe an open meeting, may be directed to: Patricia M. Hall, Foreign Claims Settlement Commission, 601 D Street NW, Suite 10300, Washington, DC 20579. Telephone: (202) 616–6975.

Brian M. Simkin,

Chief Counsel.

[FR Doc. 2018–16436 Filed 7–27–18; 11:15 am]

BILLING CODE 4410–BA–P

DEPARTMENT OF JUSTICE

[OMB Number 1121–0292]

Agency Information Collection Activities; Proposed Collection Comments Requested; Reinstatement with Change of an Expired Collection: 2017–19 Survey of Sexual Victimization

AGENCY: Bureau of Justice Statistics, Department of Justice.

ACTION: 30-day Notice.

SUMMARY: The Department of Justice (DOJ), Office of Justice Programs, Bureau of Justice Statistics, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection was previously published in the **Federal Register** Volume 83, Number 38, page 8300, on February 26, 2018, allowing a 60-day comment period. Following publication of the 60-day notice, the Bureau of Justice Statistics received one request for survey instruments indicating proposed changes, and seven comments. These comments will be addressed in the supporting statement.

DATES: Comments are encouraged and will be accepted for an additional 30 days until August 30, 2018.

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 Ramona Rantala, Statistician, Bureau of Justice Statistics, 810 Seventh Street NW, Washington, DC 20531 (email: *Ramona.Rantala@usdoj.gov;* telephone: 202–307–6170).

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 Bureau of Justice Statistics, 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:* Reinstatement with change of an expired collection.

2. *The Title of the Form/Collection:* Survey of Sexual Victimization [formerly the Survey of Sexual Violence].

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Form numbers for the questionnaire are SSV–1, SSV–2, SSV–3, SSV–4, SSV–5, SSV–6 (Summary Form); SSV–IA, SSV–IJ, (Substantiated Incident Form). The applicable component within the Department of Justice is the Bureau of Justice Statistics, in the Office of Justice Programs.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: State, Local, or Tribal Government correctional facilities. Other: Federal Government and businesses (privately operated correctional institutions, both for-profit and not-for-profit). The data will be used to develop national estimates of the incidence and prevalence of sexual assault within correctional facilities, as well as characteristics of substantiated incidents, as required under the Prison Rape Elimination Act of 2003 (Pub. L. 108–79).

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimate of the total number of respondents is 1,574 adult and juvenile correctional systems and facilities. (This estimate assumes a response rate of 100%.) Federal and state correctional systems for adults and juveniles (102 respondents) will each take an estimated 60 minutes to complete the summary form; local, military, Immigrations and Customs Enforcement, tribal, and privately operated facilities (1,472 respondents) will each take an estimated 30 minutes to complete the summary form; and incident forms (an estimated 3,000 incident forms will be completed each year, one for each incident that was substantiated) will take about 30 minutes per form. The burden estimates are based on data from the prior administration of the SSV.

6. *An estimate of the total public burden (in hours) associated with the collection:* There is an estimated 2,338 total burden hours per year associated with this collection, with a combined total of 7,014 for the three years.

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: July 26, 2018.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2018–16302 Filed 7–30–18; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF JUSTICE

Office of Justice Programs

[OJP (OJP) Docket No. 1748]

Meeting of the Public Safety Officer Medal of Valor Review Board

AGENCY: Office of Justice Programs (OJP), Bureau of Justice Assistance (BJA), Justice.

ACTION: Notice of meeting.

SUMMARY: This is an announcement of a meeting of the Public Safety Officer Medal of Valor Review Board, primarily intended to consider nominations for the 2017–2018 Medal of Valor, and to make a limited number of recommendations for submission to the U.S. Attorney General. Additional issues of importance to the Board may also be discussed. The meeting/conference call date and time is listed below.

DATES: September 10, 2018, 9:00 a.m. to 12:00 p.m. EDT.

ADDRESSES: The public may hear the proceedings of this meeting/conference call at the Office of Justice Programs, 810 7th Street NW, Washington, DC 20531.

FOR FURTHER INFORMATION CONTACT: Gregory Joy, Policy Advisor, Bureau of Justice Assistance, Office of Justice Programs, 810 7th Street NW, Washington, DC 20531, by telephone at (202) 514–1369, toll free (866) 859–2687, or by email at *Gregory.joy@usdoj.gov.*

SUPPLEMENTARY INFORMATION: The Public Safety Officer Medal of Valor Review Board carries out those advisory functions specified in 42 U.S.C. 15202. Pursuant to 42 U.S.C. 15201, the President of the United States is authorized to award the Public Safety Officer Medal of Valor, the highest national award for valor by a public safety officer.

This meeting/conference call is open to the public at the offices of BJA. For security purposes, members of the public who wish to participate must register at least seven (7) days in advance of the meeting/conference call by contacting Mr. Joy. All interested participants will be required to meet at the Bureau of Justice Assistance, Office of Justice Programs; 810 7th Street NW, Washington, DC, 20531, and will be required to sign in at the front desk. *Note:* Photo identification will be required for admission. Additional identification documents may be required.

Access to the meeting/conference call will not be allowed without prior registration. Anyone requiring special accommodations should contact Mr. Joy at least seven (7) days in advance of the meeting. Please submit any comments or written statements for consideration by the Review Board in writing at least seven (7) days in advance of the meeting date.

Gregory Joy,

Policy Advisor/Designated Federal Officer, Bureau of Justice Assistance.

[FR Doc. 2018–16328 Filed 7–30–18; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF LABOR

Notice of Initial Determination To Remove Cotton From Uzbekistan From the List of Products Requiring Federal Contractor Certification as to Forced or Indentured Child Labor Pursuant to Executive Order 13126

AGENCY: Bureau of International Labor Affairs, Department of Labor.

ACTION: Notice of initial determination; request for comments.

SUMMARY: This initial determination proposes to revise the list required by Executive Order No. 13126 (''Prohibition of Acquisition of Products Produced by Forced or Indentured Child Labor'') (E.O. List) in accordance with the Department of Labor's (DOL) ''Procedural Guidelines for the Maintenance of the List of Products Requiring Federal Contractor Certification as to Forced or Indentured Child Labor'' (the Procedural Guidelines).[1] The E.O. List identifies a list of products, by their country of origin, that DOL, in consultation and cooperation with the Department of State and the Department of Homeland Security (hereinafter ''the three Departments''), has a reasonable basis to believe might have been mined, produced, or manufactured by forced or indentured child labor. This notice proposes to remove cotton from Uzbekistan because the three Departments have preliminarily determined that the use of forced or indentured child labor in the production of that product has been significantly reduced. The Department of Labor invites public comment on this initial determination. The three Departments will consider all public comments prior to publishing a final determination revising the E.O. List.

DATES: Comments should be submitted to the Office of Child Labor, Forced Labor, and Human Trafficking (OCFT) via one of the methods described below and must be received by no later than 5 p.m. ET, August 30, 2018, to guarantee consideration.

ADDRESSES: Information submitted to the Department of Labor should be submitted directly to OCFT, Bureau of International Labor Affairs, U.S. Department of Labor. Comments, identified as ''Docket No. DOL–2018–0004,'' may be submitted by any of the following methods:

1. *Federal eRulemaking Portal:* You may submit electronic comments to: *http://www.regulations.gov.* The portal includes instructions for submitting comments. Parties submitting responses electronically are encouraged not to submit paper copies.

2. *Facsimile (fax):* OCFT, at 202–693–4830.

3. *Mail, Express Delivery, Hand Delivery, and Messenger Service (2 copies):* Rachel Rigby/Austin Pedersen, U.S. Department of Labor, OCFT, Bureau of International Labor Affairs, 200 Constitution Avenue NW, Room S–5313, Washington, DC 20210.

4. *Email:* Email submissions should be addressed to: *EO13126@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Director, Office of Child Labor, Forced Labor, and Human Trafficking, Bureau of International Labor Affairs, U.S. Department of Labor, at (202) 693–4843 (this is not a toll free number). Individuals with hearing or speech impairments may access the telephone number above via TTY by calling the Federal Information Relay Service at 1–877–889–5627.

SUPPLEMENTARY INFORMATION:

I. Information Sought

The Department of Labor is requesting public comment on the revisions to the list proposed below, as well as any other issue related to the fair and effective implementation of E.O. 13126. This notice is a general solicitation of comments from the public. All submitted comments will be made a part of the public record and will be available for inspection on *http://www.regulations.gov.*

In conducting research for this initial determination, the three Departments considered a wide variety of materials based on their own research, and which originates from other U.S. Government agencies, foreign governments, international organizations, non-governmental organizations (NGOs), U.S. Government-funded technical assistance and field research projects, academic and other independent research, media, and other sources. The Department of State and U.S. embassies

[1] 66 FR 5351 (Jan. 18, 2001).

and consulates abroad also provided important information by gathering data from contacts, conducting site visits, and reviewing local media sources. In developing the proposed revision to the E.O. List, the three Departments' review focused on information concerning the use of forced or indentured child labor that was available from the above sources.

As outlined in the Procedural Guidelines, several factors were weighed in determining whether a product should be placed, or remain on, the revised E.O. List: The nature of the information describing the use of forced or indentured child labor; the source of the information; the date of the information; the extent of corroboration of the information by appropriate sources; whether the information involved more than an isolated incident; and whether recent and credible efforts are being made to address forced or indentured child labor in a particular country and industry (66 FR 5351).

This notice constitutes an initial determination to revise the list issued December 1, 2014. Based on available information from various sources, the three Departments have preliminarily concluded that there is no longer a reasonable basis to believe that there is use of forced or indentured child labor in the production of the following product, identified by its country of origin:

Product: Cotton
Country: Uzbekistan

The Department of Labor has received recent, credible, and corroborated information from various sources on the use of forced or indentured child labor in cotton production in Uzbekistan. This information indicates that while children previously worked under forced labor conditions in cotton production, the use of forced child labor appears to have been significantly reduced. Therefore, the three Departments have preliminarily concluded that there is no longer a reasonable basis to believe that cotton from Uzbekistan is produced by forced or indentured child labor, except in a few isolated instances, and therefore it should not continue to be on the list.

DOL placed cotton from Uzbekistan on the List in 2010, based on 14 sources dating from 2002 to 2008. Sources indicated that school administrators, at the direction of central and local governments, systematically mobilized children as young as 7 years old for participation in the annual cotton harvest.[2] In 2013, the Government of Uzbekistan committed to working with the International Labor Organization (ILO) to address forced child labor. Over time, three forms of harvest monitoring were established: ILO-implemented Third Party Monitoring (TPM), Uzbekistan's own national monitoring led by the Coordination Council, and independent monitoring conducted by human rights activists, many of whom coordinate their reporting through the Uzbek German Forum. In 2017, ILO monitoring, Uzbekistan's national monitoring, and observation by independent human rights activists each found that forced child labor had been reduced to a few incidents in the cotton harvest, and only 32 additional children were found to be engaged in child labor, though not all in forced labor conditions, in the cotton harvest.[3] Both the U.S. Embassy in Tashkent's observation during the 2017 harvest, as well as DOL's review of available information, corroborated that forced child labor in the production of cotton had been significantly reduced to isolated incidents.[4] Further, the Government of Uzbekistan has taken steps to improve the monitoring environment for independent activists and follow up on all reports of child labor and forced labor in the cotton harvest, including those made by independent activists.[5] However, both the ILO and independent monitoring found that at least 300,000 adults were forced to work in the 2017 cotton harvest.[6]

The Department of Labor invites public comment on whether this product (and/or other products, regardless of whether they are mentioned in this notice) should be included in or removed from the revised E.O. List. To the extent possible, comments provided should address the criteria for inclusion of a product on the E.O. List contained in the Procedural Guidelines discussed above.

Following receipt and consideration of comments on the removal from the E.O. List set out above, the three Departments will issue a final determination in the **Federal Register**. The three Departments intend to continue to revise the E.O. List periodically to add and/or remove products as warranted by the receipt of new and credible information.

II. Background

E.O. 13126 was signed on June 12, 1999, and published in the **Federal Register** on June 16, 1999.[7] E.O. 13126 declared that it was ''the policy of the United States Government . . . that executive agencies shall take appropriate actions to enforce the laws prohibiting the manufacture or importation of goods, wares, articles, and merchandise mined, produced or manufactured wholly or in part by forced or indentured child labor.'' The E.O. defines ''forced or indentured child labor'' as all work or service exacted from any person under the age of 18 under the menace of any penalty for its nonperformance and for which the worker does not offer himself voluntarily, or performed by any person under the age of 18 pursuant to a contract the enforcement of which can be accomplished by process or penalties.

Pursuant to E.O. 13126, and following public notice and comment, the Department of Labor published in the January 18, 2001, **Federal Register** the first E.O. List of products, along with their respective countries of origin, that the Department, in consultation and cooperation with the Departments of State and Treasury (whose relevant responsibilities are now within the Department of Homeland Security), had a reasonable basis to believe might have been mined, produced or manufactured with forced or indentured child labor.[8] The Department also published the Procedural Guidelines on January 18, 2001, which provide procedures for the maintenance, review, and, as appropriate, revision of the E.O. List.[9]

The Procedural Guidelines provide that the E.O. List may be revised through consideration of submissions by individuals and on the three Departments' own initiative. When proposing a revision to the E.O. List, DOL must publish in the **Federal**

[2] ''Environmental Justice Foundation. Child Labor and Cotton in Uzbekistan.'' available from *http://www.ejfoundation.org/page145.html;* ''Environmental Justice Foundation. White Gold: The True Cost of Cotton.'' London, 2005; available from *http://www.ejfoundation.org/pdf/white_gold_the_true_cost_of_cotton.pdf;* U.S. Department of State. ''Uzbekistan. '' In Country Reports on Human Rights Practices 2007, March 11, 2008; available from *http://www.state.gov/g/drl/rls/hrrpt/2007/100623.htm;* U.S. Embassy Tashkent. reporting. June 6, 2008.

[3] ILO. ''Third-Party Monitoring of Measures Against Child Labor and Forced Labor During the 2017 Cotton Harvest in Uzbekistan.'' February 1, 2018. *http://www.ilo.org/ipec/Informationresources/WCMS_543130/lang-en/index.htm;* Government of Uzbekistan. Response to TDA Questionnaire; January 25, 2017; Uzbek German Forum for Human Rights. Cotton Harvest 2017: Summary of Key Findings. March 2018. On file.

[4] U.S. Embassy—Tashkent. Reporting. January 9, 2018; Uzbek German Forum for Human Rights, 2018; ILO, 2018.

[5] U.S. Embassy—Tashkent, 2018.

[6] ILO, 2018; Uzbek German Forum for Human Rights, 2018.

[7] 64 FR 32383.

[8] 66 FR 5353.

[9] 66 FR 5351.

Register a notice of initial determination, which includes any proposed alteration to the E.O. List. The three Departments will consider all public comments prior to the publication of a final determination of a revised E.O. List.

On January 18, 2001, pursuant to Section 3 of E.O. 13126, the Federal Acquisition Regulatory Council published a final rule to implement specific provisions of E.O. 13126 that require, among other things, that Federal contractors who supply products that appear on the list certify to the contracting officer that the contractor, or, in the case of an incorporated contractor, a responsible official of the contractor, has made a good faith effort to determine whether forced or indentured child labor was used to mine, produce, or manufacture any product furnished under the contract and that, on the basis of those efforts, the contractor is unaware of any such use of forced or indentured child labor.[10]

On September 11, 2009, the Department of Labor published an initial determination in the **Federal Register** proposing to revise the E.O. List to include 29 products from 21 countries. The Notice requested public comments for a period of 90 days. Public comments were received and reviewed by all relevant agencies and a final determination was issued on July 20, 2010. Following the same process, the E.O. List was revised again in 2011, 2012, 2013, and 2014. The most recent E.O. List, finalized on December 1, 2014, includes 35 products from 26 countries.

The current E.O. List and the Procedural Guidelines can be accessed at *http://www.dol.gov/ilab/reports/child-labor/list-of-products/* or can be obtained from: OCFT, Bureau of International Labor Affairs, Room S–5313, U.S. Department of Labor, 200 Constitution Avenue NW, Washington, DC 20210; telephone: (202) 693–4843; fax (202) 693–4830.

(Authority: E.O. 13126, 64 FR 32383)

Signed at Washington, DC, this 24 day of July 2018.

Martha E. Newton,

Deputy Undersecretary for International Affairs.

[FR Doc. 2018–16288 Filed 7–30–18; 8:45 am]

BILLING CODE 4510–28–P

[10] *See* 48 CFR subpart 22.15.

NUCLEAR REGULATORY COMMISSION

[NRC–2018–0152]

Biweekly Notice: Applications and Amendments to Facility Operating Licenses and Combined Licenses Involving No Significant Hazards Considerations

AGENCY: Nuclear Regulatory Commission.

ACTION: Biweekly notice.

SUMMARY: Pursuant to Section 189a.(2) of the Atomic Energy Act of 1954, as amended (the Act), the U.S. Nuclear Regulatory Commission (NRC) is publishing this regular biweekly notice. The Act requires the Commission to publish notice of any amendments issued, or proposed to be issued, and grants the Commission the authority to issue and make immediately effective any amendment to an operating license or combined license, as applicable, upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This biweekly notice includes all notices of amendments issued, or proposed to be issued, from June 30, 2018 to July 16, 2018. The last biweekly notice was published on July 17, 2018.

DATES: Comments must be filed by August 30, 2018. A request for a hearing must be filed by October 1, 2018.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- *Federal Rulemaking Website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2018–0152. Address questions about NRC dockets 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:* May Ma, Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Shirley Rohrer, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001; telephone: 301–415–5411; email: *Shirley.Rohrer@nrc.gov*

SUPPLEMENTARY INFORMATION:

I. Notice of Consideration of Issuance of Amendments to Facility Operating Licenses and Combined Licenses and Proposed No Significant Hazards Consideration Determination

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in section 50.92 of title 10 of the *Code of Federal Regulations* (10 CFR), this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated, or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-day period provided that its final determination is that the amendment involves no significant hazards consideration. In addition, the Commission may issue the amendment prior to the expiration of the 30-day comment period if circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example in derating or shutdown of the facility. If the Commission takes action prior to the expiration of either the comment period or the notice period, it will publish in the **Federal Register** a notice of issuance. If the Commission makes a final no significant hazards consideration determination, any hearing will take place after issuance. The Commission expects that the need to take this action will occur very infrequently.

A. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any persons (petitioner) whose interest may be affected by this action may file a request for a hearing and petition for leave to intervene (petition) with respect to the action. Petitions shall be filed in accordance with the Commission's ''Agency Rules of Practice and Procedure'' in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.309. The NRC's regulations are accessible electronically from the NRC Library on the NRC's website at *http://www.nrc.gov/reading-rm/doc-collections/cfr/.* Alternatively, a copy of the regulations is available at the NRC's Public Document Room, located at One White Flint North, Room O1–F21, 11555 Rockville Pike (First Floor), Rockville, Maryland 20852. If a petition is filed, the Commission or a presiding officer will rule on the petition and, if appropriate, a notice of a hearing will be issued.

As required by 10 CFR 2.309(d) the petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements for standing: (1) The name, address, and telephone number of the petitioner; (2) the nature of the petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the petitioner's interest.

In accordance with 10 CFR 2.309(f), the petition must also set forth the specific contentions which the petitioner seeks to have litigated in the proceeding. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner must provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to the specific sources and documents on which the petitioner intends to rely to support its position on the issue. The petition must include sufficient information to show that a genuine dispute exists with the applicant or licensee on a material issue of law or fact. Contentions must be limited to matters within the scope of the proceeding. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to satisfy the requirements at 10 CFR 2.309(f) with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene. Parties have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that party's admitted contentions, including the opportunity to present evidence, consistent with the NRC's regulations, policies, and procedures.

Petitions must be filed no later than 60 days from the date of publication of this notice. Petitions and motions for leave to file new or amended contentions that are filed after the deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i) through (iii). The petition must be filed in accordance with the filing instructions in the ''Electronic Submissions (E-Filing)'' section of this document.

If a hearing is requested, and the Commission has not made a final determination on the issue of no significant hazards consideration, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to establish when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of the amendment unless the Commission finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

A State, local governmental body, Federally-recognized Indian Tribe, or agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h)(1). The petition should state the nature and extent of the petitioner's interest in the proceeding. The petition should be submitted to the Commission no later than 60 days from the date of publication of this notice. The petition must be filed in accordance with the filing instructions in the ''Electronic Submissions (E-Filing)'' section of this document, and should meet the requirements for petitions set forth in this section, except that under 10 CFR 2.309(h)(2) a State, local governmental body, or Federally-recognized Indian Tribe, or agency thereof does not need to address the standing requirements in 10 CFR 2.309(d) if the facility is located within its boundaries. Alternatively, a State, local governmental body, Federally-recognized Indian Tribe, or agency thereof may participate as a non-party under 10 CFR 2.315(c).

If a hearing is granted, any person who is not a party to the proceeding and is not affiliated with or represented by a party may, at the discretion of the presiding officer, be permitted to make a limited appearance pursuant to the provisions of 10 CFR 2.315(a). A person making a limited appearance may make an oral or written statement of his or her position on the issues but may not otherwise participate in the proceeding. A limited appearance may be made at any session of the hearing or at any prehearing conference, subject to the limits and conditions as may be imposed by the presiding officer. Details regarding the opportunity to make a limited appearance will be provided by the presiding officer if such sessions are scheduled.

B. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including a request for hearing and petition for leave to intervene (petition), any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities that request to participate under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007, as amended at 77 FR 46562; August 3, 2012). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Detailed guidance on making electronic submissions may be found in the Guidance for Electronic Submissions to the NRC and on the NRC website at *http://www.nrc.gov/site-help/e-submittals.html.* Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at

hearing.docket@nrc.gov, or by telephone at 301–415–1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public website at *http://www.nrc.gov/site-help/e-submittals/getting-started.html.* Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit adjudicatory documents. Submissions must be in Portable Document Format (PDF). Additional guidance on PDF submissions is available on the NRC's public website at *http://www.nrc.gov/site-help/electronic-sub-ref-mat.html.* A filing is considered complete at the time the document is submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed so that they can obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's Electronic Filing Help Desk through the ''Contact Us'' link located on the NRC's public website at *http://www.nrc.gov/site-help/e-submittals.html,* by email to *MSHD.Resource@nrc.gov,* or by a toll-free call at 1–866–672–7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, 11555 Rockville Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff. Participants filing adjudicatory documents in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket which is available to the public at *https://adams.nrc.gov/ehd,* unless excluded pursuant to an order of the Commission or the presiding officer. If you do not have an NRC-issued digital ID certificate as described above, click cancel when the link requests certificates and you will be automatically directed to the NRC's electronic hearing dockets where you will be able to access any publicly available documents in a particular hearing docket. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or personal phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. For example, in some instances, individuals provide home addresses in order to demonstrate proximity to a facility or site. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

For further details with respect to these license amendment applications, see the application for amendment which is available for public inspection in ADAMS and at the NRC's PDR. For additional direction on accessing information related to this document, see the ''Obtaining Information and Submitting Comments'' section of this document.

Arizona Public Service Company (APS), et al., Docket Nos. STN 50–528, STN 50–529, and STN 50–530, Palo Verde Nuclear Generating Station, Unit Nos. 1, 2, and 3, Maricopa County, Arizona

Date of amendment request: May 25, 2018. A publicly-available version is in ADAMS under Accession No. ML18145A303.

Description of amendment request: The amendments would revise the technical specification (TS) requirement regarding response time testing of pressure transmitters.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change revises the Technical Specification (TS) Definition of Reactor Protective System (RPS) and Engineered Safety Features (ESF) system instrumentation response time to permit Arizona Public Service Company (APS) to evaluate using an NRC-approved methodology and apply a bounding response time for pressure transmitters in lieu of measurement. The requirement for the instrumentation to actuate within the response time assumed in the accident analysis is unaffected.

The response time associated with the RPS and ESF instrumentation is not an initiator of any accident. Therefore, the proposed change has no significant effect on the probability of any accident previously evaluated.

The affected RPS and ESF instrumentation are assumed to actuate their respective components within the required response time to mitigate accidents previously evaluated. Revising the TS definition for RPS and ESF instrumentation response times to allow an NRC-approved methodology for verifying response time for pressure transmitters does not alter the surveillance requirements that verify the RPS and ESF instrumentation response times are within the required limits. As such, the TS will continue to assure that the RPS and ESF instrumentation actuate their associated

components within the specified response time to accomplish the required safety functions assumed in the accident analyses. Therefore, the assumptions used in any accidents previously evaluated are unchanged and there is no significant increase in the consequences.

Therefore, the proposed amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change revises the TS Definition of RPS and ESF instrumentation response time to permit APS to evaluate using an NRC-approved methodology and apply a bounding response time for pressure transmitters in lieu of measurement. The proposed change does not involve a physical alteration of the plant (*i.e.,* no new or different type of equipment will be installed). The proposed change does not alter any assumptions made in the safety analyses. The proposed change does not alter the limiting conditions for operation for the RPS or ESF instrumentation, nor does it change the Surveillance Requirement to verify the RPS and ESF instrumentation response times are within the required limits. As such, the proposed change does not alter the operability requirements for the RPS and ESF instrumentation, and therefore, does not introduce any new failure modes.

Therefore, the proposed amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

The proposed change revises the TS Definition of RPS and ESF instrumentation response time to permit APS to evaluate using an NRC-approved methodology and apply a bounding response time for pressure transmitters in lieu of measurement. The proposed change has no effect on the required RPS and ESF instrumentation response times or setpoints assumed in the safety analyses and the TS requirements to verify those response times and setpoints.

The proposed change does not alter any Safety Limits or analytical limits in the safety analysis. The proposed change does not alter the TS operability requirements for the RPS and ESF instrumentation. The RPS and ESF instrumentation actuation of the required systems and components at the required setpoints and within the specified response times will continue to accomplish the design basis safety functions of the associated systems and components in the same manner as before. As such, the RPS and ESF instrumentation will continue to perform the required safety functions as assumed in the safety analyses for all previously evaluated accidents.

Therefore, the proposed amendment does not involve a significant reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on that review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the request for amendments involves no significant hazards consideration.

Attorney for licensee: Michael G. Green, Senior Regulatory Counsel, Pinnacle West Capital Corporation, P.O. Box 52034, Mail Station 8695, Phoenix, Arizona 85072–2034.

NRC Branch Chief: Robert J. Pascarelli.

Duke Energy Carolinas, LLC, Docket Nos. 50–369 and 50–370, McGuire Nuclear Station, Unit Nos. 1 and 2, Mecklenburg County, North Carolina

Date of amendment request: February 26, 2018. A publicly-available version is in ADAMS under Accession No. ML18065A180.

Description of amendment request: The amendments would modify Technical Specification (TS) 3.4.11, ''Pressurizer Power Operated Relief Valves (PORVs),'' to resolve non-conservative Required Actions. TS 3.8.11, Condition B for one or two PORVs inoperable and not capable of being manually cycled is revised to split it into three separate Conditions: (1) One Train B PORV inoperable and not capable of being manually cycled, (2) one Train A PORV inoperable and not capable of being manually cycled, and (3) two Train B PORVs inoperable and not capable of being manually cycled. TS 3.8.11, Condition C for one block valve inoperable is revised to split it into two separate Conditions: (1) One Train B block valve inoperable and (2) one Train A block valve inoperable. TS 3.8.11, Condition F for two block valves inoperable is revised to be new Condition I for two Train B block valves inoperable. A new Condition, Condition J, is added for one Train B PORV and the other Train B block valve inoperable. Current Condition G for three block valve inoperable is revised to be new Condition K. Current Condition D is revised and renamed as Condition E, current Condition E is revised and renamed as Condition F and current Condition H is revised and renamed as new Condition L. Surveillance Requirement (SR) 3.4.11.1 Note is revised to include additional Conditions when performing this SR is not required for inoperable block valves in these Conditions.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change revises the TS for the purpose of correcting non-conservative TS Required Actions when PORVs and associated block valves are inoperable. By requiring inoperable PORVs and block valves be returned to operable status within specified completion times, the proposed change will increase the availability of equipment for performing safety-related functions. The proposed change ensures assumptions associated with accident analyses are met. The probability of an accident previously evaluated is not affected and there is no increase in the consequences of any accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change revises the TS for the purpose of correcting non-conservative TS Required Actions. The proposed change does not introduce new equipment or new equipment operating modes. The proposed change does not increase the likelihood of the malfunction of any system, structure, or component, or negatively impact any analyzed accident. The proposed change ensures assumptions made in the safety analyses are met. Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed amendment involve a significant reduction in the margin of safety?

Response: No.

Overall plant safety would be enhanced as a result of the additional restrictions placed on the PORVs and associated block valves. The proposed change does not alter the manner in which safety limits, limiting safety system settings, or limiting conditions for operation are determined.

The safety analysis assumptions and acceptance criteria are not affected by this change. Therefore, the proposed change does not involve a reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Kate B. Nolan, Deputy General Counsel, Duke Energy Carolinas, LLC, 550 South Tryon Street—DEC45A Charlotte, NC 28202–1802.

NRC Branch Chief: Michael T. Markley.

Entergy Louisiana, LLC, and Entergy Operations, Inc., Docket No. 50–458, River Bend Station, Unit No. 1 (RBS), West Feliciana Parish, Louisiana

Date of amendment request: April 30, 2018. A publicly-available version is in ADAMS under Accession No. ML18128A044.

Description of amendment request: The proposed change would revise the Emergency Plan for RBS to adopt the revised Emergency Action Level (EAL) scheme described in Revision 6 to Nuclear Energy Institute's (NEI's), NEI 99–01, ''Development of Emergency Action Levels for Non-Passive Reactors.'' Revision 6 to NEI 99–01 was endorsed by the NRC by letter dated March 28, 2013 (ADAMS Accession No. ML12346A463).

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Do the proposed changes involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed changes to the RBS EALs do not involve any physical changes to plant equipment or systems and do not alter the assumptions of any accident analyses. The proposed changes do not adversely affect accident initiators or precursors and do not alter design assumptions, plant configuration, or the manner in which the plant is operated and maintained. The proposed changes do not adversely affect the ability of structures, systems or components (SSCs) to perform intended safety functions in mitigating the consequences of an initiating event within the assumed acceptance limits.

Therefore, the changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Do the proposed changes create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

No new accident scenarios, failure mechanisms, or limiting single failures are introduced as a result of the proposed changes. The changes do not challenge the integrity or performance of any safety-related systems. No plant equipment is installed or removed, and the changes do not alter the design, physical configuration, or method of operation of any plant SSC. Because EALs are not accident initiators and no physical changes are made to the plant, no new causal mechanisms are introduced.

Therefore, the changes do not create the possibility of a new or different kind of accident from an accident previously evaluated.

3. Do the proposed changes involve a significant reduction in a margin of safety?

Response: No.

Margin of safety is associated with the ability of the fission product barriers (*i.e.,* fuel cladding, reactor coolant system pressure boundary, and containment structure) to limit the level of radiation dose to the public. The proposed changes do not impact operation of the plant and no accident analyses are affected by the proposed changes. The changes do not affect the Technical Specifications or the method of operating the plant. Additionally, the proposed changes will not relax any criteria used to establish safety limits and will not relax any safety system settings. The safety analysis acceptance criteria are not affected by these changes. The proposed changes will not result in plant operation in a configuration outside the design basis. The proposed changes do not adversely affect systems that respond to safely shut down the plant and to maintain the plant in a safe shutdown condition.

Therefore, the changes do not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Anna Vinson Jones, Senior Counsel—Entergy Services, Inc., 101 Constitution Avenue NW, Suite 200 East, Washington DC 20001.

NRC Branch Chief: Robert J. Pascarelli.

Entergy Operations, Inc. (Entergy), System Energy Resources, Inc., Cooperative Energy, A Mississippi Electric Cooperative, and Entergy Mississippi, Inc., Docket No. 50–416, Grand Gulf Nuclear Station, Unit No. 1, Claiborne County, Mississippi

Date of amendment request: April 12, 2018, as supplemented by letter dated June 7, 2018. Publicly-available versions are in ADAMS under Accession Nos. ML18102B445 and ML18158A514, respectively.

Description of amendment request: The proposed amendment would modify the technical specifications (TSs) by relocating specific surveillance frequencies to a licensee-controlled program with the adoption of Technical Specification Task Force (TSTF) Traveler TSTF–425, Revision 3, ''Relocate Surveillance Frequencies to Licensee Control-RITSTF [Risk-Informed TSTF] Initiative 5b.'' Additionally, the change would add a new program, the Surveillance Frequency Control Program (SFCP), to TS Chapter 5.0, ''Administrative Controls.''

The NRC staff issued a ''Notice of Availability of Technical Specification Improvement to Relocate Surveillance Frequencies to Licensee Control-Risk-Informed Technical Specification Task Force (RITSTF) Initiative 5b, Technical Specification Task Force-425, Revision 3,'' in the **Federal Register** on July 6, 2009 (74 FR 31996). The notice included a model safety evaluation, a model no significant hazards consideration (NSHC) determination, and a model license amendment request. In its application dated April 12, 2018, the licensee affirmed the applicability of the model NSHC determination, which is presented below.

Basis for proposed NSHC determination: As required by 10 CFR 50.91(a), an analysis of the issue of NSHC adopted by the licensee is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of any accident previously evaluated?

Response: No.

The proposed change relocates the specified frequencies for periodic surveillance requirements to licensee control under a new Surveillance Frequency Control Program. Surveillance frequencies are not an initiator to any accident previously evaluated. As a result, the probability of any accident previously evaluated is not significantly increased. The systems and components required by the technical specifications for which the surveillance frequencies are relocated are still required to be operable, meet the acceptance criteria for the surveillance requirements, and be capable of performing any mitigation function assumed in the accident analysis. As a result, the consequences of any accident previously evaluated are not significantly increased.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any previously evaluated?

Response: No.

No new or different accidents result from utilizing the proposed change. The changes do not involve a physical alteration of the plant (*i.e.,* no new or different type of equipment will be installed) or a change in the methods governing normal plant operation. In addition, the changes do not impose any new or different requirements. The changes do not alter assumptions made in the safety analysis. The proposed changes are consistent with the safety analysis assumptions and current plant operating practice.

Therefore, the proposed changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The design, operation, testing methods, and acceptance criteria for systems, structures, and components (SSCs), specified in applicable codes and standards (or alternatives approved for use by the NRC) will continue to be met as described in the plant licensing basis (including the final safety analysis report and bases to TS), since these are not affected by changes to the surveillance frequencies. Similarly, there is no impact to safety analysis acceptance criteria as described in the plant licensing basis. To evaluate a change in the relocated surveillance frequency, Entergy will perform a probabilistic risk evaluation using the guidance contained in NRC approved [Nuclear Energy Institute] NEI 04–10, Rev. 1 in accordance with the TS SFCP. NEI 04–10, Rev. 1, methodology provides reasonable acceptance guidelines and methods for evaluating the risk increase of proposed changes to surveillance frequencies consistent with Regulatory Guide 1.177.

Therefore, the proposed changes do not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the analysis adopted by the licensee and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves NSHC.

Attorney for licensee: Anna Vinson Jones, Senior Counsel/Legal Department, Entergy Services, Inc., 101 Constitution Avenue NW, Washington, DC 20001.

NRC Branch Chief: Robert J. Pascarelli.

Entergy Operations, Inc., Docket No. 50–382, Waterford Steam Electric Station, Unit No. 3 (Waterford 3), St. Charles Parish, Louisiana

Date of amendment request: March 26, 2018, as supplemented by letter dated May 17, 2018. Publicly-available versions are in ADAMS under Accession Nos. ML18085B196 and ML18137A494, respectively.

Description of amendment request: The proposed amendment would revise Waterford 3 Technical Specifications (TS) Section 3/4.7.4, ''Ultimate Heat Sink.'' Specifically, the proposed amendment would correct the wet cooling tower basin level discrepancy, revise requirements for cooling fan operation described in TS 3.7.4 Action Statements a, c, and d, and revise TS Table 3.7–3, ''Ultimate Heat Sink Minimum Fan Requirements Per Train.''

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change modifies Technical Specification 3/4.7.4 to be consistent with the revised design basis calculations. This change is necessary to preserve the assumptions and limits of the revised ultimate heat sink design basis calculation. The calculation determines the maximum number of cooling tower fans allowed out-of-service for a given dry bulb temperature and establishes appropriate cooling tower fan operating requirements. The proposed change does not directly affect any material condition of the plant that could contribute to an accident or that could contribute to the consequences of an accident. The proposed change ensures that the mitigating effects of the ultimate heat sink will be consistent with the design basis analysis. Therefore, the proposed change will not involve a significant increase in the probability or consequences of any accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change modifies Technical Specification 3/4.7.4 to be consistent with the revised design basis calculations. [The revised calculation modifies the dry and wet cooling tower fan operability requirements to account for increased recirculation impacts for different ambient conditions and heat loads.] The proposed change to Technical Specification 3/4.7.4 does not alter the operation of the plant or the manner in which the plant is operated such that it created credible new failure mechanisms, malfunctions, or accident initiators. Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The proposed change modifies Technical Specification 3/4.7.4 to be consistent with the revised design basis calculations. The modified dry and wet cooling tower fan operability requirements result from placing lower limits on the dry bulb temperatures in the Technical Specification and limits on the number of wet cooling tower out-of-service fans per cell. The proposed change preserves the margin of safety by ensuring that the minimum number of operable fans for a given temperature are capable of removing the heat duty for the ultimate heat sink. The proposed change does not exceed or alter a design basis safety limit and maintains the ultimate heat sink capability of performing its safety function. Therefore, this change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Anna Vinson Jones, Senior Counsel, Entergy Services, Inc., 101 Constitution Avenue NW, Suite 200 East, Washington, DC 20001.

NRC Branch Chief: Robert J. Pascarelli.

Exelon Generation Company, LLC, Docket No. 50–244, R. E. Ginna Nuclear Power Plant, Wayne County, New York

Date of amendment request June 25, 2018. A publicly-available version is in ADAMS under Accession No. ML18176A327.

Description of amendment request: The proposed amendment would revise the requirements on control and shutdown rods, and rod and bank position indication in Technical Specification (TS) 3.1.4, ''Rod Group Alignment Limits,'' TS 3.1.5, ''Shutdown Bank Insertion Limit,'' TS 3.1.6, ''Control Bank Insertion Limits,'' and TS 3.1.7, ''Rod Position Indication'' consistent with NRC-approved Technical Specification Task Force Traveler (TSTF)-547, Revision 1, ''Clarification of Rod Position Requirements'' dated March 4, 2016 (ADAMS Accession Package No. ML16012A126).

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

Control and shutdown rods are assumed to insert into the core to shut down the reactor in evaluated accidents. Rod insertion limits ensure that adequate negative reactivity is available to provide the assumed shutdown margin (SDM). Rod alignment and overlap limits maintain an appropriate power distribution and reactivity insertion profile.

Control and shutdown rods are initiators to several accidents previously evaluated, such as rod ejection. The proposed change does not change the limiting conditions for operation for the rods or make any technical changes to the Technical Specifications (TS) Surveillance Requirements (SRs) governing the rods. Therefore, the proposed change has no effect on the probability of any accident previously evaluated.

Revising the TS Required Actions to provide a limited time to repair rod movement control has no effect on the SDM assumed in the accident analysis as the

proposed Required Actions require verification that SDM is maintained. The effects on power distribution will not cause a significant increase in the consequences of any accident previously evaluated as all TS requirements on power distribution continue to be applicable.

Revising the TS Required Actions to provide an alternative to frequent use of the moveable incore detector system to verify the position of rods with an inoperable rod position indicator does not change the requirements for the rods to be aligned and within the insertion limits.

Therefore, the assumptions used in any accidents previously evaluated are unchanged and there is no significant increase in the consequences.

The proposed change to resolve the differences in the TS ensure that the intended Actions are followed when equipment is inoperable. Actions taken with inoperable equipment are not assumptions in the accidents previously evaluated and have no significant effect on the consequences.

The proposed change to eliminate an unnecessary action has no effect on the consequences of accidents previously evaluated as the analysis of those accidents did not consider the use of the actions.

The proposed change to increase consistency within the TS has no effect on the consequences of accidents previously evaluated as the proposed change clarifies the application of the existing requirements and does not change the intent.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different accident from any accident previously evaluated?

Response: No.

The proposed change does not involve a physical alteration of the plant (*i.e.,* no new or different type of equipment will be installed). The change does not alter assumptions made in the safety analyses. The proposed change does not alter the limiting conditions for operation for the rods or make any technical changes to the Surveillance Requirements governing the rods. The proposed change [to actions] maintains or improves safety when equipment is inoperable and does not introduce new failure modes.

Therefore, the proposed change does not create the possibility of a new or different accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

[The proposed change to allow time for rod position indication to stabilize after rod movement and to allow an alternative method of verifying rod position has no effect on the safety margin as actual rod position is not affected.] The proposed change to provide time to repair rods that are operable but immovable does not result in a significant reduction in the margin of safety because all rods must be verified to be operable, and all other banks must be within the insertion limits. The remaining proposed changes to make the requirements internally consistent and to eliminate unnecessary actions do not affect the margin of safety as the changes do not affect the ability of the rods to perform their specified safety function.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

Based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Tamra Domeyer, Associate General Counsel, Exelon Generation Company, LLC, 4300 Winfield Road, Warrenville, IL 60555.

NRC Branch Chief: James G. Danna.

Southern Nuclear Operating Company, Inc., Docket Nos. 50–348 and 50–364, Joseph M. Farley Nuclear Plant, Unit Nos. 1 and 2, Houston County, Alabama

Date of amendment request: December 21, 2017, as supplemented by letter dated June 7, 2018. Publicly-available versions are in ADAMS under Accession Nos. ML17355A516, and ML18158A579, respectively.

Description of amendment request: The proposed amendment would revise TS 3.3.2, ''Engineered Safety Feature Actuation System (ESFAS) Instrumentation,'' by adding TS Actions that allow time to restore one high steam flow channel per steam line to Operable status before requiring a unit shutdown in the event two channels in one or more steam lines are discovered inoperable due to the trip setting not within Allowable Value.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed amendment does not affect accident initiators or precursors nor adversely alter the design assumptions, conditions, and configuration of the facility. The proposed amendment does not alter any plant equipment or operating practices with respect to such initiators or precursors in a manner that the probability of an accident is increased.

The proposed amendment does not involve a physical change to the ESFAS, nor does it change the safety function of the ESFAS instrumentation or the equipment supported by the ESFAS instrumentation. The ESFAS high steam flow channels are not assumed in the mitigation of any previously evaluated accident or transient. Automatic steam line isolation on high steam flow, containment high pressure, or low steam pressure is assumed in the mitigation of a major secondary system pipe rupture accident which bounds minor secondary system pipe breaks and the accidental opening of a secondary system steam dump, relief, or safety valve. Manual steam line isolation capability is also provided [assumed] in the mitigation of spectra of smaller secondary system pipe ruptures. During the time proposed to normalize the high steam flow channels, automatic ESFAS steam line isolation continues to be provided from either a containment high pressure signal or a low steam pressure signal, which are not impacted by the proposed license change. Additionally, manual steam line isolation continues to be provided by the ESFAS manual channels, which are not impacted by the proposed license change. As a result, the proposed amendment does not significantly alter assumptions relative to the mitigation of an accident or transient event and the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

With respect to a new or different kind of accident, there are no proposed design changes to the ESFAS; nor are there any changes in the method by which safety related plant structures, systems, and components perform their specified safety functions. The proposed amendment will not affect the normal method of plant operation or revise any operating parameters. No new accident scenarios, transient precursor, failure mechanisms, or limiting single failures will be introduced as a result of this proposed change and the failure modes and effects analyses of SSCs important to safety are not altered as a result of this proposed change.

The proposed amendment does not alter the design or performance of the ESFAS, rather, it adds actions that allow time to normalize the high steam flow channels associated with the ESFAS steam line isolation before requiring a unit shutdown in the event multiple channels are discovered inoperable due to the trip settings not within the required accuracy. The process to normalize the high steam flow channels uses current procedures, methods, and processes already established and currently in use and, therefore, does not constitute a new type of test.

No changes are being proposed to the procedures that operate the plant equipment and the change does not have a detrimental impact on the manner in which plant equipment operates or responds to an actuation signal.

Therefore, the proposed change will not create the possibility of a new or different accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The margin of safety is related to the ability of the fission product barriers to perform their design functions during and following an accident. These barriers include the fuel cladding, the reactor coolant system, and the containment. The performance of these fission product barriers will not be affected by the proposed change.

Instrumentation safety margin is established by ensuring the limiting safety system settings (LSSSs) automatically actuate the applicable design function to correct an abnormal situation before a safety limit is exceeded. Safety analysis limits are established for reactor trip system and ESFAS instrumentation functions related to those variables having significant safety functions. Containment pressure and steam line pressure provide the limiting parameter values assumed in the safety and transient analyses for mitigation of previously evaluated accidents and transients, including steam line break accidents. The high steam flow in two steam lines instrument function is not used in the safety analysis and a safety analysis limit is not specified for this trip function. Therefore, the high steam flow in two steam lines instrument function does not represent an LSSS because this instrumentation does not monitor a plant variable on which a safety limit has been placed.

The controlling parameters established to isolate the steam lines during an accident or transient are not affected by the proposed amendment and no design basis or safety limit is altered as a result of the proposed change. Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Jennifer M. Buettner, Associate General Counsel, Southern Nuclear Operating Company, Inc., 40 Inverness Center Parkway, Birmingham, AL 35242.

NRC Branch Chief: Michael T. Markley.

STP Nuclear Operating Company (STPNOC), Docket Nos. 50–498 and 50–499, South Texas Project, Unit Nos. 1 and 2, Matagorda County, Texas

Date of amendment request: March 27, 2018. A publicly-available version is in ADAMS under Accession No. ML18086B761.

Description of amendment request: The proposed amendment would revise certain minimum voltage and frequency acceptance criteria for steady-state standby diesel generator (SBDG) surveillance requirement testing. Specifically, the licensee would revise several subsections of Technical Specification 3.8.1.1, ''A.C. [Alternating Current] Sources, Operating,'' to correct non-conservative acceptance criteria.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The SBDGs are not initiators for any accidents evaluated in the Updated Final Safety Analysis Report (UFSAR). The proposed change provides a more conservative range of acceptable SBDG voltage and frequency values. Thus, Technical Specification Surveillance Requirements will continue to demonstrate sufficient margin such that mitigation of accidents evaluated in the UFSAR is not impacted. The proposed change does not alter the design function of the SBDGs nor does it affect how the SBDGs are operated or physically tested. Therefore, the proposed change does not involve an increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change does not involve any physical alterations and no new or different types of equipment are being installed. Requiring a more conservative range of acceptable SBDG voltage and frequency values does not affect SBDG operation and does not affect the ability of the SBDGs to perform their design function. There are no new credible failure mechanisms, malfunctions, or accident initiators introduced as a result of the proposed change. Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

Since the proposed change provides a more conservative range of acceptable SBDG voltage and frequency values, the margin of safety is maintained. Where required, Technical Specification Surveillance Requirement acceptance criteria have been procedurally adjusted to ensure equipment performance meets accident analysis assumptions considering uncertainties in steady-state SBDG voltage and frequency. STPNOC has evaluated the effects of SBDG voltage and frequency variations on affected equipment and confirmed that the design basis analyses are not adversely affected. Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the request for amendments involves no significant hazards consideration.

Attorney for licensee: Kym Harshaw, Vice President and General Counsel, STP Nuclear Operating Company, P.O. Box 289, Wadsworth, TX 77483.

NRC Branch Chief: Robert J. Pascarelli.

II. Previously Published Notices of Consideration of Issuance of Amendments to Facility Operating Licenses and Combined Licenses, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The following notices were previously published as separate individual notices. The notice content was the same as above. They were published as individual notices either because time did not allow the Commission to wait for this biweekly notice or because the action involved exigent circumstances. They are repeated here because the biweekly notice lists all amendments issued or proposed to be issued involving no significant hazards consideration.

For details, see the individual notice in the **Federal Register** on the day and page cited. This notice does not extend the notice period of the original notice.

Nebraska Public Power District, Docket No. 50–298, Cooper Nuclear Station (CNS), Nemaha County, Nebraska

Date of amendment request: May 10, 2018. A publicly-available version is in ADAMS under Accession No. ML18137A199.

Brief description of amendment request: The proposed amendment would modify the CNS technical specifications by revising the two recirculation loop and single recirculation loop Safety Limit Minimum Critical Power Ratio values to reflect the results of a cycle specific calculation.

Date of publication of individual notice in ***Federal Register:*** July 2, 2018 (83 FR 30984).

Expiration date of individual notice: August 1, 2018 (public comments); August 31, 2018 (hearing requests).

III. Notice of Issuance of Amendments to Facility Operating Licenses and Combined Licenses

During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application

complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR chapter I, which are set forth in the license amendment.

A notice of consideration of issuance of amendment to facility operating license or combined license, as applicable, proposed no significant hazards consideration determination, and opportunity for a hearing in connection with these actions, was published in the **Federal Register** as indicated.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.22(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action see (1) the applications for amendment, (2) the amendment, and (3) the Commission's related letter, Safety Evaluation and/or Environmental Assessment as indicated. All of these items can be accessed as described in the ''Obtaining Information and Submitting Comments'' section of this document.

Duke Energy Progress, LLC, Docket Nos. 50–325 and 50–324, Brunswick Steam Electric Plant (BSEP), Unit Nos. 1 and 2, Brunswick County, North Carolina

Date of amendment request: November 15, 2017, as supplemented by letter dated May 23, 2018.

Brief description of amendments: The amendments revised fire protection license condition 2.B.(6) to allow, as a performance-based method, certain currently-installed thermal insulation materials to be retained and allow future use of these insulation materials in limited applications subject to appropriate engineering reviews and controls, as a deviation from the National Fire Protection Association Standard 805, Chapter 3, Section 3.3, Prevention.

Date of issuance: July 6, 2018.

Effective date: As of the date of issuance and shall be implemented within 120 days.

Amendment Nos.: 284 (Unit 1) and 312 (Unit 2). A publicly-available version is in ADAMS under Accession No. ML18106B169; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Renewed Facility Operating License Nos. DPR–71 and DPR–62: Amendments revised the Renewed Facility Operating Licenses.

Date of initial notice in ***Federal Register:*** February 13, 2018 (83 FR 6221). The supplemental letter dated May 23, 2018, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated July 6, 2018.

No significant hazards consideration comments received: No.

Florida Power & Light Company, et al., Docket Nos. 50–335 and 50–389, St. Lucie Plant, Unit Nos. 1 and 2, St. Lucie County, Florida

Date of amendment request: September 14, 2017, as supplemented by letter dated February 14, 2018.

Brief description of amendments: The amendments revised the St. Lucie Plant, Unit Nos. 1 and 2, Technical Specifications related to inoperable Auxiliary Feedwater pump steam supply.

Date of issuance: July 9, 2018.

Effective date: As of the date of issuance and shall be implemented within 90 days of issuance.

Amendment Nos.: 245 (Unit 1) and 196 (Unit 2). A publicly-available version is in ADAMS under Accession No. ML18129A149; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Renewed Facility Operating License Nos. DPR–67 and NPF–16: The amendments revised the Renewed Facility Operating Licenses and Technical Specifications.

Date of initial notice in ***Federal Register:*** November 7, 2017 (82 FR 51652). The supplement dated February 14, 2018, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated July 9, 2018.

No significant hazards consideration comments received: No.

Indiana Michigan Power Company, Docket Nos. 50–315 and 50–316, Donald C. Cook Nuclear Plant, Unit Nos. 1 and 2, Berrien County, Michigan

Date of amendment request: November 7, 2017, as supplemented by letter dated May 4, 2018.

Brief description of amendments: The amendments allow for deviation from National Fire Protection Association 805 requirements to allow for currently installed non-plenum listed cables routed above suspended ceilings and to allow for the use of thin wall electrical metallic tubing and embedded/buried plastic conduit.

Date of issuance: July 6, 2018.

Effective date: As of the date of issuance and shall be implemented within 90 days of issuance.

Amendment Nos.: 340 (Unit 1) and 322 (Unit 2). A publicly-available version is in ADAMS under Accession No. ML18131A253; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Facility Operating License Nos. DPR–58 and DPR–74: The amendments revised the Facility Operating Licenses.

Date of initial notice in ***Federal Register:*** January 2, 2018 (83 FR 169). The supplemental letter dated May 4, 2018, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated July 6, 2018.

No significant hazards consideration comments received. No.

Tennessee Valley Authority, Docket No. 50–259, Browns Ferry Nuclear Plant, Unit No. 1, Limestone County, Alabama

Date of amendment request: March 16, 2018, as supplemented by letter dated April 19, 2018.

Brief description of amendment: The amendment revised License Condition 2.C(18)(a)3 for Unit No. 1 to alter the time for submittal of a revised replacement steam dryer analysis from at least 90 days prior to the start of the Unit No. 1 extended power uprate outage to 60 days prior to exceeding 3458 megawatt thermal after the outage.

Date of issuance: July 10, 2018.

Effective date: As of the date of issuance and shall be implemented immediately.

Amendment No.: 304. A publicly-available version is in ADAMS under Accession No. ML18171A337; documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

Renewed Facility Operating License No. DPR–33: Amendment revised the Unit 1 operating license.

Date of initial notice in ***Federal Register:*** The license amendment request was originally noticed in the **Federal Register** on April 10, 2018 (83 FR 15418). The supplement dated April 19, 2018, was noticed on May 8, 2018 (83 FR 20862), which superseded the original notice in its entirety.

The Commission's related evaluation of the amendment is contained in the Safety Evaluation dated July 10, 2018.

No significant hazards consideration comments received: No.

Dated at Rockville, Maryland, this 18th day of July 2018.

For the Nuclear Regulatory Commission.

Tara Inverso,

Acting Deputy Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2018–15682 Filed 7–30–18; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–83708; File No. SR–NYSEARCA–2018–52]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the NYSE Arca Options Fees and Charges and the NYSE Arca Equities Fees and Charges

July 25, 2018.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on July 13, 2018, NYSE Arca, Inc. (''Exchange'' or ''NYSE Arca'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C.78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the NYSE Arca Options Fees and Charges (the ''Options Fee Schedule'') and the NYSE Arca Equities Fees and Charges (the ''Equities Fee Schedule'' and, together with the Options Fee Schedule, the ''Fee Schedules'') related to colocation to provide Users with access to the systems, and connectivity to the data feeds, of various additional third parties. In addition, the Exchange proposes to amend its Fee Schedules to update the names of certain third parties to reflect their current names. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the co-location [4] services offered by the Exchange to provide Users [5] with access to the systems, and connectivity to the data feeds, of various additional third parties. In addition, the Exchange proposes to amend its Fee Schedules to update the names of certain third parties to reflect their current names. The Exchange proposes to make the corresponding amendments to the Exchange's Fee Schedules related to these co-location services to reflect these proposed changes.

As set forth in the Fee Schedules, the Exchange charges fees for connectivity to the execution systems of third party markets and other content service providers (''Third Party Systems''), and data feeds from third party markets and other content service providers (''Third Party Data Feeds'').[6] The lists of Third Party Systems and Third Party Data Feeds are set forth in the Fee Schedules.

The Exchange proposes to provide access to BM&F Bovespa, Canadian Securities Exchange (''CSE''), ITG TriAct MatchNow, NASDAQ Canada, Neo Aequitas, Omega, and OTC Markets Group as additional Third Party Systems (''Proposed Third Party Systems''). In addition, it proposes to provide connectivity to the same third parties' data feeds, with the exception of the OTC Markets Group [7] (''Proposed Third Party Data Feeds'').

BM&F Bovespa is a Brazilian national securities exchange. CSE and Neo Aequitas are Canadian national securities exchanges. NASDAQ Canada, also Canadian national securities exchange, operates three trading books for trading in Canadian securities: CXC, CXD, and CX2. ITG TriAct MatchNow and Omega are Canadian alternative markets that match customer orders in Canadian securities. OTC Markets Group operates trading platforms for over-the-counter securities.

The Exchange would provide access to the Proposed Third Party Systems (''Access''), and connectivity to the Proposed Third Party Data Feeds (''Connectivity''), as conveniences to Users. Use of Access or Connectivity would be completely voluntary. The Exchange is not aware of any impediment to third parties offering Access or Connectivity.

The Exchange does not have visibility into whether third parties currently offer, or intend to offer, Users access to the Proposed Third Party Systems and

[4] The Exchange initially filed rule changes relating to its co-location services with the Commission in 2010. *See* Securities Exchange Act Release No. 63275 (November 8, 2010), 75 FR 70048 (November 16, 2010) (SR–NYSEArca–2010–100). The Exchange operates a data center in Mahwah, New Jersey (the ''data center'') from which it provides co-location services to Users.

[5] For purposes of the Exchange's co-location services, a ''User'' means any market participant that requests to receive co-location services directly from the Exchange. *See* Securities Exchange Act Release No. 76010 (September 29, 2015), 80 FR 60197 (October 5, 2015) (SR–NYSEArca–2015–82). As specified in the Fee Schedules, a User that incurs co-location fees for a particular co-location service pursuant thereto would not be subject to co-location fees for the same co-location service charged by the Exchange's affiliates New York Stock Exchange LLC (''NYSE LLC''), NYSE National, Inc. (''NYSE National''), and NYSE American LLC (''NYSE American and, together with NYSE LLC and NYSE National, the ''Affiliate SROs''). *See* Securities Exchange Act Release No. 70173 (August 13, 2013), 78 FR 50459 (August 19, 2013) (SR–NYSEArca–2013–80).

[6] *See* Securities Exchange Act Release No. 80310 (March 24, 2017), 82 FR 15763 (March 30, 2017) (SR–NYSEArca–2016–89).

[7] The Exchange currently provides connectivity to the OTC Markets Group data feed as a Third Party Data Feed.

connectivity to the Proposed Third Party Data Feeds, as such third parties are not required to make that information public. However, if one or more third parties presently offer, or in the future opt to offer, such Access and Connectivity to Users, a User may utilize the Secure Financial Transaction Infrastructure (''SFTI'') network, a third party telecommunication network, third party wireless network, a cross connect, or a combination thereof to access such services and products through a connection to an access center outside the data center (which could be a SFTI access center, a third-party access center, or both), another User, or a third party vendor.

Access to the Proposed Third Party Systems

The Exchange proposes to revise the Fee Schedules to provide that Users may obtain connectivity to the Proposed Third Party Systems for a fee. As with the current Third Party Systems, Users would connect to the Proposed Third Party Systems over the internet protocol (''IP'') network, a local area network available in the data center.[8]

As with the current Third Party Systems, in order to obtain access to a Proposed Third Party System, the User would enter into an agreement with the relevant Proposed Third Party, pursuant to which the third party content service provider would charge the User for access to the Proposed Third Party System. The Exchange would then establish a unicast connection between the User and the Proposed Third Party System over the IP network.[9] The Exchange would charge the User for the connectivity to the Proposed Third Party System. A User would only receive, and only be charged for, access to the Proposed Third Party System for which it enters into agreements with the third party content service provider.

The Exchange has no ownership interest in any of the Proposed Third Party Systems. Establishing a User's access to a Proposed Third Party System would not give the Exchange any right to use the Proposed Third Party System. Connectivity to a Proposed Third Party System would not provide access or order entry to the Exchange's execution system, and a User's connection to the Proposed Third Party System would not be through the Exchange's execution system.

As with the existing connections to Third Party Systems, the Exchange proposes to charge a monthly recurring fee for connectivity to the Proposed Third Party Systems. Specifically, when a User requests access to a Proposed Third Party System, it would identify the applicable content service provider and what bandwidth connection it required.

The Exchange proposes to modify its Fee Schedules to add the Proposed Third Party Systems to its existing list of Third Party Systems. The Exchange does not propose to change the monthly recurring fee the Exchange charges Users for unicast connectivity to each Third Party System, including the Proposed Third Party Systems.

Connectivity to the Proposed Third Party Data Feeds

The Exchange proposes to revise the Fee Schedules to provide that Users may obtain connectivity to the Proposed Third Party Data Feeds for a fee. The Exchange would receive a Proposed Third Party Data Feed from the content service provider at the Exchange's data center. The Exchange would then provide connectivity to that data to Users for a fee. Users would connect to the Proposed Third Party Data Feeds over the IP network.[10] The Proposed Third Party Data Feeds would include trading information concerning the securities that are traded on the relevant Proposed Third Party Systems.

In order to connect to a Proposed Third Party Data Feed, a User would enter into a contract with the content service provider, pursuant to which the content service provider would charge the User for the data feed. The Exchange would receive the Proposed Third Party Data Feed over its fiber optic network and, after the content service provider and User entered into the contract and the Exchange received authorization from the content service provider, the Exchange would re-transmit the data to the User over the User's port. The Exchange would charge the User for the connectivity to the Proposed Third Party Data Feed. A User would only receive, and would only be charged for, connectivity to a Proposed Third Party Data Feed for which it entered into a contract.

The Exchange has no affiliation with the sellers of the Proposed Third Party Data Feeds. It would have no right to use the Proposed Third Party Data Feeds other than as a redistributor of the data. The Proposed Third Party Data Feeds would not provide access or order entry to the Exchange's execution system. The Proposed Third Party Data Feeds would not provide access or order entry to the execution systems of the third parties generating the feeds. The Exchange would receive the Proposed Third Party Data Feeds via arms-length agreements and it would have no inherent advantage over any other distributor of such data.

As it does with the existing Third Party Data Feeds, the Exchange proposes to charge a monthly recurring fee for connectivity to the Proposed Third Party Data Feeds. Depending on its needs and bandwidth, a User may opt to receive all or some of the feeds or services included in the Proposed Third Parties' Data Feeds.

The Exchange proposes to add the following fees for connectivity to the Proposed Third Party Data Feeds to its existing list in the Fee Schedules: (i) A $3,000 per month fee for BM&F Bovespa; (ii) a $1,500 per month fee for NASDAQ Canada; (iii) a $1,200 fee for Neo Aequitas; and (iv) a $1,000 per month fee for each of the CSE, ITG TriAct MatchNow and Omega.

Name Changes

The Exchange proposes to update references to the International Securities Exchange, LLC (''ISE'') to reflect its acquisition by NASDAQ, Inc. (''NASDAQ'').[11] The Exchange also proposes to update references to Bats and Chicago Board Options Exchange (''Cboe'') to reflect their business combination and name changes.[12] In the sections entitled, ''Connectivity to Third Party Systems'' and ''Connectivity to Third Party Data Feeds'', the Exchange proposes to replace references to ''International Securities Exchange (ISE)'' with ''NASDAQ ISE''. The

[8] *See* Securities Exchange Act Release No. 74219 (February 6, 2015), 80 FR 7899 (February 12, 2015) (SR–NYSEArca2015–03) (notice of filing and immediate effectiveness of proposed rule change to include IP network connections).

[9] Information flows over existing network connections in two formats: ''unicast'' format, which is a format that allows one-to-one communication, similar to a phone line, in which information is sent to and from the Exchange; and ''multicast'' format, which is a format in which information is sent one-way from the Exchange to multiple recipients at once, like a radio broadcast.

[10] *See supra* note 8, at 7899 (''The IP network also provides Users with access to away market data products'').

[11] *See* Securities Exchange Act Release No. 78119 (June 27, 2016), 81 FR 41611 (SR–ISE2016–11; SR–ISE Gemini–2016–05; SR–ISE Mercury–2016–10) (Order Granting Accelerated Approval of Proposed Rule Changes, Each as Modified by Amendment No. 1 Thereto, Relating to a Corporate Transaction in Which Nasdaq, Inc. Will Become the Indirect Parent of ISE, ISE Gemini, and ISE Mercury). *See also* Securities Exchange Act Release No. 80325 (March 29, 2017), 82 FR 16445 (April 4, 2017) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Rename the Exchange as Nasdaq ISE, LLC).

[12] *See, e.g.,* Securities Exchange Act Release No. 81981 (October 30, 2017), 82 FR 51309 (November 3, 2017) (SR–CBOE–2017–066); and 81962 (October 26, 2017), 82 FR 50711 (November 1, 2017) (SR–BatsBZX–2017–70).

Exchange also proposes to delete a reference to ''BATS'' and replace it with ''Cboe BYX Exchange (CboeBYX), Cboe BZX Exchange (CboeBZX), Cboe EDGA Exchange (CboeEDGA), and Cboe EDGX Exchange (CboeEDGX)'' and to replace references to ''Chicago Board Options Exchange (CBOE)'' with ''Cboe Exchange (Cboe) and Cboe C2 Exchange (C2)''. In each case, the names would be updated to their current names, clearly delineating the third parties to which the Exchange provides connectivity and access.

In a non-substantive change, the Exchange proposes to reorganize the table of Third Party Systems to ensure it remains alphabetical in light of the proposed name changes. The Exchange does not propose to amend any fee related to connectivity to ISE or Cboe systems or access to ISE or Cboe data.

General

As is the case with all Exchange co-location arrangements, (i) neither a User nor any of the User's customers would be permitted to submit orders directly to the Exchange unless such User or customer is a member organization, a Sponsored Participant or an agent thereof (*e.g.,* a service bureau providing order entry services); (ii) use of the co-location services proposed herein would be completely voluntary and available to all Users on a non-discriminatory basis; [13] and (iii) a User would only incur one charge for the particular co-location service described herein, regardless of whether the User connects only to the Exchange or to the Exchange and one or more of the Affiliate SROs.[14]

The proposed change is not otherwise intended to address any other issues relating to co-location services and/or related fees, and the Exchange is not aware of any problems that Users would have in complying with the proposed change.

[13] As is currently the case, Users that receive co-location services from the Exchange will not receive any means of access to the Exchange's trading and execution systems that is separate from, or superior to, that of other Users. In this regard, all orders sent to the Exchange enter the Exchange's trading and execution systems through the same order gateway, regardless of whether the sender is co-located in the data center or not. In addition, co-located Users do not receive any market data or data service product that is not available to all Users, although Users that receive co-location services normally would expect reduced latencies in sending orders to, and receiving market data from, the Exchange.

[14] *See* SR–NYSEArca–2013–80, *supra* note 6 at 50459. The Affiliate SROs have also submitted substantially the same proposed rule change to propose the changes described herein. *See* SR–NYSE–2018–32, SR–NYSEAmerican–2018–35, and SR–NYSENat–2018–15.

2. Statutory Basis

The Exchange believes that the proposed fee change is consistent with Section 6(b) of the Act,[15] in general, and furthers the objectives of Sections 6(b)(5) of the Act,[16] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to, and perfect the mechanisms of, a free and open market and a national market system and, in general, to protect investors and the public interest and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed changes would remove impediments to, and perfect the mechanisms of, a free and open market and a national market system and, in general, protect investors and the public interest because, by offering additional services, the Exchange would give each User additional options for addressing its access and connectivity needs, responding to User demand for access and connectivity options. Providing additional services would help each User tailor its data center operations to the requirements of its business operations by allowing it to select the form and latency of access and connectivity that best suits its needs.

The Exchange would provide Access and Connectivity as conveniences to Users. Use of Access or Connectivity would be completely voluntary. The Exchange is not aware of any impediment to third parties offering Access or Connectivity. The Exchange does not have visibility into whether third parties currently offer, or intend to offer, Users access to the Proposed Third Party Systems and connectivity to the Proposed Third Party Data Feeds. However, if one or more third parties presently offer, or in the future opt to offer, such access and connectivity to Users, a User may utilize the SFTI network, a third party telecommunication network, third party wireless network, a cross connect, or a combination thereof to access such services and products through a connection to an access center outside the data center (which could be a SFTI access center, a third-party access center, or both), another User, or a third party vendor.

The Exchange believes that the proposed changes would remove impediments to, and perfect the mechanisms of, a free and open market and a national market system and, in general, protect investors and the public interest because, by offering Access and Connectivity to Users when available, the Exchange would give Users additional options for connectivity and access to new services as soon as they are available, responding to User demand for access and connectivity options.

The Exchange also believes that the proposed fee change is consistent with Section 6(b)(4) of the Act,[17] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Exchange believes that the proposed fee changes are consistent with Section 6(b)(4) of the Act for multiple reasons. The Exchange operates in a highly competitive market in which exchanges offer co-location services as a means to facilitate the trading and other market activities of those market participants who believe that co-location enhances the efficiency of their operations. Accordingly, fees charged for co-location services are constrained by the active competition for the order flow of, and other business from, such market participants. If a particular exchange charges excessive fees for co-location services, affected market participants will opt to terminate their co-location arrangements with that exchange, and adopt a possible range of alternative strategies, including placing their servers in a physically proximate location outside the exchange's data center (which could be a competing exchange), or pursuing strategies less dependent upon the lower exchange-to-participant latency associated with co-location. Accordingly, the exchange charging excessive fees would stand to lose not only co-location revenues but also the liquidity of the formerly co-located trading firms, which could have additional follow-on effects on the market share and revenue of the affected exchange.

The Exchange believes that the additional services and fees proposed herein would be equitably allocated and not unfairly discriminatory because, in addition to the services being completely voluntary, they would be

[15] 15 U.S.C. 78f(b).

[16] 15 U.S.C. 78f(b)(5).

[17] 15 U.S.C. 78f(b)(4).

available to all Users on an equal basis (*i.e.,* the same products and services would be available to all Users). All Users that voluntarily selected to receive Access or Connectivity would be charged the same amount for the same services. Users that opted to use Access or Connectivity would not receive access or connectivity that is not available to all Users, as all market participants that contracted with the relevant market or content provider would receive access or connectivity.

The Exchange believes that the proposed charges would be reasonable, equitably allocated and not unfairly discriminatory because the Exchange would offer the Access and Connectivity as conveniences to Users, but in order to do so must provide, maintain and operate the data center facility hardware and technology infrastructure. The Exchange must handle the installation, administration, monitoring, support and maintenance of such services, including by responding to any production issues. Since the inception of co-location, the Exchange has made numerous improvements to the network hardware and technology infrastructure and has established additional administrative controls. The Exchange has expanded the network infrastructure to keep pace with the increased number of services available to Users, including resilient and redundant feeds. In addition, in order to provide Access and Connectivity, the Exchange would maintain multiple connections to each Proposed Third Party Data Feed and Proposed Third Party System, allowing the Exchange to provide resilient and redundant connections; adapt to any changes made by the relevant third party; and cover any applicable fees charged by the relevant third party, such as port fees. In addition, Users would not be required to use any of their bandwidth for Access and Connectivity unless they wish to do so.

The Exchange believes the proposed fees for Access and Connectivity would be reasonable because they would allow the Exchange to defray or cover the costs associated with offering Users Access and Connectivity while providing Users the convenience of receiving such Access and Connectivity within co-location, helping them tailor their data center operations to the requirements of their business operations.

For the reasons above, the proposed changes would not unfairly discriminate between or among market participants that are otherwise capable of satisfying any applicable co-location fees, requirements, terms and conditions established from time to time by the Exchange.

The Exchange also believes that the proposal to update the names of ISE, Bats and Cboe removes impediments to, and perfects the mechanisms of, a free and open market and a national market system. The Exchange does not propose to amend any fee related to connectivity to ISE or Cboe systems or access to ISE or Cboe data. The Exchange simply proposes to update its Fee Schedules to accurately reflect NASDAQ's acquisition of ISE and the business combination and name change of Bats and Cboe. Therefore, the Exchange believes the proposed rule change would avoid any potential investor confusion regarding the third parties to which the Exchange provides access and connectivity.

The Exchange believes that the non-substantive change to ensure the names in the table of Third Party Systems are in alphabetical order would remove impediments to, and perfect the mechanisms of, a free and open market and a national market system and, in general, protect investors and the public interest because the amendment would clarify Exchange rules and make it easier for market participants to find Third Party Systems in the table. The Exchange believes that this proposed non-substantive change is reasonable because the change would have no impact on pricing or services offered. Rather, the change would alleviate possible market participant confusion by making it easier to find NASDAQ, ISE and Cboe in the table.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[18] the Exchange believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act because all of the proposed services are completely voluntary.

The Exchange believes that providing Users with additional options for connectivity and access to new services would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act because such proposed Access and Connectivity would satisfy User demand for access and connectivity options. The Exchange would provide Access and Connectivity as conveniences equally to all Users. The Exchange does not have visibility into whether third parties currently offer, or intend to offer, Users access to the Proposed Third Party Systems and connectivity to the Proposed Third Party Data Feeds, as third parties are not required to make that information public. However, if one or more third parties presently offer, or in the future opt to offer, such access and connectivity to Users, a User may utilize the SFTI network, a third party telecommunication network, third party wireless network, a cross connect, or a combination thereof to access such services and products through a connection to an access center outside the data center (which could be a SFTI access center, a third-party access center, or both), another User, or a third party vendor. Users that opt to use the proposed Access or Connectivity would not receive access or connectivity that is not available to all Users, as all market participants that contract with the content provider may receive access or connectivity. In this way, the proposed changes would enhance competition by helping Users tailor their Access and Connectivity to the needs of their business operations by allowing them to select the form and latency of access and connectivity that best suits their needs.

The Exchange operates in a highly competitive market in which exchanges offer co-location services as a means to facilitate the trading and other market activities of those market participants who believe that co-location enhances the efficiency of their operations. Accordingly, fees charged for co-location services are constrained by the active competition for the order flow of, and other business from, such market participants. If a particular exchange charges excessive fees for co-location services, affected market participants will opt to terminate their co-location arrangements with that exchange, and adopt a possible range of alternative strategies, including placing their servers in a physically proximate location outside the exchange's data center (which could be a competing exchange), or pursuing strategies less dependent upon the lower exchange-to-participant latency associated with co-location. Accordingly, the exchange charging excessive fees would stand to lose not only co-location revenues but also the liquidity of the formerly co-located trading firms, which could have additional follow-on effects on the market share and revenue of the affected exchange. For the reasons described above, the Exchange believes that the

[18] 15 U.S.C. 78f(b)(8).

proposed rule change reflects this competitive environment.

The Exchange believes that the proposal to update the name of ISE to reflect its acquisition by NASDAQ and Bats and Cboe to reflect their business combination and name change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposal is ministerial in nature and is not designed to have any competitive impact. It simply seeks to update the Fee Schedules to accurately reference these markets in light of their recent name changes.

The Exchange believes that the proposed non-substantive change to ensure the names in the table of Third Party Systems are in alphabetical order would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act because the change would have no impact on pricing or the services offered. Rather, the change would alleviate possible market participant confusion by making it easier to find Third Party Systems in the table.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [19] and Rule 19b–4(f)(6) thereunder.[20] 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 prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.[21]

A proposed rule change filed under Rule 19b–4(f)(6) [22] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[23] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange requests that the Commission waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange represents that the proposed rule changes present no new or novel issues. According to the Exchange, waiver of the operative delay would allow Users to access the Proposed Third Party Systems and the Proposed Third Party Data Feeds without delay, which would assist Users in tailoring their data center operations to the requirements of their business operations. The Exchange also represents that the proposed changes to the Price List would provide Users with more complete information regarding their Access and Connectivity options. The Exchange further asserts that waiver of the operative delay would help avoid potential investor confusion by allowing the Exchange to immediately update the names of the exchanges noted above to reflect recent business combinations and name changes. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission waives the 30-day operative delay and designates the proposed rule change operative upon filing.[24]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [25] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEARCA–2018–52 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEARCA–2018–52. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEARCA–2018–52 and should be submitted on or before August 21, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[26]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–16276 Filed 7–30–18; 8:45 am]

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[19] 15 U.S.C. 78s(b)(3)(A)(iii).

[20] 17 CFR 240.19b–4(f)(6).

[21] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[22] 17 CFR 240.19b–4(f)(6).

[23] 17 CFR 240.19–4(f)(6)(iii).

[24] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[25] 15 U.S.C. 78s(b)(2)(B).

[26] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–83707; File No. SR–NYSEAMER–2018–35]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its NYSE American Equities Price List and the NYSE American Options Fee Schedule

July 25, 2018.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that on July 13, 2018, NYSE American LLC (''Exchange'' or ''NYSE American'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its NYSE American Equities Price List (''Price List'') and the NYSE American Options Fee Schedule (''Fee Schedule'') related to colocation to provide Users with access to the systems, and connectivity to the data feeds, of various additional third parties. In addition, the Exchange proposes to amend its Price List and Fee Schedule to update the names of certain third parties to reflect their current names. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the co-location [4] services offered by the Exchange to provide Users [5] with access to the systems, and connectivity to the data feeds, of various additional third parties. In addition, the Exchange proposes to amend its Price List and Fee Schedule to update the names of certain third parties to reflect their current names. The Exchange proposes to make the corresponding amendments to the Exchange's Price List and Fee Schedule related to these co-location services to reflect these proposed changes.

As set forth in the Price List and Fee Schedule, the Exchange charges fees for connectivity to the execution systems of third party markets and other content service providers (''Third Party Systems''), and data feeds from third party markets and other content service providers (''Third Party Data Feeds'').[6] The lists of Third Party Systems and Third Party Data Feeds are set forth in the Price List and Fee Schedule.

The Exchange proposes to provide access to BM&F Bovespa, Canadian Securities Exchange (''CSE''), ITG TriAct MatchNow, NASDAQ Canada, Neo Aequitas, Omega, and OTC Markets Group as additional Third Party Systems (''Proposed Third Party Systems''). In addition, it proposes to provide connectivity to the same third parties' data feeds, with the exception of the OTC Markets Group [7] (''Proposed Third Party Data Feeds'').

BM&F Bovespa is a Brazilian national securities exchange. CSE and Neo Aequitas are Canadian national securities exchanges. NASDAQ Canada, also Canadian national securities exchange, operates three trading books for trading in Canadian securities: CXC, CXD, and CX2. ITG TriAct MatchNow and Omega are Canadian alternative markets that match customer orders in Canadian securities. OTC Markets Group operates trading platforms for over-the-counter securities.

The Exchange would provide access to the Proposed Third Party Systems (''Access''), and connectivity to the Proposed Third Party Data Feeds (''Connectivity''), as conveniences to Users. Use of Access or Connectivity would be completely voluntary. The Exchange is not aware of any impediment to third parties offering Access or Connectivity.

The Exchange does not have visibility into whether third parties currently offer, or intend to offer, Users access to the Proposed Third Party Systems and connectivity to the Proposed Third Party Data Feeds, as such third parties are not required to make that information public. However, if one or more third parties presently offer, or in the future opt to offer, such Access and Connectivity to Users, a User may utilize the Secure Financial Transaction Infrastructure (''SFTI'') network, a third party telecommunication network, third party wireless network, a cross connect, or a combination thereof to access such services and products through a connection to an access center outside the data center (which could be a SFTI access center, a third-party access center, or both), another User, or a third party vendor.

Access to the Proposed Third Party Systems

The Exchange proposes to revise the Price List and Fee Schedule to provide that Users may obtain connectivity to the Proposed Third Party Systems for a fee. As with the current Third Party Systems, Users would connect to the Proposed Third Party Systems over the internet protocol (''IP'') network, a local area network available in the data center.[8]

[4] The Exchange initially filed rule changes relating to its co-location services with the Commission in 2010. See Securities Exchange Act Release No. 62961 (September 21, 2010), 75 FR 59299 (September 27, 2010) (SR–NYSEAmex–2010–80) (the ''Original Co-location Filing''). The Exchange operates a data center in Mahwah, New Jersey (the ''data center'') from which it provides co-location services to Users.

[5] For purposes of the Exchange's co-location services, a ''User'' means any market participant that requests to receive co-location services directly from the Exchange. *See* Securities Exchange Act Release No. 76009 (September 29, 2015), 80 FR 60213 (October 5, 2015) (SR–NYSEMKT–2015–67). As specified in the Price List and Fee Schedule, a User that incurs co-location fees for a particular co-location service pursuant thereto would not be subject to co-location fees for the same co-location service charged by the Exchange's affiliates New York Stock Exchange LLC (''NYSE LLC''), NYSE Arca, Inc. (''NYSE Arca'') and NYSE National, Inc. (''NYSE National'' and, together, the ''Affiliate SROs''). *See* Securities Exchange Act Release No. 70176 (August 13, 2013), 78 FR 50471 (August 19, 2013) (SR–NYSEMKT–2013–67).

[6] *See* Securities Exchange Act Release No. 80309 (March 24, 2017), 82 FR 15725 (March 30, 2017) (SR–NYSEMKT–2016–63).

[7] The Exchange currently provides connectivity to the OTC Markets Group data feed as a Third Party Data Feed.

[8] *See* Securities Exchange Act Release No. 74220 (February 6, 2015), 80 FR 7894 (February 12, 2015) (SR–NYSEMKT–2015–08) (notice of filing and immediate effectiveness of proposed rule change to include IP network connections).

As with the current Third Party Systems, in order to obtain access to a Proposed Third Party System, the User would enter into an agreement with the relevant Proposed Third Party, pursuant to which the third party content service provider would charge the User for access to the Proposed Third Party System. The Exchange would then establish a unicast connection between the User and the Proposed Third Party System over the IP network.[9] The Exchange would charge the User for the connectivity to the Proposed Third Party System. A User would only receive, and only be charged for, access to the Proposed Third Party System for which it enters into agreements with the third party content service provider.

The Exchange has no ownership interest in any of the Proposed Third Party Systems. Establishing a User's access to a Proposed Third Party System would not give the Exchange any right to use the Proposed Third Party System. Connectivity to a Proposed Third Party System would not provide access or order entry to the Exchange's execution system, and a User's connection to the Proposed Third Party System would not be through the Exchange's execution system.

As with the existing connections to Third Party Systems, the Exchange proposes to charge a monthly recurring fee for connectivity to the Proposed Third Party Systems. Specifically, when a User requests access to a Proposed Third Party System, it would identify the applicable content service provider and what bandwidth connection it required.

The Exchange proposes to modify its Price List and Fee Schedule to add the Proposed Third Party Systems to its existing list of Third Party Systems. The Exchange does not propose to change the monthly recurring fee the Exchange charges Users for unicast connectivity to each Third Party System, including the Proposed Third Party Systems.

Connectivity to the Proposed Third Party Data Feeds

The Exchange proposes to revise the Price List and Fee Schedule to provide that Users may obtain connectivity to the Proposed Third Party Data Feeds for a fee. The Exchange would receive a Proposed Third Party Data Feed from the content service provider at the Exchange's data center. The Exchange would then provide connectivity to that data to Users for a fee. Users would connect to the Proposed Third Party Data Feeds over the IP network.[10] The Proposed Third Party Data Feeds would include trading information concerning the securities that are traded on the relevant Proposed Third Party Systems.

In order to connect to a Proposed Third Party Data Feed, a User would enter into a contract with the content service provider, pursuant to which the content service provider would charge the User for the data feed. The Exchange would receive the Proposed Third Party Data Feed over its fiber optic network and, after the content service provider and User entered into the contract and the Exchange received authorization from the content service provider, the Exchange would re-transmit the data to the User over the User's port. The Exchange would charge the User for the connectivity to the Proposed Third Party Data Feed. A User would only receive, and would only be charged for, connectivity to a Proposed Third Party Data Feed for which it entered into a contract.

The Exchange has no affiliation with the sellers of the Proposed Third Party Data Feeds. It would have no right to use the Proposed Third Party Data Feeds other than as a redistributor of the data. The Proposed Third Party Data Feeds would not provide access or order entry to the Exchange's execution system. The Proposed Third Party Data Feeds would not provide access or order entry to the execution systems of the third parties generating the feeds. The Exchange would receive the Proposed Third Party Data Feeds via arms-length agreements and it would have no inherent advantage over any other distributor of such data.

As it does with the existing Third Party Data Feeds, the Exchange proposes to charge a monthly recurring fee for connectivity to the Proposed Third Party Data Feeds. Depending on its needs and bandwidth, a User may opt to receive all or some of the feeds or services included in the Proposed Third Parties' Data Feeds.

The Exchange proposes to add the following fees for connectivity to the Proposed Third Party Data Feeds to its existing list in the Price List and Fee Schedule: (i) A $3,000 per month fee for BM&F Bovespa; (ii) a $1,500 per month fee for NASDAQ Canada; (iii) a $1,200 fee for Neo Aequitas; and (iv) a $1,000 per month fee for each of the CSE, ITG TriAct MatchNow and Omega.

Name Changes

The Exchange proposes to update references to the International Securities Exchange, LLC (''ISE'') to reflect its acquisition by NASDAQ, Inc. (''NASDAQ'').[11] The Exchange also proposes to update references to Bats and Chicago Board Options Exchange (''Cboe'') to reflect their business combination and name changes.[12] In the sections entitled, ''Connectivity to Third Party Systems'' and ''Connectivity to Third Party Data Feeds'', the Exchange proposes to replace references to ''International Securities Exchange (ISE)'' with ''NASDAQ ISE''. The Exchange also proposes to delete a reference to ''BATS'' and replace it with ''Cboe BYX Exchange (CboeBYX), Cboe BZX Exchange (CboeBZX), Cboe EDGA Exchange (CboeEDGA), and Cboe EDGX Exchange (CboeEDGX)'' and to replace references to ''Chicago Board Options Exchange (CBOE)'' with ''Cboe Exchange (Cboe) and Cboe C2 Exchange (C2)''. In each case, the names would be updated to their current names, clearly delineating the third parties to which the Exchange provides connectivity and access.

In a non-substantive change, the Exchange proposes to reorganize the table of Third Party Systems to ensure it remains alphabetical in light of the proposed name changes. The Exchange does not propose to amend any fee related to connectivity to ISE or Cboe systems or access to ISE or Cboe data.

General

As is the case with all Exchange co-location arrangements, (i) neither a User nor any of the User's customers would be permitted to submit orders directly to the Exchange unless such User or customer is a member organization, a Sponsored Participant or an agent thereof (*e.g.,* a service bureau providing order entry services); (ii) use of the co-location services proposed herein would

[9] Information flows over existing network connections in two formats: ''unicast'' format, which is a format that allows one-to-one communication, similar to a phone line, in which information is sent to and from the Exchange; and ''multicast'' format, which is a format in which information is sent one-way from the Exchange to multiple recipients at once, like a radio broadcast.

[10] *See supra* note 8, at 7894 (''The IP network also provides Users with access to away market data products'').

[11] *See* Securities Exchange Act Release No. 78119 (June 27, 2016), 81 FR 41611 (SR–ISE2016–11; SR–ISE Gemini-2016–05; SR–ISE Mercury-2016–10) (Order Granting Accelerated Approval of Proposed Rule Changes, Each as Modified by Amendment No. 1 Thereto, Relating to a Corporate Transaction in Which Nasdaq, Inc. Will Become the Indirect Parent of ISE, ISE Gemini, and ISE Mercury). *See also* Securities Exchange Act Release No. 80325 (March 29, 2017), 82 FR 16445 (April 4, 2017) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Rename the Exchange as Nasdaq ISE, LLC).

[12] *See, e.g.,* Securities Exchange Act Release No. 81981 (October 30, 2017), 82 FR 51309 (November 3, 2017) (SR–CBOE–2017–066); and 81962 (October 26, 2017), 82 FR 50711 (November 1, 2017) (SR–BatsBZX–2017–70).

be completely voluntary and available to all Users on a non-discriminatory basis;[13] and (iii) a User would only incur one charge for the particular co-location service described herein, regardless of whether the User connects only to the Exchange or to the Exchange and one or more of the Affiliate SROs.[14]

The proposed change is not otherwise intended to address any other issues relating to co-location services and/or related fees, and the Exchange is not aware of any problems that Users would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed fee change is consistent with Section 6(b) of the Act,[15] in general, and furthers the objectives of Sections 6(b)(5) of the Act,[16] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to, and perfect the mechanisms of, a free and open market and a national market system and, in general, to protect investors and the public interest and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed changes would remove impediments to, and perfect the mechanisms of, a free and open market and a national market system and, in general, protect investors and the public interest because, by offering additional services, the Exchange would give each User additional options for addressing its access and connectivity needs, responding to User demand for access and connectivity options. Providing additional services would help each User tailor its data center operations to the requirements of its business operations by allowing it to select the form and latency of access and connectivity that best suits its needs.

The Exchange would provide Access and Connectivity as conveniences to Users. Use of Access or Connectivity would be completely voluntary. The Exchange is not aware of any impediment to third parties offering Access or Connectivity. The Exchange does not have visibility into whether third parties currently offer, or intend to offer, Users access to the Proposed Third Party Systems and connectivity to the Proposed Third Party Data Feeds. However, if one or more third parties presently offer, or in the future opt to offer, such access and connectivity to Users, a User may utilize the SFTI network, a third party telecommunication network, third party wireless network, a cross connect, or a combination thereof to access such services and products through a connection to an access center outside the data center (which could be a SFTI access center, a third-party access center, or both), another User, or a third party vendor.

The Exchange believes that the proposed changes would remove impediments to, and perfect the mechanisms of, a free and open market and a national market system and, in general, protect investors and the public interest because, by offering Access and Connectivity to Users when available, the Exchange would give Users additional options for connectivity and access to new services as soon as they are available, responding to User demand for access and connectivity options.

The Exchange also believes that the proposed fee change is consistent with Section 6(b)(4) of the Act,[17] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Exchange believes that the proposed fee changes are consistent with Section 6(b)(4) of the Act for multiple reasons. The Exchange operates in a highly competitive market in which exchanges offer co-location services as a means to facilitate the trading and other market activities of those market participants who believe that co-location enhances the efficiency of their operations. Accordingly, fees charged for co-location services are constrained by the active competition for the order flow of, and other business from, such market participants. If a particular exchange charges excessive fees for co-location services, affected market participants will opt to terminate their co-location arrangements with that exchange, and adopt a possible range of alternative strategies, including placing their servers in a physically proximate location outside the exchange's data center (which could be a competing exchange), or pursuing strategies less dependent upon the lower exchange-to-participant latency associated with co-location. Accordingly, the exchange charging excessive fees would stand to lose not only co-location revenues but also the liquidity of the formerly co-located trading firms, which could have additional follow-on effects on the market share and revenue of the affected exchange.

The Exchange believes that the additional services and fees proposed herein would be equitably allocated and not unfairly discriminatory because, in addition to the services being completely voluntary, they would be available to all Users on an equal basis (*i.e.,* the same products and services would be available to all Users). All Users that voluntarily selected to receive Access or Connectivity would be charged the same amount for the same services. Users that opted to use Access or Connectivity would not receive access or connectivity that is not available to all Users, as all market participants that contracted with the relevant market or content provider would receive access or connectivity.

The Exchange believes that the proposed charges would be reasonable, equitably allocated and not unfairly discriminatory because the Exchange would offer the Access and Connectivity as conveniences to Users, but in order to do so must provide, maintain and operate the data center facility hardware and technology infrastructure. The Exchange must handle the installation, administration, monitoring, support and maintenance of such services, including by responding to any production issues. Since the inception of co-location, the Exchange has made numerous improvements to the network hardware and technology infrastructure and has established additional administrative controls. The Exchange has expanded the network infrastructure to keep pace with the increased number of services available to Users, including resilient and redundant feeds. In addition, in order to provide Access and Connectivity, the Exchange would maintain multiple connections to each

[13] As is currently the case, Users that receive co-location services from the Exchange will not receive any means of access to the Exchange's trading and execution systems that is separate from, or superior to, that of other Users. In this regard, all orders sent to the Exchange enter the Exchange's trading and execution systems through the same order gateway, regardless of whether the sender is co-located in the data center or not. In addition, co-located Users do not receive any market data or data service product that is not available to all Users, although Users that receive co-location services normally would expect reduced latencies in sending orders to, and receiving market data from, the Exchange.

[14] *See* SR–NYSEMKT–2013–67, *supra* note 6 at 50471. The Affiliate SROs have also submitted substantially the same proposed rule change to propose the changes described herein. *See* SR–NYSE–2018–32, SR–NYSEArca–2018–52, and SR–NYSENat–2018–15.

[15] 15 U.S.C. 78f(b).

[16] 15 U.S.C. 78f(b)(5).

[17] 15 U.S.C. 78f(b)(4).

Proposed Third Party Data Feed and Proposed Third Party System, allowing the Exchange to provide resilient and redundant connections; adapt to any changes made by the relevant third party; and cover any applicable fees charged by the relevant third party, such as port fees. In addition, Users would not be required to use any of their bandwidth for Access and Connectivity unless they wish to do so.

The Exchange believes the proposed fees for Access and Connectivity would be reasonable because they would allow the Exchange to defray or cover the costs associated with offering Users Access and Connectivity while providing Users the convenience of receiving such Access and Connectivity within co-location, helping them tailor their data center operations to the requirements of their business operations.

For the reasons above, the proposed changes would not unfairly discriminate between or among market participants that are otherwise capable of satisfying any applicable co-location fees, requirements, terms and conditions established from time to time by the Exchange.

The Exchange also believes that the proposal to update the names of ISE, Bats and Cboe removes impediments to, and perfects the mechanisms of, a free and open market and a national market system. The Exchange does not propose to amend any fee related to connectivity to ISE or Cboe systems or access to ISE or Cboe data. The Exchange simply proposes to update its Price List and Fee Schedule to accurately reflect NASDAQ's acquisition of ISE and the business combination and name change of Bats and Cboe. Therefore, the Exchange believes the proposed rule change would avoid any potential investor confusion regarding the third parties to which the Exchange provides access and connectivity.

The Exchange believes that the non-substantive change to ensure the names in the table of Third Party Systems are in alphabetical order would remove impediments to, and perfect the mechanisms of, a free and open market and a national market system and, in general, protect investors and the public interest because the amendment would clarify Exchange rules and make it easier for market participants to find Third Party Systems in the table. The Exchange believes that this proposed non-substantive change is reasonable because the change would have no impact on pricing or services offered. Rather, the change would alleviate possible market participant confusion by making it easier to find NASDAQ, ISE and Cboe in the table.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[18] the Exchange believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act because all of the proposed services are completely voluntary.

The Exchange believes that providing Users with additional options for connectivity and access to new services would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act because such proposed Access and Connectivity would satisfy User demand for access and connectivity options. The Exchange would provide Access and Connectivity as conveniences equally to all Users. The Exchange does not have visibility into whether third parties currently offer, or intend to offer, Users access to the Proposed Third Party Systems and connectivity to the Proposed Third Party Data Feeds, as third parties are not required to make that information public. However, if one or more third parties presently offer, or in the future opt to offer, such access and connectivity to Users, a User may utilize the SFTI network, a third party telecommunication network, third party wireless network, a cross connect, or a combination thereof to access such services and products through a connection to an access center outside the data center (which could be a SFTI access center, a third-party access center, or both), another User, or a third party vendor. Users that opt to use the proposed Access or Connectivity would not receive access or connectivity that is not available to all Users, as all market participants that contract with the content provider may receive access or connectivity. In this way, the proposed changes would enhance competition by helping Users tailor their Access and Connectivity to the needs of their business operations by allowing them to select the form and latency of access and connectivity that best suits their needs.

The Exchange operates in a highly competitive market in which exchanges offer co-location services as a means to facilitate the trading and other market activities of those market participants who believe that co-location enhances the efficiency of their operations. Accordingly, fees charged for co-location services are constrained by the active competition for the order flow of, and other business from, such market participants. If a particular exchange charges excessive fees for co-location services, affected market participants will opt to terminate their co-location arrangements with that exchange, and adopt a possible range of alternative strategies, including placing their servers in a physically proximate location outside the exchange's data center (which could be a competing exchange), or pursuing strategies less dependent upon the lower exchange-to-participant latency associated with co-location. Accordingly, the exchange charging excessive fees would stand to lose not only co-location revenues but also the liquidity of the formerly co-located trading firms, which could have additional follow-on effects on the market share and revenue of the affected exchange. For the reasons described above, the Exchange believes that the proposed rule change reflects this competitive environment.

The Exchange believes that the proposal to update the name of ISE to reflect its acquisition by NASDAQ and Bats and Cboe to reflect their business combination and name change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposal is ministerial in nature and is not designed to have any competitive impact. It simply seeks to update the Price List and Fee Schedule to accurately reference these markets in light of their recent name changes.

The Exchange believes that the proposed non-substantive change to ensure the names in the table of Third Party Systems are in alphabetical order would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act because the change would have no impact on pricing or the services offered. Rather, the change would alleviate possible market participant confusion by making it easier to find Third Party Systems in the table.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

[18] 15 U.S.C. 78f(b)(8).

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)(iii) of the Act [19] and Rule 19b–4(f)(6) thereunder.[20] 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 prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.[21]

A proposed rule change filed under Rule 19b–4(f)(6) [22] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[23] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange requests that the Commission waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange represents that the proposed rule changes present no new or novel issues. According to the Exchange, waiver of the operative delay would allow Users to access the Proposed Third Party Systems and the Proposed Third Party Data Feeds without delay, which would assist Users in tailoring their data center operations to the requirements of their business operations. The Exchange also represents that the proposed changes to the Price List would provide Users with more complete information regarding their Access and Connectivity options. The Exchange further asserts that waiver of the operative delay would help avoid potential investor confusion by allowing the Exchange to immediately update the names of the exchanges noted above to reflect recent business combinations and name changes. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission waives the 30-day operative delay and designates the proposed rule change operative upon filing.[24]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [25] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEAMER–2018–35 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEAMER–2018–35. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEAMER–2018–35 and should be submitted on or before August 21, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[26]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–16275 Filed 7–30–18; 8:45 am]

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[19] 15 U.S.C. 78s(b)(3)(A)(iii).

[20] 17 CFR 240.19b–4(f)(6).

[21] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[22] 17 CFR 240.19b–4(f)(6).

[23] 17 CFR 240.19b–4(f)(6)(iii).

[24] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[25] 15 U.S.C. 78s(b)(2)(B).

[26] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–83702; File No. SR–NASDAQ–2018–057]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Fees and Credits Under Rule 7018(a)

July 25, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 12, 2018, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared 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 amend the Exchange's transaction fees at Rule 7018(a) to amend qualification criteria for a credit tier applicable to securities of all three Tapes, and to reduce the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

charge assessed members applicable to DOT and LIST Orders in Tape A securities, as described further below.[3]

The text of the proposed rule change is available on the Exchange's website at *http://nasdaq.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.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend Rule 7018(a), concerning the fees and credits provided for the use of the order execution and routing services of the Nasdaq Market Center by members for all securities priced at $1 or more that it trades. Rule 7018(a)(1) sets forth the fees and credits for the execution and routing of orders in Nasdaq-listed securities (Tape C); Rule 7018(a)(2) sets forth the fees and credits for the execution and routing of securities listed on the New York Stock Exchange LLC (Tape A); and Rule 7018(a)(3) sets forth the fees and credits for the execution and routing of securities listed on exchanges other than Nasdaq and NYSE (Tape B).

The Exchange is proposing to amend the criteria required to qualify for credits provided to a member for displayed quotes/orders that provide liquidity, and to reduce a fee applicable to Tape A securities. Currently, under Rules 7018(a)(1)–(3) the Exchange provides credits to, and assesses fees on, members for execution of displayed quotes/orders (other than Supplemental Orders or Designated Retail Orders) if they qualify by meeting the requirements of the various credit and fee tiers under those rules. As described below, the Exchange is proposing to amend the Exchange's transaction fees at Rule 7018(a)(1)–(3) to amend qualification criteria for a credit tier applicable to securities of all three Tapes, and to reduce a fee under Rule 7018(a)(2) applicable to only Tape A securities, as described further below.

First Change

The Exchange is proposing to amend the criteria required to qualify for a $0.0030 per share executed credit, which will apply to securities of all three Tapes under Rules 7018(a)(1)–(3). Currently, the Exchange provides the credit if a member has shares of liquidity provided in all securities through one or more of its Nasdaq Market Center MPIDs that represent 0.575% or more of Consolidated Volume[4] during the month, including shares of liquidity provided with respect to securities that are listed on exchanges other than Nasdaq or NYSE that represent 0.10% or more of Consolidated Volume. The Exchange is proposing to increase the level of shares of liquidity required to be provided in all securities through one or more of its [sic] Nasdaq Market Center MPIDs from 0.575% to 0.625% or more of Consolidated Volume during the month. The Exchange is also proposing to increase the required level of shares of liquidity provided from 0.10% to 0.15% or more of Consolidated Volume with respect to securities that are listed on exchanges other than Nasdaq or NYSE.

Second Change

The purpose of the second proposed change is to reduce the fee assessed for a DOT[5] or LIST[6] Order that executes in the NYSE opening or reopening process.[7] Currently, the Exchange assesses a $0.0015 per share executed charge on a DOT or LIST Order in a Tape A security that executes in the NYSE opening or reopening process. DOT is a routing option for Orders that the entering firm wishes to route to NYSE or NYSE American. LIST is a routing option that allows an Order to participate in the opening and/or closing process of the primary listing market for a security. The Exchange is proposing to reduce the fee assessed members for DOT or LIST Order in a Tape A security that executes in the NYSE opening or reopening process from $0.0015 to $0.0010 per share executed.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[8] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[9] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

First Change

The Exchange believes that changing the Consolidated Volume qualification criteria required to qualify for the $0.0030 per share executed credit under Rules 7018(a)(1)–(3) is reasonable. Nasdaq believes that the changes to the volume thresholds are reasonable because the increased volume thresholds are more closely aligned to the corresponding credit than the current volume thresholds. This increase is also reflective of the Exchange's desire to provide incentives to attract order flow to the Exchange in return for significant market-improving behavior. By modestly increasing both the requirement that members add liquidity in all securities through one or more of its [sic] Nasdaq Market Center MPIDs from 0.575% to 0.625%, or more, of Consolidated Volume, and the requirement that the member provide shares of liquidity with respect to securities that are listed on exchanges other than Nasdaq or NYSE from 0.10% to 0.15%, or more, of Consolidated Volume, the Exchange is increasing the volume of liquidity that a member must add during the month in order to qualify for the corresponding credit. This change will help ensure that members are providing significant market-improving behavior in return for credits.

The Exchange believes that the increase in the Consolidated Volume thresholds needed to qualify for the $0.0030 per share executed credit under Rules 7018(a)(1)–(3) is an equitable allocation and is not unfairly discriminatory because the Exchange will apply the same credit to all

[3] Tape C securities are those that are listed on the Exchange, Tape A securities are those that are listed on NYSE, and Tape B securities are those that are listed on exchanges other than Nasdaq or NYSE.

[4] Rule 7018(a) defines ''Consolidated Volume'' as the total consolidated volume reported to all consolidated transaction reporting plans by all exchanges and trade reporting facilities during a month in equity securities, excluding executed orders with a size of less than one round lot. For purposes of calculating Consolidated Volume and the extent of a member's trading activity the date of the annual reconstitution of the Russell Investments Indexes shall be excluded from both total Consolidated Volume and the member's trading activity.

[5] *See* Rule 4758(a)(i)–(ii).

[6] *See* Rule 4758(a)(x).

[7] The Exchange is also making a minor technical correction to the rule.

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(4) and (5).

similarly-situated members that meet its requirements. The credit and its corresponding volume requirements will apply equally to transactions in securities of all the Tapes. The Exchange believes that the new volume requirements will not significantly impact the number of members that will likely qualify for the corresponding credit, since the new volume thresholds are a modest increase over the current volume thresholds. Participation in the Exchange's various credit tiers is completely voluntary, and members may always elect to either qualify for the corresponding credit by adding sufficient liquidity to the Exchange to meet the new volume requirement, or by electing to qualify for a different credit. Finally, by modestly increasing the total volume of liquidity as well as the liquidity provided with respect to securities that are listed on exchanges other than Nasdaq or NYSE that a member must add during the month in order to qualify for the corresponding credit, the proposed change will help ensure that members are providing significant market-improving behavior in return for credits.

Second Change

The Exchange believes that reducing the fee assessed for a DOT or LIST Order in a Tape A security that executes in the NYSE opening or reopening process from $0.0015 to $0.0010 per share executed is reasonable. The Exchange notes that it currently assesses a charge of $0.00095 per share executed for the execution of a LIST Order in a Tape B security in the NYSEAmex closing process.[10] This fee decrease is reflective of the Exchange's desire to provide incentives to market participants to use the routing function of the Exchange. When routing Orders to non-Nasdaq exchanges such as NYSE, the Exchange incurs costly connectivity charges related to telecommunication lines, membership and access fees, and other related costs when routing orders. Although the Exchange may realize less overall fees from [sic] proposed fee decrease for DOT and LIST Orders that execute in the NYSE opening or reopening processes, the Exchange believes that it will continue to be able to recover the costs it incurs to route such Orders to NYSE.

The Exchange believes that reducing the fee assessed for a DOT or LIST Order that executes in the NYSE opening or reopening process is an equitable allocation and is not unfairly discriminatory because the Exchange will apply the same fee to all similarly situated members that meet its requirements. The proposed fee is only available to Tape A securities because DOT and LIST Orders include Tape A securities, whereas the Exchange's fee tiers for routing and execution of Tape C and B securities are covered under Rules 7018(a)(1) and (3), respectively. These rules provide the fees assessed for execution of Tape C and B securities on the primary listing exchange, which have previously been found to be equitably allocated.[11] Moreover, the fee is more closely aligned with the fee that the Exchange assesses for the execution of LIST Orders in Tape B securities that execute in the NYSEAmex closing process. The Exchange believes that the lower fee may attract more Orders in Tape A securities to the Exchange and promote the use of the Exchange's routing functionality, while also providing all members with reduced fees for the execution of their DOT and LIST Orders. Last, the Exchange notes that participation in the Exchange's various fee and credit tiers is completely voluntary, and members may always elect to enter Orders in Tape A securities that they wish to execute on NYSE either directly or through intermediaries.

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. In terms of inter-market competition, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges and with alternative trading systems that have been exempted from compliance with the statutory standards applicable to exchanges. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited.

In this instance, the proposed rule change does not impose a burden on competition because the Exchange's execution services are completely voluntary and subject to extensive competition both from other exchanges and from off-exchange venues. With respect to the first proposed change, the Exchange will apply the same volume thresholds to all members for transactions in the securities of all three of the Tapes. As noted, participation in the Exchange's various credit tiers is completely voluntary, and the Exchange does not believe that the new Consolidated Volume thresholds will significantly impact the number of members that will likely qualify for the corresponding credit. Members may always elect to either qualify for the new Consolidated Volume thresholds by adding sufficient liquidity to the Exchange to meet the new volume requirement, or by electing to qualify for a different credit. As such, the Exchange believes that the proposed Consolidated Volume thresholds will not negatively impact who will qualify for the corresponding credits, but will rather have a positive impact on overall market quality as members increase their participation in the market to qualify for the particular credit. With respect to the second proposed change, the Exchange does not believe that the reduction in the fee assessed for execution of DOT and LIST Orders in Tape A securities burdens competition, but it rather promotes competition by making the Exchange a more attractive venue to enter such Orders. If, however, the Exchange is incorrect and the changes proposed herein are unattractive to members, it is likely that Nasdaq will lose market share as a result. Accordingly, Nasdaq does not believe that the proposed changes will impair the ability of members or competing order execution venues to maintain their competitive standing in the financial markets.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[12]

At any time within 60 days of the filing of the proposed rule change, the

[10] *See* Rule 7018(a)(3).

[11] The Commission notes that these fees were filed effective on filing pursuant to Section 19(b)(3)(A) of the Act and thus the Commission made no findings regarding the fees.

[12] 15 U.S.C. 78s(b)(3)(A)(ii).

Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2018–057 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–NASDAQ–2018–057. 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–NASDAQ–2018–057, and should be submitted on or before August 21, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–16270 Filed 7–30–18; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–83703; File No. SR–ISE–2018–59]

Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Align Existing Investigatory and Disciplinary Processes and Related Rules With the Investigatory and Disciplinary Processes and Associated Rules of Nasdaq BX, Inc.

July 25, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 12, 2018, Nasdaq ISE, LLC (''ISE'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared 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 align its existing investigatory and disciplinary processes and related rules with the investigatory and disciplinary processes and associated rules of Nasdaq BX, Inc. (''BX'').

The text of the proposed rule change is available on the Exchange's website at *http://ise.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.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to eliminate its existing processes for: (1) Summarily suspending and limiting or prohibiting access to Exchange services by Exchange members (''Members''), persons associated with such Members (''Associated Persons''), (2) investigating and disciplining Exchange Members and Associated Persons, and (3) adjudicating actions brought by persons economically aggrieved by certain Exchange actions. The Exchange also seeks to eliminate Chapters 15, 16, and 17[3] of the Exchange's Rules (with certain exceptions, discussed below), which set forth and govern such processes, respectively, and it proposes to eliminate the Exchange's Business Conduct Committee (''BCC''), which is a body that exists to help to enforce the Exchange's Rules. The Exchange further proposes to adopt, in place of the aforementioned Rules, the investigatory, disciplinary, and adjudicatory processes of the Exchange's sister exchange, BX. It also proposes to replace the BCC with an Exchange Review Council that is similar to one that BX has in place. Specifically, the Exchange proposes to establish new Chapters 80 and 90 of its Rules[4] and incorporate by reference into those Chapters (again with certain exceptions, described below) the BX

[13] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] As discussed below, the Exchange proposes to replace Chapter 17, which sets forth processes for persons aggrieved by Exchange actions, including adverse membership or association determinations, by adding to Exchange Rules 302 and 307 provisions adapted from BX Rules 1015 and 1016, which provide for similar adjudicative processes. Portions of proposed Chapter 90 also replace portions of Chapter 17, *e.g.,* statutory disqualification in the 9520 Series.

[4] The Exchange proposes to add Chapters 23–79 and Chapters 81–89 to its Rules, but reserve such Chapters for future use.

Rule 8000 and 9000 Series,[5] which set forth and govern the BX investigatory, disciplinary, and adjudicative processes.[6] The proposed changes, when coupled with certain changes to the Exchange's other Rules, including Rules that govern appeals of the Exchange's membership and other decisions, will render the Exchange's investigative, disciplinary, and adjudicatory processes substantially the same as those, not only of BX, but also of other Nasdaq, Inc. family of [sic] exchanges (the ''Nasdaq, Inc. Exchanges'').[7] The proposal [sic] change will also further harmonize the work that the Financial Industry Regulatory Authority (''FINRA'') conducts for all these exchanges.

Overview of the Exchange's Existing Investigatory, Disciplinary, and Adjudicatory Processes and Rules

The existing processes for investigating and disciplining Exchange Members[8] and Associated Persons,[9] for taking summary action against them, and for adjudicating Exchange actions that aggrieve them, are set forth in Existing Chapters 15–17 of the Exchange's Rulebook.

With respect to investigations, Existing Rule 1602 authorizes the Exchange's regulatory staff (hereinafter described in this filing, for consistency with the BX rules, as ''Regulation Department'' or ''Exchange Regulation Department'')[10] to investigate Members and Associated Persons based on information it receives from a variety of sources, such as surveillance reviews, examinations, industry notifications, third party complaints, and referrals.[11] Alternatively, the Rule provides that the Exchange may, and it typically does, refer such investigatory matters to FINRA.

FINRA performs, among other things, investigatory and prosecutorial work for the Exchange pursuant to a Regulatory Services Agreement between the two parties (the ''RSA'').[12] Under the RSA, FINRA is responsible[13] for the investigation of potential violations of the Exchange Rules and the Act, and for the prosecution of any such violations thereof, by Exchange Members and Associated Persons.[14] Upon completion of an investigation, FINRA analyzes the evidence and applicable law, and makes preliminary determinations, known as ''Sufficiency of Evidence'' reviews, as to whether or not violations have occurred.[15] The Sufficiency of Evidence review determines the nature of FINRA's recommendation to the Exchange's Chief Regulatory Officer (''CRO'') as to whether and how to proceed further with matters. If probable cause exists that a Member or Associated Person has violated the Exchange Rules or the Act, then the Regulation Department may file charges against the Member or Associated Person for adjudication before a Current Hearing Panel.[16] A Current Hearing Panel consists of a professional hearing officer and two members of the Exchange's BCC.

Currently, the BCC is charged with enforcing the Rules of the Exchange with respect to Members and Associated Persons. The BCC is a committee, established by the Board,[17] whose enforcement jurisdiction includes the following: (1) Ordering investigations of possible Rule violations; (2) considering letters of consent in expedited disciplinary actions; (3) making its members available to serve on Current Hearing Panels that adjudicate formal disciplinary proceedings; (4) imposing sanctions on Members or Associated Persons in disciplinary proceedings (''Respondents''); (5) reviewing Exchange actions involving minor rule violations; (6) appointing panels to conduct hearings and reviews of Exchange actions that deny membership or Member association privileges; and (7) generally overseeing all matters relating to the conduct of disciplinary hearings and hearings for review of Exchange decisions, and providing the Exchange with advice for improving disciplinary procedures.[18]

The Existing Rules provide several means by which the Exchange may pursue disciplinary actions.

First, Existing Rule 1603 permits informal disposition of disciplinary matters through ''letters of consent.'' The Existing Rule states that disciplinary matters are disposable in this manner if: (1) The Parties agree to the terms of such a letter, including any sanctions imposed therein; (2) the CRO approves of the draft letter; and (3) the BCC subsequently approves of the draft letter. If the Parties to the letter cannot reach agreement to [sic] its terms, or if the CRO or BCC reject [sic] it, then the disciplinary matter proceeds through formal channels.

Second, Existing Rules 1604–1613 provide for formal adjudication of disciplinary matters. These Existing Rules state that, whenever probable cause exists for finding that a Member or Associated Person has committed a violation within the disciplinary jurisdiction of the Exchange, regulatory staff may prepare a ''statement of charges,'' subject to the approval of the CRO. The Existing Rules further provide for Current Hearing Panels to adjudicate disciplinary matters. Current Hearing Panels are composed of a professional hearing officer, who serves as the Current Hearing Panel Chair, and two members of the BCC. The Existing Rules provide for the Parties to a disciplinary proceeding to receive at least 28 calendar days' notice prior to the occurrence of a hearing. They also provide for a pre-hearing conference to

[5] Citation herein to rules of the proposed Chapters 80 and 90 will be preceded by the term ''BX Rule'' to reflect incorporation of the BX Rule 8000 and 9000 Series. References to current rules will be preceded by the term ''Existing Rule.''

[6] The Exchange proposes to separately request an exemption from the rule filing requirements of Section 19(b) of the Act for changes to Chapters 80 and 90 to the extent such rules are effected solely by virtue of a change to the BX Rule 8000 and 9000 Series.

[7] The Exchange notes that the BX Rule 8000 and 9000 Series are substantially similar to corresponding rules of The Nasdaq Stock Market, LLC (''Nasdaq'') and Nasdaq PHLX, LLC (''Phlx''). Moreover, the Exchange notes that Nasdaq MRX, LLC and Nasdaq GEMX, LLC will propose similar changes to their respective investigatory and disciplinary processes and associated rules that will render them substantially similar to those of BX.

[8] As defined in Existing Rule 100(a)(30).

[9] As defined in Existing Rule 100(a)(4).

[10] The Exchange notes that the scope of its Regulation Department is the same as that of the BX Regulation Department.

[11] Existing Rule 1601 obligates each Member and Associated person to comply with investigatory requests by the Exchange (or FINRA, acting on its behalf) for testimony, or for written information or documentary materials.

[12] *See* RSA, dated June 10, 2013, as amended. The Exchange retains ultimate legal responsibility for the regulation of its Members, persons associated with its Members, and its market. *See* Existing Rule 1615 and its Supplementary Material.

[13] Although Existing Rule 1615 and its Supplementary Material authorizes the Exchange to contract with FINRA or another self-regulatory organization (''SRO'') to perform its disciplinary functions, the Existing Rule states that the Exchange retains ultimately legal responsibility for and control over such functions.

[14] Under the RSA, ISE's Regulation Department may elect to exercise jurisdiction over a matter involving an ISE Member or an Associated Person, performing the investigation and any resulting prosecutorial work without FINRA's involvement.

[15] *See* FINRA Regulatory Notice 09–17 (March 2009) (available at *http://www.finra.org/sites/default/files/NoticeDocument/p118171.pdf*).

[16] Both the Existing Rules and the BX Rules refer to their respective disciplinary adjudication panels as ''Hearing Panels.'' In the discussion that follows, the Exchange distinguishes between these two types of panels, which differ from one another substantively, by referring to the type of panel that exists under the Existing Rules as a ''Current Hearing Panel'' and the panel that the Exchange proposes to establish under the BX Rules as a ''New Hearing Panel.'' For purposes of the following discussion, the term New Hearing Panel shall also refer to an ''Extended Hearing Panel,'' as that term is defined in BX Rule 9120(l).

[17] *See* Resolution of the Board of Directors of the International Securities Exchange LLC Delegating Authority, dated May 11, 2000.

[18] *See* ISE Business Conduct Committee Charter, as amended, May 1, 2003.

expedite disciplinary proceedings by, among other things, seeking the Parties' agreement regarding undisputed facts. They permit non-Parties to proceedings to intervene, under certain circumstances, and they grant the Current Hearing Panel Chair broad discretion to determine the course of the proceedings, including with respect to timing, filing deadlines, if not specified in the Rules, and evidentiary matters. They generally prohibit interlocutory review of Current Hearing Panel decisions as well as *ex parte* communications among Members and Associated Persons and Panelists, the BCC, or the Board concerning the merits of a disciplinary matter. They require Current Hearing Panels to issue their decisions by majority vote and in writing.

Existing Rule 1608 permits Current Hearing Panels to engage in summary disciplinary proceedings, meaning that they may reach decisions and impose penalties without holding hearings as to violations that Respondents admit, do not dispute, or fail to answer. The Rule provides, in such instances, that Respondents have 10 calendar days following service of such summary decisions to request hearings as to matters not previously admitted or to contest the penalties imposed.

Existing Rule 1609 sets forth procedures for settlements of disciplinary matters. The Rule generally provides that a Party may submit up to two written ''offers of settlement'' at any time period prior to 120 calendar days following service of the statement of charges. Settlements must be approved by the Current Hearing Panel (or the CRO if a Current Hearing Panel has yet to be appointed).

Pursuant to Existing Rule 1610, Respondents may appeal Current Hearing Panel decisions to the Board. The Rule also permits the Board to review Current Hearing Panel decisions upon its own initiative within 30 calendar days after service of such decisions. The Rule permits the Board to delegate responsibility for its review to a committee composed of at least three of its Directors whose decision must be ratified by the Board. The Board may affirm, reverse, or modify decisions of Current Hearing Panels, and such Board decisions are final.

Third, Existing Rule 1614 provides for the disposition of certain minor disciplinary violations through the summary assessment of fines.[19] This Rule comprises violations of the Rules listed in Rule 1614(d) and that are set forth in the Exchange's Minor Rule Violation Plan (''MRVP'') approved by the Commission pursuant to SEC Rule 19d–1 (''MRVP violations'') as well as violations that are not included in the Exchange's MRVP but may be considered ''minor'' in nature (''minor rule violations'') and thus possibly resolved outside of the formal disciplinary process.[20] Existing Rule 1614(a) sets forth the Exchange's general authority to assess such fines in amounts no greater than $5,000 (up to $2,500 for MRVP violations, and up to $5,000 for minor rule violations). Existing Rule 1614(b) sets forth the notice requirements for service upon the Member or person against which the fine is to be levied (a ''Subject''). The Existing Rule requires the Exchange to serve notice upon the Subject, along with a written statement that describes the nature of the alleged violation and the basis for finding that the Subject committed the violation, the amount of the fine to be imposed for each violation, and a date, not less than 30 calendar days after service of the notice, by which such determination becomes final and such fine must be paid or contested.

Under Existing Rule 1614(c), a Subject may contest the fine by filing an answer to this written determination prior to the date when the fine is payable. Additionally, the Subject may request a hearing as part of the answer.[21] The Rule charges the BCC, or a subcommittee thereof, with adjudicating contested fines. The BCC may decide to overturn, affirm, or modify fines levied by the Exchange.[22] A Subject or the Exchange staff may appeal such determinations to the Board, and the Board may also call the matter for review on its own initiative.[23]

Existing Rule 1614(d) sets forth the list of violations and a corresponding schedule of fines that the Exchange may impose and disciplinary actions it may pursue for MRVP violations and minor rule violations.[24] They include the following:

- Violations of Rule 412 pertaining to position limits (with fines ranging from $500 for the first offense within any 24 month rolling period to $5,000 for the fourth and subsequent offenses within the same period);
- Violation of Rule 1403 for failing to file focus reports (with sanctions ranging from a $200 fine for delinquencies of up to 30 calendar days and formal disciplinary action for delinquencies of 90 or more calendar days);
- Failing to make timely responses to requests for trade data in violation of Rule 1404 (with sanctions for the first offense ranging from a $200 fine for delinquencies of up to 9 business days to formal disciplinary action for delinquencies of 30 or more business days, and sanctions for subsequent offenses ranging from a $500 fine for the second offense to formal disciplinary action beginning with the fifth offense);
- Violating Rule 717(d) and (e) regarding limits on orders entered by Electronic Access Members (with a letter of caution for the first five offenses within one calendar year, fines escalating from $500 to $2,000 for the sixth through the twentieth offenses within the same period, and formal disciplinary action thereafter);
- Violations of Rule 803 and 805(b)(1)(i) regarding pre- and post-opening quote spread parameters for market maker quotations (with a letter of caution for the first offense within any 24 month rolling period, fines escalating from $1,000 to $5,000 for the second through the fourth offenses within the same period, and formal disciplinary action thereafter);
- Violations of Rule 805, which requires market makers to execute in appointed options classes a minimum percentage of the total number of contracts executed during a quarter (with a letter of caution for the first offense within any 12 month rolling period, fines escalating from $500 to $2,500 for the second through the fourth offenses within the same period, and formal disciplinary action thereafter);
- Failure to conduct mandatory systems testing in violation of Rule 419 (with fines escalating from $250 to $2,000 for the first through the fourth offenses within one calendar year, and formal disciplinary action thereafter);
- Failure to timely submit information or instructions regarding the exercise or non-exercise of noncash-settled equity options in violation of Rule 1100 (with fines for member

[19] Generally, notice to the SEC of final disciplinary action by an SRO is required pursuant to Rule 19d–1 of the Act; however, uncontested fines of $2,500 or less assessed for violations of MRVP rules are subject to abbreviated periodic SEC reporting. None of the fines assessed in lieu of formal disciplinary action exceed $5,000.

[20] Determinations to issue a fine under Rule 1614 are made on a case-by-case basis, whereby the Exchange considers the individual facts and circumstances to determine whether a fine of more or less than the recommended amount is appropriate for the violation, or whether the violation requires formal disciplinary action.

[21] Existing Rule 1614(c).

[22] *See id.*

[23] *See id.*

[24] *See* n.20, *infra.*

organizations[25] escalating from $1,000 for the first offense within any 24 month rolling period to $5,000 for the third and subsequent offenses within the same period, and for individuals, from $500 for the first offense within any 24 month rolling period to $2,500 for the third and subsequent offenses within the same period);

• Failure to accurately report positions and account information in violation of Rule 415 (with fines escalating from $500 for the first offense within any 24 month rolling period to $5,000 for the fourth and subsequent offenses within the same period); and

• Failure of a market maker to enter continuous quotations for the option classes to which it is appointed in violation of Rule 804(e) (with fines ranging from a letter of caution for the first offense within any 24 month rolling period, to fines ranging from $1,000 to $5,000 for the second through fourth offenses within the same period, and formal disciplinary actions beginning with the fifth offense).[26]

As explained below, the Exchange proposes to retain but renumber Existing Rule 1614(d) insofar as the Exchange's MRVP and schedule of minor violations are unique to it. The Exchange cannot and does not seek to simply incorporate by reference the BX MRVP.

Existing Rule 1615 and its Supplementary Material authorizes the Exchange to contract with FINRA or another SRO to perform its disciplinary functions, but the Existing Rule states that the Exchange retains ultimately [sic] legal responsibility for and control over such functions.

Existing Rule 1616 authorizes and prescribes the process for adjudicating expedited client suspensions that may be imposed upon Members or Associated Persons that violate the prohibition in Existing Rule 403 on disruptive quoting and trading activity. Existing Rule 1616 states that the initiation of expedited suspension proceedings requires the prior written authorization of the CRO or his designees. It requires the Exchange to provide prior notice to the Respondent as well as to convene a Current Hearing Panel to adjudicate the matter. The Existing Rule provides that such hearings are to be administered generally in accordance with Existing Rule 1606. If a Respondent fails to appear at a hearing for which it receives proper notice, the Existing Rule states that the Current Hearing Panel may issue a suspension order without further proceedings, while the failure of the Exchange to appear may result in the dismissal of the suspension proceeding. Existing Rule 1616(d) requires a Current Hearing Panel to issue a written decision as to whether to order [sic] suspension not later than 10 days after receiving the hearing transcript. It further provides that a Panel may issue an order imposing suspension only if it finds, by a preponderance of the evidence, that the alleged violation specified in the notice occurred. At any time after a Respondent is served with a suspension order, a Party may apply to the Current Hearing Panel to modify, set aside, limit, or revoke the order, and the Current Hearing Panel must respond to the request within 10 days after receipt thereof, unless extended. Finally, Existing Rule 1616(f) provides for the right of a Respondent to seek Commission review of a suspension order.

Chapter 15 of the Existing Rules states that the Board, a committee thereof, or an Exchange Official designated by the Board may summarily suspend a Member or an Associated Person that has been expelled or suspended from any other SRO or has been barred or suspended from being associated with a member of another SRO, if the Board, a committee thereof, or a designated Exchange Official determines that their ongoing transaction of business on the Exchange would compromise the safety of investors, creditors, other Members of the Exchange, or the Exchange itself.[27] On the same grounds, the Board, a committee thereof, or a designated Exchange Official may summarily suspend a Member if it is experiencing operational or financial difficulties and cannot continue doing business as a member with safety to investors, creditors, other Members, or the Exchange.[28] Furthermore, the Board, committee, or Exchange Official may limit or prohibit any person's access to services offered by the Exchange for these same reasons or, as to a Member, they [sic] may take such actions if they [sic] determine that such Member does not meet the qualification requirements or other prerequisites for access with safety to investors, creditors, Members, or the Exchange.[29] Chapter 15 provides for the Exchange to notify the SEC upon imposing a summary suspension or when summarily limiting or prohibiting access to Exchange services.[30]

Chapter 15 provides that, following the imposition of a suspension or a limitation on or prohibition against accessing Exchange services, the Exchange will conduct an investigation of the affairs of the affected Member, Associated Person, or person.[31] A suspended, limited, or prohibited Member, Associated Person, or person must file with the Exchange a written statement covering all information that the Exchange may request in this regard, including a complete list of creditors and amounts owed to each as well as a complete list of positions in Exchange options contracts they [sic] maintain on their [sic] own behalf and that of their [sic] customers.[32]

Those subject to summary suspension or that are limited or prohibited with respect to access to Exchange services may petition for reinstatement within six months of their suspension, limitation, or prohibition, if they are suspended, limited, or prohibited due to operating difficulty, or within 30 days of suspension, limitation, or prohibition, if they are suspended, limited, or prohibited for reason of financial difficulty.[33] An applicant for reinstatement is afforded an opportunity for a hearing, in certain circumstances.[34] The Exchange may approve an application for reinstatement if it finds that the applicant is operationally and financially able to conduct their [sic] business with safety to investors, creditors, Members, and the Exchange.[35]

[25] The Exchange notes that it proposes to amend the term ''Member Organization'' so that it merely reads ''Member.'' These terms are synonymous.

[26] As explained below, the Exchange also proposes to retain Existing Rule 1600, which sets forth the general jurisdiction of the Exchange with respect to disciplinary matters. Existing Rule 1600 states that a Member or Associated Person who is alleged to have violated or aided and abetted a violation of the Act, the rules and regulations promulgated thereunder, and the By-Laws or Rules of the Exchange, or any interpretation thereof are subject to the disciplinary jurisdiction of the Exchange and may be, after notice and opportunity for a hearing, appropriately disciplined by expulsion, suspension, fine, censure, limitation or termination as to activities, functions, operations, or association with a Member, or any other fitting sanction in accordance with the provisions of the disciplinary rules. It also permits the Exchange to charge a supervisor with a violation of a rule within the disciplinary jurisdiction of the Exchange committed by an employee under his supervision or by the Member as though such violations were his own. Finally, it extends the disciplinary jurisdiction of the Exchange to continue after deregistration of the Member from the Exchange or a person's termination of association with a Member as to matters that occurred prior to such termination or deregistration. The Exchange must serve written notice to the former Member within one year of receipt by the Exchange of notice of such termination or deregistration that the Exchange is making inquiry into a matter or matters.

[27] *See* Existing Rule 1500.

[28] *See id.*

[29] *See id.*

[30] *See id.*

[31] *See* Existing Rule 1501.

[32] *See id.*

[33] *See* Existing Rule 1502.

[34] *See id.*

[35] *See id.*

The failure of a suspended, limited, or prohibited Member to obtain reinstatement will result in disposition of membership, unless the Member sells or leases their [sic] membership.[36] Finally, Existing Rule 1504 provides that a Member suspended under Chapter 15 shall be deprived for [sic] all of the rights and privileges of being a Member of the Exchange during the period of suspension.

Lastly, Chapter 17 of the Existing Rules sets forth a procedure by which persons who are economically aggrieved by Exchange actions, including but not limited to those organizations whose applications for membership are denied, persons who are prohibited from becoming associated with a Member, and organizations and persons that are prohibited or limited with respect to the use of Exchange services or the services of Members, may seek review of such actions.[37]

Existing Rule 1701 provides that aggrieved persons must file written applications for hearing and review within 30 days of the occurrence of relevant Exchange actions, unless the Chair of the BCC grants, in writing, an extension of time to file an appeal.

Existing Rule 1702 provides for the BCC, or a panel comprised of at least three members thereof, to review applications. The BCC, or the panel, must set a hearing date and receive materials relevant to the proceeding at least 72 hours in advance of the hearing.

Existing Rule 1703 provides for intervention in a hearing by a third party under certain circumstances. Current Rule 1703 also authorizes the panel to determine all questions concerning the admissibility of evidence and to otherwise regulate the conduct of hearings. Finally, Existing Rule 1703 directs panels to render their decisions in writing and to include in such decisions the Panel's reasons for their [sic] conclusions.

Existing Rule 1704 states that panel decisions are subject to review by the Board (or a committee composed of at least three Directors thereof), either upon the Board's own motion (within 30 days of issuance of the decision), upon written request of the President of the Exchange (within 15 days after issuance of the decision), or upon written request by the applicant. The Board has discretion to grant requests for written or oral arguments before it. The Board may affirm, reverse, or modify the decision of the panel. A decision of the Board is a final Exchange Action [sic].

Existing Rule 1705 governs the service of process for notices or other documents served pursuant to the proceedings set forth in Chapter 17 and the extension of time limits for the submission of answers, petitions, or other materials.

Existing Rule 1706 states that the Exchange may contract with another SRO to perform some or all of the functions specified in Chapter 17, provided that the Exchange shall retain ultimate legal responsibility for and control of such functions.

Overview of the Exchange Review Council and the BX Rule 8000 and 9000 Series

The Exchange proposes to amend its By-Laws to replace the BCC with a new ''Exchange Review Council.'' The Exchange also proposes, with limited exceptions described below, to delete in their entirety Chapters 15–17 of the Existing Rules, establish new Chapters 80 and 90 of the Exchange's Rulebook, and then incorporate by reference into Chapters 80 and 90 the BX Rule 8000 and 9000 Series, respectively. The principal purpose of these proposals is to harmonize the Exchange's disciplinary processes and Rules consistent with those of its sister exchanges, including not only BX, but also Nasdaq and Phlx.

Broadly speaking, the BX Rules and processes will be similar to the existing ones. Both provide processes for informal resolution and formal adjudication of disciplinary matters. Both set forth procedures that are designed to provide due process to Members and Associated Persons, including fair notice of allegations and proceedings, opportunities to be heard and to present and rebut arguments and evidence before hearing panels, and opportunities to appeal adverse determinations made by such panels.

However, in a number of respects, the new Rules and processes will differ from the existing ones. One key difference concerns the role that FINRA will play in the new regime. Not only will FINRA continue to assist the Exchange in investigating matters under the BX Rules, through FINRA's Department of Enforcement and Department of Market Regulation (collectively, the ''Departments'') [38] but it will also assist in the adjudication of matters. Specifically, the adjudicatory functions of the BCC and Current Hearing Panels will be administered by FINRA's Office of Disciplinary Affairs (''ODA'') and Office of Hearing Officers (''OHO''), respectively.[39] The ODA and OHO are offices within FINRA that are independent of the FINRA enforcement function and not involved in investigating or litigating cases. The ODA will review each proposed complaint to determine the legal and evidentiary sufficiency of proposed charges as well as proposed settlements, in certain instances.[40] A recommendation proposed by the Departments or the Exchange's Regulation Department in a matter involving formal disciplinary action will require approval by the ODA. Going forward, the ODA will authorize (pursuant to a request by the Exchange's Regulation Department or the Departments) the issuance of a complaint.[41] The OHO, in turn, will be responsible for convening and administering New Hearing Panels in lieu of the Exchange's Current Hearing Panels.

Another key difference involves the replacement of the BCC with the Exchange Review Council. The Exchange Review Council, as the successor to the BCC, will play a more limited role in disciplinary matters than does the BCC presently. As to disciplinary matters, the Exchange Review Council will not be responsible for approving the issuance of complaints (formerly, statements of charges) or routinely approving [42] letters of acceptance, waiver, and consent or offers of settlement. Instead, the

[36] *See* Existing Rule 1503.

[37] *See* Existing Rule 1700.

[38] The Departments are authorized to act on behalf of BX in investigating and administering disciplinary matters pursuant to the RSA, and will do the same for the Exchange upon adoption of the new process.

[39] *See* FINRA Rule 9211(a); *see also* BX Rule 9211(a). The Exchange notes, however, that the Board may direct the ODA to authorize a complaint when, on the basis of information and belief, it is of the opinion that a Member or Associated Person has committed a violation which the Exchange has jurisdiction to enforce. *See* BX Rule 9211(a)(2).

[40] Pursuant to BX Rule 9270, proposed settlements must be submitted to and accepted by the Exchange Review Council, except that proposed settlements involving an affiliate of the Exchange must be reviewed by the ODA. BX Rule 9216(a) provides that proposed letters of acceptance, waiver, and consent must be submitted to and accepted by either the ODA, the Review Subcommittee, or the Exchange Review Council.

[41] BX Rule 9211(a) also provides that the Board has authority to direct the issuance of a complaint.

[42] Under BX Rule 9216(a), the ODA or a Review Subcommittee of the Exchange Review Council may accept or refer letters of acceptance, waiver, and consent to the Exchange Review Council for approval or rejection. The Review Subcommittee can also reject such letters. Similarly, under BX Rule 9270, a Review Subcommittee of the Exchange Review Council may accept, reject, or refer offers of settlement to the Exchange Review Council for approval or rejection (except where the offer of settlement involves an affiliate of the Exchange, in which case the ODA must decide whether to accept or reject the offer). As a practical matter and based upon the experiences of Nasdaq and BX, the Exchange expects such referrals to the Exchange Review Council to occur infrequently.

Exchange Review Council will function principally as an intermediate appellate body for decisions rendered by the New Hearing Panels. As to non-disciplinary matters, the Exchange Review Council will assume regulatory responsibilities that currently rest with various panels, including reviews of staff determinations made as to obvious errors.

Other noteworthy differences between the Existing Rules and the BX Rules and processes include the following:

• The BX Rules generally include more comprehensive rights and detailed procedures for, among other things, discovery and service of process than do the Existing Rules.

• As to the assessment of fines for violations of the Exchange's MRVP or other minor rule violations, the BX Rules do not authorize the issuance of minor rule violation letters or the imposition of fines of more than $2,500.[43] Should a Respondent fail to consent to the imposition of a fine or if the Review Subcommittee or the Exchange Review Council reject [sic] the terms of an MRVP or minor rule violation letter, then the matter will proceed through formal disciplinary channels. The BX Rules do not allow for a fine to be reversed, modified or affirmed, prior to formal disciplinary proceedings.

The following is a more detailed overview of each of the Exchange's proposals.

Overview of the Exchange Review Council

The Exchange proposes to retire the BCC[44] and to amend its By-Laws to establish in its place an Exchange Review Council. The amended By-Laws that the Exchange proposes to adopt in this regard are substantially the same as those that BX adopted to establish the BX Exchange Review Council.[45] Thus, the By-Laws provide for the Exchange Review Council to have the same general structure and powers as does the BX Exchange Review Council.[46] The proposed By-Laws will authorize the Exchange Review Council to adjudicate disciplinary actions and approve settlements thereof as well as make recommendations to the Board on certain policy matters and rule changes. Such policy functions of the Exchange Review Council render its jurisdiction broader than that of the BCC.

Specifically, proposed Article VI, Section 1 of the proposed By-Laws provides that the Exchange Review Council may be authorized to act for the Board with respect to: an appeal or review of a disciplinary proceeding, a statutory disqualification proceeding, or a membership proceeding; a review of an offer of settlement, a letter of acceptance, waiver, and consent, and a minor rule violation plan letter; the exercise of exemptive authority; and such other proceedings or actions as may be authorized by the Exchange rules. The Exchange Review Council also may consider and make recommendations to the Board on policy and rule changes relating to business and sales practices of Exchange Members and Associated Persons and enforcement policies, including policies with respect to fines and other sanctions. It may advise the Board on regulatory proposals and industry initiatives relating to quotations, execution, trade reporting, and trading practices and it may advise the Board in its administration of programs and systems for the surveillance and enforcement of rules governing Exchange Members' conduct and trading activities in the Exchange.

Proposed Article VI, Section 2 states that the Exchange Review Council would consist of no fewer than eight and no more than 12 members. The Exchange Review Council must include a number of Member Representative members[47] that is equal to at least 20% of the total number of members of the Exchange Review Council. The number of Non-Industry members,[48] including at least three Public members,[49] shall equal or exceed the sum of the number of Industry members[50] and Member Representative members. As soon as practicable, following the appointment of members, the Exchange Review Council shall elect a Chair from among its members. The Chair shall have such powers and duties as may be determined from time to time by the Exchange Review Council. The Board, by resolution adopted by a majority of Directors then in office, may remove the Chair from such position at any time for refusal, failure, neglect, or inability to discharge the duties of Chair. No more than 50% of the members of the Exchange Review Council shall be engaged in market making activity or employed by an Exchange Member firm whose revenues from market making activity exceed 10 percent of its total revenues.

Proposed Article VI, Section 3 requires the Exchange's Secretary to collect from each nominee for the office of member of the Exchange Review Council such information as is reasonably necessary to serve as the basis for a determination of the nominee's qualifications and classification as an Industry, Member Representative, Non-Industry, or Public member. The Secretary must also certify to the Nominating Committee or the Member Nominating Committee[51] (as applicable) each nominee's qualifications and classification. After appointment to the Exchange Review Council, each member must update such information at least annually and upon request of the Exchange's Secretary, and must report immediately to the Secretary any change in such information.

Proposed Article VI, Section 4 provides that Exchange Review Council members shall serve three-year terms, or until a successor is duly appointed and qualified, except in the event of earlier

[43] As the Exchange discusses below, the Exchange proposes to retain certain of its Existing Rules to preserve its existing authorities with respect to minor rule violations, the issuance of minor rule violation letters, and the imposition of fines for such minor rule violations of up to $5,000.

[44] In a May 11, 2000 resolution, the Exchange Board delegated its authority to the President of the Exchange to establish a BCC to, among other things, conduct disciplinary hearings under Chapter 16 of the Existing Rules and conduct other hearings and reviews as set forth in Chapter 17 of the Existing Rules. On February 1, 2017, the Board passed a resolution that both revoked the President's authority to establish a BCC and authorized the establishment of an Exchange Review Council, effective upon the date when this rule filing becomes operative.

[45] The BX by-laws differ from the proposed Exchange By-Laws because the BX by-laws have a different numbering convention from the Exchange's By-Laws and, in various places, the BX by-laws refer to a Listing and Hearing Review Council, which has no analogue with respect to the Exchange.

[46] The BX by-laws do not describe in detail the process of the proceedings over which the BX Exchange Review Council presides. However, Section 7.9 of the BX by-laws state that a quorum of three BX Exchange Review Council members is necessary to adjudicate appeals of determinations made under BX Rules 4612 (appeal of denial of registration as an Equities Market Maker), 4619 (review of denial of an excused withdrawal of Equities Market Maker quotation), 4620 (appeal of denial of reinstatement of Equities Market Maker that accidentally withdraws), 11890 (appeal of clearly erroneous transaction determination), and BX Options Chapter V, Section 6 (appeal of obvious error determination). *See* BX by-laws, Article VII, Section 9. The Exchange's Rules do not have analogues to BX Rules 4612, 4620, and 11890 and, as such, the corresponding provision of the Exchange's proposed By-Laws (Article VII, Section 9) provides only that a quorum of three Exchange Review Council members is necessary for it to adjudicate appeals involving determinations made under Rules 720 (appeal of obvious error determination), 720A (appeal of determinations of erroneous trades due to system malfunctions and disruptions), and 804 (review of denial of an excused withdrawal of market maker quotation).

[47] *See* n.52, *infra*.

[48] *See id*.

[49] *See id*.

[50] *See id*.

[51] The terms ''Nominating Committee'' and ''Member Nominating Committee'' are defined in Exchange By-Laws, Article I.

termination from office by reason by death, resignation, removal, disqualification, or other reason. Members are term limited out after two consecutive terms. Proposed Article VI, Section 5 sets forth the procedures for resigning as a member of the Exchange Review Council and provides that an Exchange Review Council member may resign at any time upon written notice to the Board. Under proposed Article VI, Section 6, any member of the Exchange Review Council may be removed from office at any time for refusal, failure, neglect, or inability to discharge the duties of such office by majority vote of the Board.

Under proposed Article VI, Section 7, an Exchange Review Council member would be disqualified and removed immediately upon a determination by the Board, by a majority vote, that: (a) The member no longer satisfies the classification (Industry, Member Representative, Non-Industry, or Public) for which the member was elected; and (b) the member's continued service as such would violate the compositional requirements of the Exchange Review Council set forth in Article VI, Section 2. If the term of office of an Exchange Review Council member terminates under this Section, and the remaining term of office of such member at the time of termination is not more than six months, during the period of vacancy the Exchange Review Council shall not be deemed to be in violation of Article VI, Section 2 by virtue of such vacancy. Proposed Article VI, Section 8 contains provisions for the filling of vacancies on the Exchange Review Council and states that if a position on the Exchange Review Council becomes vacant, the Nominating Committee or the Member Nominating Committee (as applicable) shall nominate, and the Board shall appoint a person satisfying the qualifications for the position as provided in Article VI, Section 2 to fill such vacancy, except that if the remaining term of office for the vacant position is not more than six months, no replacement shall be required.

Proposed Article VI, Section 9 provides that a quorum of the Exchange Review Council will consist of a majority of its members, including not less than 50% of its Non-Industry members and one Member Representative member. Proposed Article VI, Section 10 contains provisions related to the meetings of the Exchange Review Council.

Under proposed Article VI, Section 11, the Exchange Review Council is required to establish a Review Subcommittee to determine whether disciplinary and membership proceedings decisions should be called for review by the Exchange Review Council under the disciplinary and membership rules to be proposed for the Exchange. The Review Subcommittee shall be composed of no fewer than two and no more than four members of the Exchange Review Council. The number of Non-Industry members of the Review Subcommittee shall equal or exceed the sum of the number of Industry members and Member Representative members of the Review Subcommittee, and the subcommittee must include at least one Member Representative member. At all meetings of the Review Subcommittee, a quorum for the transaction of business shall consist of not less than 50 percent of the members of the Review Subcommittee, including not less than 50 percent of the Non-Industry members of the Review Subcommittee and one Member Representative member of the Review Subcommittee.[52]

The BX Rules implement the foregoing responsibilities of the Exchange Review Council by establishing various procedures, described below, to govern its reviews. As the Exchange also describes in further detail below, the Exchange proposes to transfer to the Exchange Review Council (or panels thereof) certain responsibilities currently vested in other Exchange committees or the Board. For example, pursuant to Existing Rule 720, an Obvious Error Panel (''OEP'') is presently responsible for reviewing determinations regarding obvious and catastrophic errors. Pursuant to Existing Rule 720A, a ''Review Panel'' is responsible for reviewing determinations to nullify or adjust transactions that arise from system disruptions and malfunctions. The Exchange is proposing to eliminate the OEP and the Review Panel and to transfer their responsibilities to a panel of the new Exchange Review Council, which corresponds to the practice of BX. Subject to Chapter 90, the Exchange also proposes to transfer responsibility to the Exchange Review Council to review denials or conditions imposed upon those that seek to become or remain a Member of the Exchange or become or remain associated with a Member of the Exchange, as set forth in Existing Rule 302. Similarly, the Exchange proposes to transfer responsibility to the Exchange Review Council to review denials or conditions imposed upon Members that seek to transfer or sell market maker rights, as set forth in the Supplementary Material to Existing Rule 307.[53] In addition, the Exchange proposes to amend Existing Rule 804 to provide for the Exchange Review Council to review determinations regarding temporary withdrawals of quotations, which are not reviewable under the Existing Rules. The Exchange notes that BX vests in its Exchange Review Council responsibility for reviewing similar types of matters.[54]

The BX Rule 8000 Series

The Exchange proposes to incorporate by reference into a new Chapter 80 of its Rulebook the BX Rule 8000 Series. The BX Rule 8000 Series is entitled ''Investigation and Sanctions,'' and it governs the investigative process, including FINRA's authority under the RSA to conduct investigations of Members and Associated Persons on behalf of the Exchange.

BX Rule 8001 states that the Exchange and FINRA are parties to the RSA, pursuant to which FINRA has agreed to perform certain functions on behalf of the Exchange. It also specifies, however, that the Exchange retains ultimate legal responsibility for, and control over the functions that FINRA performs on its behalf.[55]

BX Rule 8110 requires Members to keep and maintain copies of the NASD (now known as FINRA) and Exchange Manuals in readily accessible places and make them available for examination by customers upon request.

BX Rule 8120 sets forth definitions for the BX Rule 8000 Series.

[52] In addition to adding Article VI to the By-Laws, the Exchange proposes to make changes to other articles of the By-Laws to accommodate the existence of the Exchange Review Council. For example, the Exchange proposes to amend Article I, which defines the terms that the Exchange uses in the By-Laws, to provide that the terms ''Industry member,'' ''Member representative member,'' ''Non-industry member,'' and ''Public member'' mean, in part, members of the Exchange Review Council. The Exchange also proposes to amend Article III, Section 6, to add a new subsection (a) that directs the Board to appoint an Exchange Review Council, as provided in Article VI. It also proposes to amend Article III, Section 6(b) to state that the Nominating Committee and the Member Nominating Committee of the Board shall have responsibility for nominating members of the Exchange Review Council. Finally, the Exchange proposes to amend Sections 7 and 8 of Article III, which deal with Director conflicts-of-interest/self-interested transactions and Director compensation, respectively, to ensure that the restrictions and benefits that these provisions provide apply to Exchange Review Council members.

[53] The Exchange notes that it proposes to establish procedures in Existing Rule 302 and Rule 307 to govern the review by the Exchange Review Council of adverse membership, association, or market maker sale or transfer determinations. The Exchange proposes to base these procedures upon those set forth BX Rules 1015 and 1016.

[54] *See* Securities Exchange Act Release No. 72149 (May 12, 2014), 79 FR 28564 (May 16, 2014) (SR–BX–2014–024).

[55] BX Rule 9001 also states that the Exchange has contracted with FINRA to perform some or all of the Exchange's disciplinary functions, while noting that the Exchange retains ultimate legal responsibility for and control of such functions.

BX Rule 8210 generally authorizes the Exchange's Regulation Department and FINRA, acting on the Exchange's behalf to require a Member, an Associated Person, or another person subject to the Exchange's jurisdiction to provide information orally, in writing or electronically, to provide testimony under oath, or to allow for the inspection of their [sic] books, records, and accounts, with respect to any matter associated with an investigation, complaint, examination, or proceeding of the Exchange or of other Self-Regulatory Organizations or regulators.

BX Rule 8211 requires a Member to submit certain specified trade data in an automated form, as the Regulation Department or FINRA may require or request.

BX Rule 8310 sets forth the Exchange's authority to sanction a Member or an Associated Person for violations of the federal securities laws, rules, or regulations thereunder, or the Exchange's Rules, as well as for neglect or refusal to comply with an order, direction, or decision issued under the Exchange Rules.[56] BX Rule 8310(a) provides for sanction [sic] that include censure, fine, suspension of membership or registration of a person associated with a Member, expulsion or cancellation of membership or association, suspension or bar from association with all Members, temporary or permanent cease and desist order, or any other fitting sanction. BX IM–8310–1 precludes Members from allowing Associated Persons from remaining associated with them, even in a clerical or ministerial capacity, upon issuance of orders suspending, revoking, or cancelling the registration of such Associated Persons and it prohibits payment of any salary, commission, profit, or other remuneration such Associated Persons might have earned during their periods of suspension. BX IM–8310–3 states, in part, that the Exchange's Regulation Department shall release certain information to the public regarding disciplinary complaints and decisions and release, upon request, a copy of any complaint or disciplinary decision issued by the Exchange or any committee thereof.

BX Rule 8320 states that fines and other monetary sanctions shall be paid to the Treasurer of the Exchange. It authorizes the Exchange, after seven days written notice, to in part summarily suspend or expel Members if they are delinquent in paying sanctions or fines.

BX Rule 8330 states that a Member or an Associated Person disciplined pursuant to Rule 8310 shall bear the costs of disciplinary proceedings as the New Hearing Panels or the Board deem appropriate under the circumstances.

The BX Rule 9000 Series

The Exchange proposes to incorporate by reference into a new Chapter 90 of its Rulebook the BX Rule 9000 Series. The BX Rule 9000 Series is entitled ''Code of Procedure,'' and it governs proceedings for disciplining Members and Associated Persons, proceedings for regulating Members experiencing financial or operational difficulties, proceedings for summary or non-summary suspensions, cancellations, bars, prohibitions, or limitations, and proceedings for obtaining relief from the eligibility requirements of the Exchange By-Laws and the Exchange Rules.

BX Rule 9100 Series

The BX Rule 9100 Series describes the application and purpose of the BX Rule 9000 Series, including the types of proceedings covered by the BX Rules,[57] the rights, duties, and obligations of Members and Associated Persons,[58] defined terms,[59] and rules concerning the filing and service of papers.[60] The BX Rule 9100 Series also provides rules concerning proceedings, including appearance and practice,[61] withdrawal by attorney or representative,[62] *ex parte* communications,[63] separation of functions among adjudicators and interested staff,[64] rules of evidence and official notice,[65] motions,[66] rulings on procedural matters,[67] and interlocutory review.[68]

Specifically, BX Rule 9110 sets forth the general rights, duties, and obligations of Members and Associated Persons under the Code of Procedure, including the rights, in any disciplinary matter thereunder, to be presented with specific charges, to have a hearing, to have due notice thereof, to present a defense and relevant supporting material, to be represented by counsel, to have a record kept of proceedings, and to receive a written determination that sets forth the basis therefor.

BX Rule 9120 sets forth definitions of various terms used throughout the Rule 9000 Series.

The BX Rule 9130 Series governs the requirements for service of complaints and other written documents in connection with disciplinary proceedings. The BX Rule 9130 Series prescribes the timing and form of required service based on the type of the notice. BX Rule 9134 concerns the permissible methods of service and the procedures for service. BX Rule 9134 permits personal service, service by U.S. Postal Service, or service by courier. BX Rules 9135 through 9138 set forth the form, format, and procedures for filing papers with adjudicators as well as the effect for [sic] a Party or its counsel or representative for affixing or failing to affix their [sic] signatures to such papers. Other BX Rules govern service of notices and other documents in particular situations.[69]

BX Rule 9141 concerns appearances before adjudications in proceedings, both by Parties and by their attorneys and representatives. BX Rule 9141 permits a person to represent themselves [sic] in any proceeding as

[56] The Exchange proposes to retain Existing Rule 1600, which provides a more general statement of the Exchange's disciplinary authority than that which exists in BX Rule 8310. Existing Rule 1600 states that a Member or Associated Person who is alleged to have violated or aided and abetted a violation of the Act, the rules and regulations promulgated thereunder, and the By-Laws or Rules of the Exchange, or any interpretation thereof are subject to the disciplinary jurisdiction of the Exchange and may be, after notice and opportunity for a hearing, appropriately disciplined by expulsion, suspension, fine, censure, limitation or termination as to activities, functions, operations, or association with a Member, or any other fitting sanction in accordance with the provisions of the disciplinary rules. It also permits the Exchange to charge a supervisor with a violation of a rule within the disciplinary jurisdiction of the Exchange committed by an employee under his supervision or by the Member as though such violations were his own. Finally, it extends the disciplinary jurisdiction of the Exchange to continue after termination of the Member from the Exchange or a person's termination of association with a Member as to matters that occurred prior to such termination. Staff must serve written notice to the former Member or Associated Persons within one year of receipt by the Exchange of notice of such termination that the Exchange is making inquiry into a matter or matters.

[57] *See* BX Rule 9110.

[58] *Id.*

[59] *See* BX Rule 9120.

[60] *See* BX Rules 9131–9138.

[61] *See* BX Rule 9141.

[62] *See* BX Rule 9142.

[63] *See* BX Rule 9143.

[64] *See* BX Rule 9144.

[65] *See* BX Rule 9145.

[66] *See* BX Rule 9146.

[67] *See* BX Rule 9147.

[68] *See* BX Rule 9148.

[69] *See, e.g.* BX Rule 9360 (effective dates of bars, expulsions, and permanent cease and desist orders); BX Rule 9400 (various service requirements pertaining to expedited client suspension proceedings); BX Rule 9550 Series (various service requirements pertaining to: (1) Suspensions for failures to provide information or keep information current; (2) suspensions and cancellations for failures to pay Exchange dues, fees, or other charges; (3) suspensions or cancellations for failures to comply with arbitration awards, settlements, or restitution orders or settlements; (4) suspensions, cancellations, or bars from membership or suspensions or bars from association with Members, or limitations or prohibitions of access to Exchange services; (5) suspensions, cancellations, and bars for failure to comply with cease and desist orders; (6) restrictions on Members' activities due to financial or operational difficulties; and (7) suspensions for actions authorized by Section 6(d)(3) of the Act).

well as to be represented by others (pursuant to a notice of appearance), including a licensed attorney,[70] a member of a partnership (to represent a partnership), and a bona fide officer of a corporation, trust or association (to represent a corporation, trust or association).

BX Rule 9143(a) prohibits Parties, their representatives, or Interested Staff[71] from having *ex parte* communications with adjudicators or with Exchange staff who are participating in or advising on a proceeding about the merits of the proceeding.[72] BX Rule 9143(b) also requires adjudicators participating in a proceeding to disclose and place in the record any written *ex parte* communications (or memoranda summarizing any oral *ex parte* communications) concerning the merits of the proceeding. BX Rule 9143(c) furthermore permits the Exchange Regulation Department or an adjudicator (consistent with the interests of justice, the policies, [sic] underlying the Act, and the Rules of the Exchange) to order any Party that violates the *ex parte* prohibition to show cause why the Party's claim or interest in the proceeding should not be dismissed, denied, disregarded, or otherwise adversely affected by reason of such [sic] *ex parte* communication. BX Rule 9143(d) generally specifies that the *ex parte* prohibition applies beginning with the authorization of a complaint. Finally, BX Rule 9143(e) specifies circumstances in which a Party's claim as to a violation of the *ex parte* rules are [sic] waived, including when a Respondent submits an offer of settlement, an executed letter of acceptance, waiver, and consent, or an MRVP letter.[73]

BX Rule 9145 states that formal rules of evidence do not apply to proceedings brought under the BX Rule 9000 Series. It also permits adjudicators, after providing notice and an opportunity for a Party to comment or oppose, to take official notice of matters that may be judicially noticed by courts or of other matters within the specialized knowledge of the Exchange.

BX Rules 9146 through 9148 govern motion practice before adjudicators. BX Rule 9146 provides that the filing of a motion does not stay a proceeding, unless an adjudicator orders otherwise. It also provides that, unless otherwise ordered by an adjudicator, a Party may file an opposition or response to a written motion within 14 days after service of the motion and that, if the Party fails to do so, it shall be deemed to have waived its objection to the motion. However, BX Rule 9146 states that a moving Party is not entitled to file a reply to such an opposition or response, except at the discretion of the adjudicator. BX Rule 9146 also authorizes an adjudicator to permit oral arguments on motions and to summarily deny frivolous motions. It specifically provides for motions for protective orders. Finally, along with BX Rule 9147, BX Rule 9146 designates adjudicators for procedural and summary disposition motions at both the Hearing Panel and appellate levels. BX Rule 9148 specifies that there are no interlocutory reviews of rulings on motions or orders.

BX Rule 9150 authorizes an adjudicator to exclude from disciplinary proceedings an attorney for a Party or any other person authorized to represent a Party to the extent that the adjudicator deems said attorney or persons to be engaging in contemptuous conduct, under BX Rule 9280, or unethical or improper professional conduct. The BX Rule authorizes an attorney or person so excluded to seek review of their [sic] exclusion from the Exchange Review Council. Moreover, BX Rule 9150(b) states that even if it prohibits an attorney or other person authorized to represent others from practicing or appearing in an Exchange proceeding, such action by the Exchange shall not preclude it from initiating other proceedings against such person.

BX Rule 9160 sets forth conditions for the recusal or disqualification of an adjudicator. Such conditions include a conflict of interest, bias, or other circumstances in which the adjudicator's fairness might reasonably be questioned. The Rule also designates those who are authorized to order the disqualification of Board Directors, members of the Exchange Review Council or committees thereof, or New Hearing Panels.

The BX Rule 9200 Series

The BX Rule 9200 Series sets forth the disciplinary process, providing rules concerning the issuance of a complaint, the briefing and hearings process, issuance of a decision and the settlement process. The BX Rule 9200 Series also governs permanent cease and desist orders.

BX Rule 9211(a)(1) states that if the Departments believe that a Member or an Associated Person has violated any law, rule, or regulation over which the Exchange has jurisdiction, then the Regulation Department or the Departments may request authorization from the ODA to issue a complaint. Likewise, BX Rule 9211(a)(2) states that the Board may direct the ODA to authorize and the Departments to issue a complaint when the Board is of the opinion that any Member or Associated Person has violated any law, rule, or regulation within the Exchange's jurisdiction. Unlike the Existing Rule, the BX Rules do not specify that ''probable cause'' or any other legal standard must be satisfied for the ODA to authorize issuance of a complaint.

BX Rule 9212 sets forth the requirements for the issuance of complaints. It states that if a complaint is authorized, the Departments shall issue it.[74] It furthermore states that complaints must be in writing and specify, in reasonable detail, the conduct alleged to constitute the violative activity and the rule, regulation, or statutory provision allegedly violated by such conduct.[75] The BX Rule provides that complaints must be signed by the Department of Enforcement or of Market Regulation and served by the Departments on the Parties in accordance with the Rules.[76] The BX Rules permit amendments to and withdrawals of complaints. As to amendments, BX Rule 9212(b) provides that the Departments may amend a complaint once, as a matter of course, at any time before the Respondent answers the complaint, and otherwise, upon a motion to the Hearing Officer, a showing of good cause, and a determination that the Respondent will suffer no unfair prejudice as a result of the amendment. As to withdrawals, BX Rule 9212(c) states that the Departments may withdraw a complaint with prior leave of the Hearing Officer. BX Rule

[70] Pursuant to BX Rule 9142, an attorney or representative may withdraw from a proceeding for good cause, pursuant to written notice and at least 30 days prior notice.

[71] BX Rule 9120(t) defines ''Interested Staff'' to include certain enumerated Exchange or FINRA employees. The applicable employees who constitute ''Interested Staff'' under this BX Rule vary depending upon the type of disciplinary proceeding at issue.

[72] BX Rule 9144(a) generally prohibits Interested Staff from advising adjudicators, and adjudicators from advising Interested Staff, with respect decisions of the other, including as to whether to file complaints, appeals or cross appeals. BX Rule 9144(b) also prohibits Hearing Officers and Panelists, absent waivers in certain circumstances, from participating in decisions as to whether to issue complaints, appeal or cross-appeal disciplinary proceedings to the Exchange Review Council, or call decisions for review.

[73] In the proposed introduction to Chapter 90, the Exchange states that the Exchange's procedure for handling MRVP letters, including as set forth in BX Rule 9143(e)(3), shall also apply to minor rule violation letters.

[74] *See* BX Rule 9212(a)(1).

[75] *See id.*

[76] *See id.*

9212(d) provides for the docketing of complaints.

BX Rule 9214 governs the consolidation and severance of disciplinary proceedings. Unlike Existing Rule 1606(d), BX Rule 9214 does not permit a non-Party to intervene in disciplinary proceedings, but it does permit the consolidation of proceedings. Under the BX Rule, either the Hearing Officer may order or a Party may request consolidation of two or more disciplinary proceedings if such consolidation would further the efficiency of the disciplinary process, or if the subject complaints involve common questions of law or fact or one or more of the same Respondents. When determining whether to order the consolidation of such disciplinary proceedings, BX Rule 9214(a) requires the Chief Hearing Officer to consider whether the same or similar evidence reasonably would be expected to be offered at each of the hearings, whether the proposed consolidation would conserve the time and resources of the Parties, and whether any unfair prejudice would be suffered by one or more Parties as a result of the consolidation. If consolidation is ordered, BX Rule 9214(c) provides that the Chief Hearing Officer shall issue an order specifying which New Hearing Panel will preside over the consolidated proceedings or the Chief Hearing Panel shall appoint another New Hearing Panel to do so.

BX Rule 9215 requires a Respondent to file an answer to a complaint with the OHO within 25 days after service of the complaint (unless the Hearing Officer extends that deadline for good cause) and to state in such answer whether they [sic] admit, deny, or lack sufficient information to admit or deny each allegation made in the complaint. However, the BX Rule differs in certain respects from Existing Rule 1605, which governs answers to statements of charges. For example, it specifically authorizes a Respondent to file a motion for a more definite statement of the allegations set forth in the complaint as well as to amend the answer.[77] Although the BX Rule, similar to Existing Rule 1605, permits extensions of time to respond to an amended complaint, the BX Rule provides for the greater of the original remaining answer period or 14 days to do so, rather than 25 days.[78] Finally, instead of simply providing that a failure to file an answer shall be deemed to be an admission of the matters alleged, BX Rule 9215(f) requires the Departments to send a second notice to Respondents before they may impose sanctions, which may include, not only the admission of unanswered allegations, but also the issuance of default decisions pursuant to BX Rule 9269.

BX Rule 9216 sets forth procedures to informally dispose of matters, where appropriate. Specifically, BX Rule 9216 provides that the Departments may prepare and request that a Member or Associated Person execute a letter of acceptance, waiver, and consent (''AWC'') accepting a finding of a violation and consenting to the imposition of sanctions. Unlike Existing Rule 1603, which governs analogous ''letters of consent,'' the BX Rule provides that in executing an AWS [sic] letter, a Member or Associated Person is deemed to waive their [sic] rights to a hearing, to appeal, to otherwise challenge the terms of a letter, to claim bias or prejudgment, or to claim violation of the *ex parte* prohibitions of BX Rule 9143. The BX Rule states that executed AWC letters are subject to approval by the ODA, the Exchange Review Council, or the Review Subcommittee and, if rejected, they may not be introduced into evidence in connection with any subsequent disciplinary hearing that occurs.

BX Rule 9216(b) concerns the process for assessing fines for MRVP violations.[79] Under BX Rule 9216(b), if the Departments have reason to believe that a Member or an Associated Person has violated certain specified Rules, then they may prepare an MRVP letter (for fines of up to $2,500 for violations subject to the Exchange's MRVP plan) and request that the Member or Associated Person accept [sic] the letter and the fine set forth in it.[80] BX Rule 9216(b) provides that executed MRVP letters are to be submitted for approval to the Exchange Review Council. The Review Subcommittee or the ODA may accept such letters or refer them to the Exchange Review Council for acceptance or rejection. The Review Subcommittee may also reject such letters or refer them to the Exchange Review Council. If the letter is accepted, then it is deemed to be a final decision of the Exchange. If a Member or an Associated Person chooses not to consent to the issuance of an MRVP letter, or the Review Subcommittee or the Exchange Review Council rejects the letter, then the matter becomes subject to formal disciplinary adjudication.[81]

BX Rule 9216(b) will replace Existing Rule 1614, with three exceptions. First, the Exchange proposes to retain Existing Rule 1614(a), which sets forth its authority to impose fines of up to $2,500 for MRVP violations and up to $5,000 for minor rule violations (other than those subject to an MRVP), because BX Rule 9216(b) does not authorize the imposition of fines of up to $5,000 for minor rule violations. Existing Rule 1614(a) also includes a sentence (that the BX Rules lack) clarifying that the Exchange has discretion to decide, on a case-by-case basis, whether to impose a fine for an MRVP violation or a minor rule violation or whether instead to proceed with a formal disciplinary action under proposed Chapter 90. Second and relatedly, the Exchange proposes to include in its introduction to Chapter 90 a statement that the procedures set forth in BX Rule 9216(b) for handling MRVP violations and MRVP violation letters also apply to the handling of minor rule violations and minor rule violation letters, except that the Exchange will promptly report to the Commission any final Exchange action, in accordance with SEC Rule 19d–1(c)(1). Third, the Exchange proposes to retain Existing Rule 1614(d) (renumbered as Rule 1614(b)), which presently sets forth the Exchange's schedule of MRVP violations and minor rule violations and their associated fines. This schedule is particular to the Exchange and cannot be replaced summarily with the corresponding BX schedule, which is set forth in BX IM–9216. The Exchange will not incorporate by reference BX IM–9216.

The BX Rule 9200 Series sets forth the procedures of the Exchange for holding disciplinary hearings. Although the BX hearing rules are broadly similar to the Existing Rules, the BX Rules are more comprehensive and robust. One noteworthy difference between them is that under the Existing Rule 1606, a Respondent is entitled to a hearing as a matter of course, whereas under BX Rule 9221, a Respondent must affirmatively request a hearing in their [sic] answer or else, in absence of good

[77] *See* BX Rule 9215(c) and (d).

[78] If the Respondent files an answer before the complaint is amended, the Respondent receives 14 days to respond to the amended complaint. *See* BX Rule 9215(e).

[79] As discussed previously, the Exchange proposes to retain its existing MRVP fine schedule.

[80] Pursuant to BX Rule 9216(b), if a Member or Associated Person agrees to execute an MRVP or a violation letter, they [sic] also agree [sic] to waive certain of their [sic] rights with respect to the alleged violations, including their [sic] rights to dispute the allegations or the validity of the letter, as well as to make claims of bias or prejudgment, and to raise violations of the *ex parte* and separation of functions rules.

[81] Because the minor rule violation process proceeds only to the extent that a Member or Associated Person assents to the letter and its terms, there is no provision under the BX Rules, as there is under the Existing Rules, for a Member or Associated Person to contest a minor rule violation fine.

cause shown, they are [sic] deemed to waive their [sic] right to one.[82] A Hearing Officer or the Hearing Panel may also call a hearing on their [sic] own initiative or the Hearing Panel may issue its decision on the record.[83] BX Rule 9221(d) provides for notice of a hearing to be given to the Parties at least 28 days beforehand, but the BX Rule provides an exception if the Hearing Officer determines that extraordinary circumstances require a shorter notice period or the Parties waive the notice period.

BX Rule 9231(a) states that the Chief Hearing Officer of the OHO shall appoint a New Hearing Panel or an Extended New Hearing Panel [84] to conduct formal disciplinary procedures. BX Rule 9231(b) specifies that a New Hearing Panel, in most instances, is to be composed of a Hearing Officer and two Panelists,[85] that the Hearing Officer shall preside over the hearings, and that the Chief Hearing Officer is responsible for selecting the Panelists, who must be associated with a Members or retired therefrom.[86] BX Rule 9231(e) states that the Chief Hearing Officer may appoint a replacement Hearing Officer if the Hearing Officer withdraws, is incapacitated, or otherwise is unable to continue service after being appointed.[87] Meanwhile, BX Rule 9234 authorizes the Chief Hearing Officer to appoint new Hearing Panelists under similar circumstances. Like Existing Rule 1606(a)(3), BX Rules 9233 and 9234 provide for the recusal or withdrawal of Hearing Officers and Panelists with conflicts of interest or biases and their replacement by the Chief Hearing Officer. Unlike the Existing Rule, however, BX Rules 9233 and 9234 authorize a Party to file a request that Hearing Officers or Panelists be disqualified for such reasons.[88]

BX Rule 9241 governs pre-hearing conferences. BX Rule 9241(a) states that such conferences may be held to expedite proceedings, establish efficient procedures to manage proceedings, or to improve the quality of hearings through preparation. BX Rule 9241(b) states that pre-hearing conferences may be held upon the motion of the Hearing Officer or at the request of a Party. BX Rule 9241(c) provides that subjects for discussion at pre-hearing conferences may include, not only the simplification of issues for adjudication and the expedition of proceedings, but also the exchange of witness and exhibit lists and exhibits, the stipulation of the authenticity and admissibility of evidence, taking official notice of facts, the scheduling of pre-hearing motions or briefs, the method of service, the scheduling of hearing dates, any amendments to the complaint or answers, and the production of documents. Generally, under BX Rule 9241(d), initial pre-hearing conferences, unless determined by a Hearing Officer to be unnecessary or premature, shall be held within 21 days after the filing of an answer. BX Rule 9241(e) provides for agreements and procedural determination [sic] made during pre-hearing conferences to be recorded in orders issued by the Hearing Officer. Under BX Rule 9241(f), a Hearing Officer may issue a default decision against a Party that fails to appear at a pre-hearing conference, if the Party was provided due notice.

Additionally, prior to a hearing, BX Rule 9242 authorizes a Hearing Officer to order a Party to furnish information to all other Parties and to the New Hearing Panel that may include an outline or narrative summary of the Party's case or defense, the legal theories upon which a Party will rely, a list and copies of documents that the Party intends to introduce at the hearing, a list of witnesses that the Party intends to call to testify on their [sic] behalf and a summary of the expected testimony, and if a witness is to be called as an expert witness, a statement of the witness' expertise.

The BX Rule 9250 Series governs discovery during disciplinary proceedings. The BX Rule 9250 Series provides for more extensive discovery than that which exists under the Existing Rules. BX Rule 9251(a) generally provides that the Departments must make available to Respondents information and documents obtained in connection with the investigations that led to the institution of disciplinary proceedings, such as requests for information and documents, responses thereto, and all transcripts and exhibits. BX Rule 9251(b) permits the Departments to withhold certain documents from Respondents under certain circumstances, including to the extent that they are privileged, contain attorney work product, constitute internal memoranda or examination reports, reveal examination or investigatory methods, the identities of confidential sources, or the existence of other prospective investigations or enforcement actions, or if the Hearing Officer grants leave to withhold a document.[89] The BX Rule does not permit the Departments to withhold from Respondents exculpatory evidence. The Hearing Officer may require the Departments to submit a list of withheld documents.[90] However, the Rule states that unless the Hearing Officer orders otherwise, the Departments generally must make documents available to a Respondent not later than 21 days after service of the Respondent's answer.[91] If the Departments fail to make documents or witness statements available to Respondents as required under BX Rule

[82] BX Rule 9221(a) provides that any request by a Respondent for a hearing shall be granted.

[83] *See* BX Rule 9221(b)-(c).

[84] Like Extended New Hearing Panels, Extended Proceeding Committees are established for proceedings that involve unusually complex issues or will require an extended period of time to hear. Pursuant to BX Rule 9331(a)(2), members of Extended Proceeding Committees may be entitled to compensation at the rates then in effect for arbitrators appointed under the FINRA Rule 10000 Series.

[85] BX Rule 9120(z) defines the term ''Panelist'' as used in the Rule 9200 Series, the Rule 9550 Series, and the Rule 9800 Series, to mean a ''member of a Hearing Panel or Extended Hearing Panel who is not a Hearing Officer.'' As used in the Rule 9300 Series, the term means a ''current or former member of the Exchange Review Council or a former Director who is appointed to serve on a Subcommittee or an Extended Proceeding Committee.'' The Exchange will select Panelists in accordance the requirements set forth in BX Rules 9120(z) and 9231.

[86] BX Rule 9232 sets forth other criteria for the Chief Hearing Officer to use when selecting New Hearing Panels, including their level of expertise, the absence of any conflicts of interest or bias and any appearance thereof, their availability for service, and the frequency of their prior service on New Hearing Panels (with a preference towards providing opportunities for new or infrequently-serving individuals).

[87] BX Rule 9235(b) also authorizes the Chief Hearing Officer or his or her Deputy to exercise the authority of a Hearing Officer in his or her temporary absence.

[88] BX Rule 9233(b) permits a Party to move for the disqualification of a Hearing Officer not later than 15 days after the later of: (1) When the Party learned of the facts believed to constitute the disqualification; or (2) when the Party was notified of the assignment of the Hearing Officer. Similarly, BX Rule 9234(b) permits a Party to move for the disqualification of a Hearing Panelist within 15 days after the later of: (1) When the Party learned of the facts believed to constitute the disqualification; or (2) when the Party was notified of the assignment of the Hearing Panelist. BX Rule 9233(c) provides that the Chief Hearing Officer shall promptly investigate whether disqualification is required and issue a written ruling on the motion. BX Rule 9234 provides for a similar process for motions and decisions on motions to disqualify Hearing Panelists.

[89] BX Rule 9253 provides in part that, notwithstanding BX Rule 9251(b), a Respondent may file a motion requesting that the Departments produce witness statements or witness deposition transcripts. It provides that the failure to produce such materials shall not result in rehearing or an amended decision unless the Respondent establishes that the failure was not harmless error. The Hearing Officer, or upon appeal or review, a Subcommittee, an Extended Proceeding Committee, or the Exchange Review Council, shall determine whether the failure to provide any statement was not harmless error.

[90] *See* BX Rule 9251(c).

[91] *See* BX Rule 9251(d).

9251, no rehearing or amended decision may be in order, unless the Hearing Officer determines that the failure was not harmless error.[92]

BX Rule 9252 provides for a process by which a Respondent may request that the Exchange invoke BX Rule 8210 to compel the production of documents or testimony at the hearing. Pursuant to BX Rule 9252(a), such a request must be submitted to the Hearing Officer no later than 21 days before the hearing date. The request may be granted upon a showing that the information sought is relevant, material, and non-cumulative, that the requesting Party has been unsuccessful in obtaining the requested documents or testimony despite good faith attempts to do so, and that each of the persons for whom the documents and testimony are sought is subject to the Exchange's jurisdiction.[93] The Hearing Officer shall also consider whether the request is unreasonable, oppressive, excessive, [sic] in scope, or unduly burdensome, or whether it should be denied, limited, or modified.[94] If the Hearing Officer determines that a request is unreasonable, excessive, or unduly burdensome, he or she may deny the request or grant it only upon such conditions as fairness requires.[95] If the Hearing Officer grants the request, the Hearing Officer shall order that requested documents be produced to all Parties not less than ten days before the hearing, and order that witnesses whose testimony was requested appear and testify at the hearing. If the Hearing Officer grants the request ten or fewer days before a hearing on the merits is scheduled to begin or after such hearing begins, the documents or testimony shall be produced immediately to all Parties.[96]

Several BX Rules govern the hearing process. Broadly speaking, these Rules are similar to, albeit more comprehensive than, the hearings process that exists under Existing Rule 1606(e). BX Rule 9261(a) requires a Party to submit to all other Parties and to the Hearing Officer, no later than 10 days before a hearing, or at such earlier date as may be specified by the Hearing Officer, copies of documentary evidence and the names of the witnesses that it intends to present at the hearing. BX Rule 9261(b) states that a Party is entitled to appear at a hearing in person, by counsel, or by their [sic] representative. BX Rule 9262 requires sworn testimony at hearings. BX Rule 9263(a) grants the Hearing Officer authority to receive relevant evidence and to exclude all evidence that is irrelevant, immaterial, unduly repetitious, or unduly prejudicial. BX Rule 9145(a) provides that the formal rules of evidence shall not apply in a proceeding brought under the Rule 9000 Series. BX Rule 9265 requires hearings and (unless otherwise ordered by a Hearing Officer) pre-hearing conferences to be recorded by a court reporter and for transcripts to be available for correction and purchase. BX Rule 9266 states that the Hearing Officer may require the Parties to file proposed findings of fact and conclusions of law, or post-hearing briefs, and it prescribes a procedure for doing so. BX Rule 9267 lists the contents of the evidentiary record.

BX Rule 9268 governs New Hearing Panel decisions. Similar to Existing Rule 1607, BX Rule 9268(a) requires a New Hearing Panel to make a determination in a matter based on a majority vote, which is reflected in a written decision drafted by the Hearing Officer. Also similar to the Existing Rule, BX Rule 9268(b) requires that each decision include a statement of the specific violations alleged, findings of underlying facts, and conclusions of law. Unlike the Existing Rule, however, BX Rule 9268(c) permits the Hearing Officer or a Hearing Panelist to prepare a written dissenting opinion. BX Rule 9268(a) also specifically requires that the decision be issued within 60 days of the final date allowed for filing proposed findings of fact, conclusions of law, and post hearing briefs, or by a date established by the Chief Hearing Officer. Last, under subparagraph (d) of the BX Rule, the OHO must serve the decision and any dissenting opinion on the Parties, publish notice of the decision and any dissenting opinion in the Central Registration Depository (''CRD'') and provide a copy of the decision and any dissent thereto to the each Member of the Exchange with which the Respondent is associated.

BX Rules 9264 and 9269 concern the disposition of a disciplinary matter through a summary proceeding. BX Rule 9264 states that a motion for summary disposition must be initiated by a Party. Under BX Rule 9264(a), the Respondent and/or staff may, prior to the hearing but after the Respondent has filed an answer and had opportunity to inspect documents in the record, make a motion for summary disposition of any or all the causes of action in the complaint with respect to that Respondent, as well as any defense raised in a Respondent's answer. If a hearing on the merits has begun, then BX Rule 9264(b) states that Parties may submit a motion for summary disposition only with leave of the Hearing Officer. BX Rule 9264(c) provides the process for proceeding when a summary motion does not dispose of the matter entirely. BX Rule 9264(d) requires motions for summary disposition to be supported by a statement of undisputed facts, a supporting memorandum of points and authorities, and affidavits or declarations that set forth such facts. BX Rule 9264(e) concerns rulings on motions for summary disposition. This provision of the BX Rule provides that a Hearing Officer may deny or defer a decision on any motion for summary disposition, yet only a New Hearing Panel may grant such a motion (except the Hearing Officer may grant motions for summary disposition with respect to questions of jurisdiction). BX Rule 9264(e) also provides that a motion for summary disposition may be granted if there is no genuine issue with regard to any material fact and the Party that files the motion is entitled to summary disposition as a matter of law.

Meanwhile, BX Rule 9269 governs the issuance of default decisions by the Hearing Officer against Respondents that fail to provide timely answers to complaints or any Party that fails to appear at any hearing for which they have [sic] due notice. Where the defaulting Party is the Respondent, the BX Rule specifies that the Hearing Officer may issue a default decision that deems the allegations against the Respondent to be admitted. Where the defaulting Party is the Departments, the Hearing Officer may issue a default decision that dismisses the complaint with prejudice. The Hearing Officer also may order a Party who fails to attend a pre-hearing conference or a hearing to pay the costs of attendance for the other Party. Like Existing Rule 1608, the BX Rule provides for default decisions to be set aside, but unlike the Existing Rule, BX Rule 9269 provides for the Hearing Officer to set them aside only upon a motion and a showing of good cause. The BX Rule provides, however, that default decisions may be appealed to or called for review by the Board within 25 days after service.[97]

[92] *See* BX Rule 9251(g). The Hearing Officer, or, upon appeal or review, a Subcommittee, an Extended Proceeding Committee, or the Exchange Review Council, shall determine whether the failure to make the document available was not harmless error. *See id.*

[93] *See* BX Rule 9252(b).

[94] *See id.*

[95] *See* BX Rule 9252(c).

[96] *See id.*

[97] In addition to the above, BX Rule 9280 authorizes a New Hearing Panel to exclude or impose sanctions upon a Party, an attorney for a Party, or another authorized representative of a Party that violates an order or otherwise engages in contemptuous conduct during a proceeding.

Continued

BX Rule 9270 governs settlements. It permits a Party to propose in writing an offer of settlement at any time and to do so without limit to the number of offers it proposes. Under BX Rule 9270(e), if an offer of settlement is uncontested, then the Departments must, if a hearing has not yet commenced, transmit the offer and a proposed order of acceptance to the Exchange Review Council (or the ODA, if the Respondent is an affiliate of the Exchange) for approval or rejection. If a hearing has already commenced when the offer is made, then the Departments must send the offer and proposed order to the New Hearing Panel for preliminary approval and then to the Exchange Review Council (or, if a Respondent is an affiliate of the Exchange, to the ODA) for ultimate approval or rejection. Under BX Rule 9270(f), if an offer of settlement is made and it is contested, then the Departments must provide a written opposition to the New Hearing Panel, which may issue an order approving the offer, or it may order the Parties to attend a settlement conference. If a New Hearing Panel approves a contested offer of settlement, then the Hearing Officer shall send the order of acceptance of the offer of settlement to the Exchange Review Council (or, if a Respondent is an affiliate of the Exchange, to the ODA) for ultimate acceptance or rejection. Pursuant to BX Rule 9270(h), if an offer of settlement is rejected, then the Respondent shall be notified in writing, the offer shall be withdrawn, and the rejected order shall not constitute part of the record in any subsequent proceeding against the Respondent. BX Rule 9270(j) further clarifies that a Respondent shall not be prejudiced by a rejected order of settlement.[98]

BX Rule 9280 authorizes the issuance of sanctions for Parties, their attorneys, and their representatives, for contemptuous conduct. As set forth in BX Rule 9280(a)(2), such sanctions may include exclusion of an attorney or representative from proceedings. They may also include, in part, orders that establish disputed facts in favor of the non-sanctioned Party, preclude the disobedient Party from supporting or opposing claims or defenses, or strike pleadings or portions thereof.[99] The exclusion of an attorney or representative is subject to review by the Exchange Review Council.[100]

BX Rule 9290 states that hearings shall be held and orders shall be issued as to temporary cease and desist proceedings on an expedited basis. BX Rule 9291 governs the form and delivery of permanent cease and desist orders.

The BX Rule 9300 Series

The BX Rule 9300 Series sets forth the process for review of disciplinary proceedings by the Exchange Review Council and the Board.

BX Rule 9311 sets forth the process for appellate reviews of New Hearing Panel decisions. Under BX Rule 9311, a Party may appeal a New Hearing Panel decision to the Exchange Review Council within 25 days after service of a decision.[101] Additionally, on their [sic] own motion, any member of the Exchange Review Council, a Review Subcommittee thereof, or the CRO (as to default decisions) may issue a call to review a New Hearing Panel decision within 45 days after the date of service of the decision (or within 25 days after the date of service, as to calls for review that the CRO initiates). BX Rule 9311(c) and (d) require [sic] that Parties file written notices of appeal (and cross-appeal) with the OHO and it prescribes requirements for such notices. BX Rule 9311(e) states that the Exchange Review Council, in its discretion, may waive any issues not raised in appeal or cross-appeal notices, but it provides a process by which the Parties may petition for consideration of such issues.

Meanwhile, BX Rule 9312 governs the process by which the Exchange Review Council, the Review Subcommittee, or the CRO may call a matter for review. It provides that a decision of a New Hearing Panel issued pursuant to BX Rule 9268 may be called for review by any member of the Exchange Review Council or any member of a Review Subcommittee within 45 days after service of the decision. It also provides that a default decision against a Respondent, pursuant to BX Rule 9269, may be called for review by the CRO, on his or her own motion, within 25 days after service of the decision. Additionally, it provides that a decision with respect to a Member that is an affiliate of the Exchange may not be called for review by the Exchange Review Council. BX Rule 9312(b) states that a decision to call a matter for review by the Exchange Review Council, the Review Subcommittee, or the CRO operates as a stay of a final decision until such time as the Council or Board issues its decision, except with respect to permanent cease and desist orders.

BX Rule 9321 provides for the transmission of the record of a disciplinary proceeding to the Exchange Review Council within 21 days after the filing of a notice of appeal or notice of review, or at such a later time as the Council may designate. BX Rule 9322 grants discretion, with good cause shown, to the Exchange Review Council, the Review Subcommittee, a Subcommittee, an Extended Proceeding Committee, and Counsel to the Exchange Review Council (defined below) to modify filing deadlines, adjourn appeal proceedings, and change hearing locations in certain instances and subject to certain limitations.

BX Rule 9331 states that, following the filing of a notice of appeal or a call for review, the Exchange Review Council or the Review Subcommittee shall appoint a Subcommittee or an Extended Proceeding Committee, composed of two or more persons who are or were members of the Exchange Review Council or former Directors, for the purpose of making recommendations to the full Council as to how to dispose of matters before it.[102]

Authorized sanctions include, but are not limited to, imposing orders that establish facts in favor of the opposing Party, precluding a Party from making claims or defenses, striking portions of pleadings, or staying procedures until compliance occurs. No similar provisions exist in the Existing Rules. Meanwhile, BX Rule 9150(a) authorizes an adjudicator to exclude from disciplinary proceedings an attorney for a Party or any other person authorized to represent a Party to the extent that the adjudicator deems said attorney or persons to be engaging in contemptuous conduct, under BX Rule 9280, or unethical or unprofessional conduct. The BX Rule authorizes an attorney or person so excluded to seek review of their exclusion from the Exchange Review Council.

[98] Finally, BX Rule 9270(i) states that, when a disciplinary proceeding names multiple respondents, settlement offers may be accepted or rejected as to any one or all of the Respondents submitting offers.

[99] *See* BX Rule 9280(b).

[100] *See* BX Rule 9280(c).

[101] However, the Exchange notes that a decision involving a Respondent who is an affiliate of the Exchange may not be appealed to the Exchange Review Council.

[102] Under the BX Rules, the Exchange Review Council is assigned its own counsel in appellate matters. BX Rule 9120(e) defines the term ''Counsel to the Exchange Review Committee'' as an attorney that reports to the CRO of the Exchange who is responsible for advising the Exchange Review Council, the Review Subcommittee, a Subcommittee, or an Extended Proceeding Committee regarding a disciplinary proceeding on appeal or review before the Exchange Review Council. Counsel also may decide a motion on a procedural matter in the BX Rule 9300 Series. *See* BX Rule 9146(j)(2). BX Rule 9313 describes the authority of the Counsel and the process for seeking the review of a Counsel decision. Under BX Rule 9313(a), Counsel has authority to take ministerial and administrative actions to further the efficient administration of a proceeding. A Party may seek review of a Counsel decision on motion to the Exchange Review Council, the Review Subcommittee, a Subcommittee or, if applicable, an Extended Proceeding Committee. *See* BX Rule 9313(b). Counsel is subject to the same conflict of interest prohibitions as the Exchange Review Council, *see* BX Rule 9332, which requires Counsel to withdraw from a matter any time that the Counsel has a conflict of interest or bias or circumstances otherwise exists where the fairness of the Counsel might reasonably be questioned.

Under BX Rule 9332, Exchange Review Council members, including members of the Review Subcommittee, panelists of a Subcommittee or an Extended Proceeding Committee, or Counsel to the Exchange Review Council, are subject to the same disqualification and recusal standards as the Hearing Panelists and Hearing Officers.

The BX Rule 9340 Series governs the proceedings of the Exchange Review Council, Extended Proceeding Committee, and Subcommittees. BX Rule 9341 provides for oral arguments before a Subcommittee and the Extended Proceeding Committee, upon written request of a Party or otherwise at the discretion of Subcommittee or Committee.[103] BX Rule 9343 provides that, if no oral argument is held, a matter shall be decided on the record, supplemented by any written materials submitted to or issued by the Exchange Review Council, a Subcommittee, or the Extended Proceeding Committee. BX Rule 9344 grants discretion to the Council or the Review Subcommittee to proceed with or dismiss the appeal and remand appeals of Parties that failed to participate in initial disciplinary hearings and show good cause for their failure to participate. It also prescribes circumstances under which an appeal or cross-appeal will be deemed abandoned. BX Rule 9345 states that a Subcommittee or the Extended Proceeding Committee shall present a recommended decision to the Exchange Review Council. Pursuant to BX Rule 9346, the Exchange Review Council is charged with issuing a decision based on the record, supplemented by briefs and other papers submitted to the Subcommittee, Extended Proceedings Committee, or the Exchange Review Council, any oral arguments that occur, and upon a showing of good cause and with the leave of the Council, Extended Proceeding Committee, or Subcommittee, additional evidence that is introduced on appeal.[104] It also provides that the formal rules of evidence shall not apply during the appeals process.[105] BX Rule 9347 sets forth the form, format, and filing procedures and deadlines for papers filed in Exchange Review Council proceedings. BX Rule 9348 states the powers of the Exchange Review Council to affirm, dismiss, modify, or reverse New Hearing Panel decisions with respect to each finding, or to remand the proceeding with instructions. It also provides that the Exchange Review Council may affirm, modify, reverse, increase, or reduce any sanction, or impose any other fitting sanction. The Exchange Review Council must issue a decision consistent with BX Rule 9349(b), which provides elements required to be included in an Exchange Review Council decision.

BX Rule 9351 governs discretionary review by the Board. Pursuant to BX Rule 9351(a), a Director may call for review a decision of the Exchange Review Council (other than a decision with respect to a Member that is an affiliate of the Exchange) not later than the next meeting of the Board that is at least 15 days after the date on which the Board receives the Exchange Review Council decision. As set forth in BX Rule 9351(d), the Board may affirm, modify, or reverse the proposed written decision of the Exchange Review Council and it may affirm, modify, reverse, increase, or reduce any sanction (including the terms of any permanent cease and desist order) or impose any other fitting sanction. The Board also may remand the proceeding with instructions. The Board is required to issue its decision in writing pursuant to BX Rule 9351(e).[106]

Unlike the Existing Rules, BX Rule 9370 expressly provides for a Respondent aggrieved by a final disciplinary action to apply for review by the Commission pursuant to Section 19(d)(2) of the Act.

The BX Rule 9400 and 9500 Series

The BX Rule 9400 Series provides the process for expedited client suspension proceedings involving alleged violations of Rule 403 (Disruptive Quoting and Trading Activity Prohibited). The BX Rule 9500 Series provides the process for proceedings other than formal disciplinary proceedings. The Exchange proposes that these BX Rules will replace Chapter 15 of the Existing Rules, which also provide for the Exchange to impose summary suspensions in various circumstance [sic].

BX Rule 9400 authorizes and prescribes the process for adjudicating expedited client suspensions that may be imposed upon Members or Associated Persons that violate the prohibition on disruptive quoting and trading activity.[107] BX Rule 9400 states that the Regulation Department, with the prior authorization of the CRO, may issue a notice initiating a suspension proceeding of a Member or an Associated Person for engaging in disruptive quoting and trading activity, which shall trigger the appointment of a New Hearing Panel and the occurrence of a hearing not later than 15 days after service of the notice, unless extended for good cause shown. The New Hearing Panel may issue a written decision imposing a suspension (within 10 days of receipt of the hearing transcript, unless otherwise extended) only if the New Hearing Panel finds by a preponderance of the evidence that the violation occurred and that it is likely to result in significant market disruption or harm to investors. BX Rule 9400(e) also permits a Respondent to apply to the New Hearing Panel to modify, set aside, limit, or revoke a suspension order and it requires the New Hearing Panel to respond to such a request in writing within 10 days after receiving it, unless such time period is extended with the consent of the Parties for good cause shown. Finally, BX Rule 9400(f) states that suspensions imposed by New Hearing Panels may be appealed to the Commission as set forth in Section 19 of the Act.

The BX Rule 9500 Series permits the Exchange to impose sanctions, such as suspensions, cancellations of membership, bars of association with Members, and prohibitions or restrictions on access to Exchange services, as well as the adjudication of such sanction orders, for actions or circumstances that include the following: (1) Failures to provide information, reports, data, or testimony requested or required by the Exchange or failures to keep membership applications or supporting documentation current (BX Rule 9552); (2) failures to pay Exchange dues, fees and other charges or to submit a required report or information related to such payment (BX Rule 9553); (3) failures to comply with arbitration awards or settlements or orders of restitution (BX Rule 9554); (4) failures to meet the eligibility or qualification standards or prerequisites for access to

Moreover, the Counsel may be removed on motion based upon a good faith belief that the Counsel has a conflict of interest or bias or circumstances otherwise exists where the fairness of the Counsel might reasonably be questioned.

[103] BX Rule 9342 states that if a Party requests, but fails to appear at an oral argument, then the Committee or Subcommittee may proceed with oral arguments without that Party or consider the matter on the basis of the record, without oral argument, as to that Party.

[104] BX Rule 9346(f) also permits the Council, Extended Proceeding Committee, or Subcommittee to order, on its own motion, that the record be supplemented with such additional evidence as they deem relevant.

[105] *See* BX Rule 9346(g).

[106] BX Rules 9360 and 9370 states [sic] when sanctions become effective, including when a Respondent appeals a decision to the Commission.

[107] Although BX Rule 9400 references the BX Rule that prohibits disruptive quoting and trading, the Exchange proposes to substitute reference to its own analogous provision, Rule 403.

services (BX Rule 9555); (5) failures to comply with temporary and permanent cease and desist orders (BX Rule 9556); (6) financial or operational difficulties that require limiting or ceasing certain business activities (BX Rule 9557); and (7) actions authorized by Section 6(d)(3) of the Act, including in part summary suspensions of or limitations or prohibitions with respect to services offered by the Exchange on Members, Associated Persons, or other persons subject to the Exchange's jurisdiction, including those who have been suspended or expelled from another SRO, barred or suspended from being associated with a member of another SRO, or are experiencing severe financial or operation [sic] difficulties threaten [sic] investors, creditors, other Members, or the Exchange (BX Rule 9558). The BX Rule 9520 Series also provides for adjudication of statutory disqualifications or determinations of ineligibility to become or remain a Member or associated with a Member. Generally, each of these provisions of the BX Rules require [sic] the Exchange to serve written notice to the Member or Associated Person, offer them an opportunity to request a hearing in writing, and permit them to request termination of sanctions upon achieving compliance.[108] Meanwhile, BX Rule 9559 sets forth extensive procedures governing hearings and it provides for appellate reviews by the Exchange Review Council, upon its call for review, and by the Commission, pursuant to Section 19 of the Act.

The BX Rule 9600 Series

The BX Rule 9600 Series provides procedures to be followed when a Member seeks exemptive relief pursuant to any Rule that references the BX Rule 9600 Series. As discussed below, the Exchange proposes to amend the Supplementary Material to Existing Rule 303 to provide for the BX Rule 9600 Series to govern requests to waive applicable qualification examination requirements for applicants that apply to become associated with Members of the Exchange.

The BX Rule 9800 Series[109]

The BX Rule 9800 Series provides the process followed by the Exchange in administering temporary cease and desist orders, including the initiation of proceeding to issue such an order,[110] service thereof,[111] subsequent review of the order by the Hearing Panel,[112] the consequences of non-compliance,[113] and the process for seeking Commission review of the order.[114]

The BX Rule 9800 Series provides for temporary cease and desist orders and a process for adjudicating them. BX Rule 9810 states that with the prior written authorization of the CRO and FINRA's Chief Executive Officer (or such other senior officers as he or she designates), the Departments may initiate a temporary cease and desist proceeding with respect to alleged violations of Section 10(b) of the Act and SEC Rule 10b-5, SEC Rules 15g-1 through 15g-9, and BX Rules 2110, 2120, or 2150 (references to these BX Rules will be replaced with references to Exchange Rules 400, 405, and Chapter 6, respectively). The Departments must serve written notice upon Respondents of a proposed temporary cease and desist order and file a copy of such notice with the OHO. Additionally, if a complaint has not already been issued against the Respondents, then the Departments must file and serve a complaint together with the notice of the temporary cease and desist order. BX Rule 9820 provides for the Chief Hearing Officer of the OHO to assign a New Hearing Panel to adjudicate the proposed cease and desist order. BX Rule 9830 provides for a hearing to be held, generally speaking, not later than 15 days after service of the notice. BX Rule 9840 states that the New Hearing Panel shall issue a written decision as to whether to impose a temporary cease and desist order within 10 days after receipt of the hearing transcript, unless such deadline is extended for good cause. It states that the New Hearing Panel should impose such an order if it finds that the Departments have demonstrated a likelihood of success on the merits and that the alleged misconduct or continuation thereof is likely to result in significant dissipation or conversion of assets or other significant harm to investors prior to the completion of disciplinary proceedings. BX Rule 9850 permits a Party to apply to the New Hearing Panel to modify, set aside, limit, or suspend a temporary cease and desist order. BX Rule 9860 states that a Respondent that violates a temporary cease and desist order may have its association or membership suspended or cancelled or be subject to any fitting sanction, pursuant to BX Rule 9556. Finally, BX Rule 9870 states that a Respondent may apply to the Commission to review the issuance of a temporary cease and desist order, as set forth in Section 19 of the Act.

Additional Conforming Rule Changes

As discussed above, the Exchange is amending its By-Laws to conform to the BX by-laws, largely deleting the Existing Rule 1500, 1600, and 1700 Series,[115] and adopting in their place the BX Rule 8000 and 9000 Series. As a consequence of these changes, the Exchange proposes to amend or delete certain other Existing Rules, which are either not needed, duplicated elsewhere, or reference the deleted Existing Rules. Below is a description of the specific changes the Exchange proposes to make to its Existing Rules.

Existing Rule 100 provides definitions for purposes of the Existing Rules. The Exchange is proposing to amend this Existing Rule to include definitions for several new terms. For example, the proposed Rules will define the new term ''Code of Procedure'' as the procedural rules contained in Chapter 90. The Exchange also defines the new term ''Exchange Review Council,'' which is largely copied from BX Rule 0120(m). The Exchange notes that item (6) of the new definition differs from the BX item (6) in that it cites the analogous rules of the Exchange, which have different rule numbers. Finally, the Exchange proposes to amend the

[108] The BX Rule 9520 Series provides for a somewhat different process from the BX Rule 9550 Series. BX Rule 9522 requires Members and Associated Persons to file applications for relief from statutory disqualifications or determinations of ineligibility. BX Rule 9522(e) authorizes the Department of Member Regulation, to the extent it deems consistent with the public interest and the protection of investors, to approve a written request for relief from the eligibility requirements by a disqualified Member with or without the filing of an application by such disqualified Member, under certain specified conditions. Pursuant to BX Rule 9523, the Department of Member Regulation also may recommend membership or association or continued membership or association pursuant to a supervisory plan that is subject to approval by the Chair of the Statutory Disqualification Committee (a Subcommittee of the Exchange Review Council, as defined in BX Rule 9120(cc)) or the Exchange Review Council. Pursuant to BX Rule 9523(a), the Member or Associated Person may request a hearing before a New Hearing Panel to seek relief from disqualification or conditions imposed upon continued membership or association. In such instances, the Hearing Panel shall issue a recommended decision to the Statutory Disqualification Committee, which in turn shall issue a recommended decision to the Exchange Review Council for ultimate determination. The decision of the Exchange Review Council is subject to discretionary review by the Board. *See id.* The BX Rule also provides for the Exchange Review Council to conduct an expedited review of a recommended decision of the Statutory Disqualification Committee. *See id.* Finally, it provides for review by the Commission of any action taken pursuant to the BX Rule 9520 Series. *See id.*

[109] The BX Rule 9700 Series is reserved.

[110] BX Rule 9810.

[111] *Id.*

[112] BX Rule 9850.

[113] BX Rule 9860.

[114] BX Rule 9870.

[115] As noted elsewhere, the Exchange proposes to retain Existing Rules 1600 and 1614(a) and (d) in their current form (and to renumber Rule 1614(d) as 1614(b)).

definition of ''SEC'' so that it also includes the word ''Commission.''

Existing Rule 210 concerns the consequences of a Member's or an Associated Person's failure to pay dues, fees and other charges. The Exchange proposes to delete this Existing Rule in favor of BX Rule 9553, which is more comprehensive than the Existing Rule and differs from it in several respects. Existing Rule 210 provides that instances of nonpayment shall be reported to the Exchange President when they are 30 days past due, and that the President thereafter shall provide reasonable notice to the delinquent Member that continued non-payment will result in suspension of trading privileges. An Associated Person that fails to pay may be suspended from association with a Member. Moreover, although Existing Rule 210(a) does not specify a time period for a reasonable notice that precedes suspension, it nevertheless provides that the Exchange shall dispose of the memberships of Members who are more than six months delinquent. By contrast, BX Rule 9553 states that the Regulation Department, within an unspecified period of time period [sic] after the onset of a delinquency, may issue a written notice to the delinquent Member or Associated Person that failure to comply within 21 days of service of the notice will result in suspension or cancellation of membership or suspension or bar of association with a Member, as applicable. BX Rule 9553 also provides for detailed provisions for serving such notice, a provision for requesting a hearing with respect to such a notice, a provision declaring the effectiveness of such notices (21 days after service) when no hearing is requested, and a means to request termination of a suspension, which may be granted for good cause shown.

Existing Rule 302 sets forth circumstances in which the Exchange may deny or condition approval of membership applications or applications to associate with Members. Existing Rule 302(c) also sets forth circumstances in which the Exchange may determine not to permit a Member or Associated Person from continuing their [sic] membership or association with a Member, including because they become [sic] subject to [sic] statutory disqualification under the Act. Existing Rule 302(f) furthermore permits a Member or Associated Person that becomes subject to [sic] statutory disqualification under the Act to apply to the Exchange to continue as a Member or as an Associated Person, within 30 days of becoming subject to the statutory disqualification. Existing Rule 302(g) states that, subject to the summary suspension rules in Chapter 15, any applicant for membership or association with a Member whose application is denied or conditioned or who is not permitted to continue as a Member or Associated Person may appeal such determinations under Chapter 17 of the Existing Rules.

The Exchange proposes to modify Existing Rule 302(f) so that it refers to new and more robust procedures, set forth in the BX Rule 9520 series, by which a Member or an Associated Person may obtain relief from disqualification or ineligibility determinations (BX Rule 9522).

The Exchange also proposes to amend Existing Rule 302(g), which states that subject to Chapter 15, the BCC may review in part Exchange determinations to deny membership or association with a Member pursuant to Chapter 17 of the Existing Rules. The Exchange proposes to re-assign responsibility for these reviews from the BCC to the Exchange Review Council and replace the review process presently set forth in Chapter 17 of the Existing Rules with processes that are substantially the same as those set forth in BX Rules 1015 and 1016. Specifically, the proposed amendments to Exchange Rule 302(g) state that, subject to Chapter 90, the Exchange Review Council will have jurisdiction to review these decisions. Proposed Rule 302(g) states that anyone whose application for membership on the Exchange, association with an Exchange Member, or whose continuing membership or association is denied or conditioned by the Exchange's Membership Department, may file a written request for review by the Exchange Review Council within 25 days after service of the Exchange's decision.[116] The request must state specifically why the applicant believes that the Membership Department's decision is inconsistent with the permissible bases for denial set forth in Rule 302, or otherwise should be set aside and state whether a hearing is requested.[117] The request will be heard by a Subcommittee appointed by the Exchange Review Council or the Review Subcommittee composed of two or more persons who are either current or past members of the Council or former Directors of the Exchange.[118] If a hearing is requested or directed, it must be held within 45 days after the request for review is filed with the Exchange or service of the notice by the Subcommittee.[119] Applicants and the Membership Department may be represented by counsel at the hearing and formal rules of evidence will not apply during the hearing.[120] The Subcommittee must present a recommended decision in writing to the Exchange Review Council within 60 days after the date of the hearing, and not later than seven days before the meeting of the Exchange Review Council at which the proceeding shall be considered.[121] The Exchange Review Council must issue a proposed written decision that affirms, modifies, or reverses the Membership Department's decision, or remands the proceedings with instructions and provide the proposed decision to the Exchange Board.[122] If the Exchange Board does not call the decision for review, it shall become final. If the Exchange Review Council does not serve its final written decision within the time period prescribed by Rule 302(g)(10)(C), then the Applicant may file a written request with the Exchange Board for the Board to direct the Exchange Review Council to issue its decision immediately or show good cause why it needs additional time to issue its decision.[123] Proposed Rule 302(h), which mirrors BX Rule 1016, grants the Exchange Board discretion, at the request of a Director, to review decisions of the Exchange Review Council.[124]

Existing Rule 305(b) requires Members to file with the Exchange and keep current their addresses at which notices may be served. The Exchange proposes to amend this Existing Rule to incorporate the language set forth in BX Rule 1160. Rather than merely requiring Members to provide the Exchange with

[116] *See* proposed Rule 302(g)(1). The Exchange notes that the deadline for filing petitions for BCC review of an Exchange action under Existing Rule 1701(a) is 30 days from the date of such action. The Existing Rules pertaining to membership do not reference or define the terms ''Membership Department'' or ''Department.'' As part of this proposal, the Exchange proposes to amend Rule 302(g) to specify that the Exchange's Membership Department—rather than simply the ''Exchange''—makes determinations as to whether to grant, deny, or conditionally grant applications for membership or association or to continue as a Member or an Associated Person.

[117] *See id.*

[118] *See* proposed Rule 302(g)(4). The Exchange notes that Existing Rule 1702 provides for review by a BCC panel composed of two or more of its members.

[119] *See* proposed Rule 302(g)(6)(A).

[120] *See* proposed Rule 302(g)(6)(B) & (C). Unlike Existing Rule 1703, proposed Rule 302(g) does not provide for intervention in proceedings by interested non-Parties.

[121] *See* proposed Rule 302(g)(9).

[122] *See* proposed Rule 302(g)(10)(A).

[123] *See* proposed Rule 302(g)(10)(D).

[124] Unlike Existing Rule 1704, proposed Rule 302(h) does not authorize the applicant or the President of the Exchange to request that the Board review the decision of the Exchange Review Council.

their current address, the proposed amendment more broadly requires Members to report to the Exchange, through the FINRA Contact System, all of their contact information, including their mailing addresses, email addresses, facsimile numbers, and other information. It also requires members to update such contact information in the FINRA System within 30 days of any changes thereto, and to generally verify that such information remains accurate within 17 business days after the end of each calendar year. This proposed amendment to the Existing Rule will ensure that the Exchange has available to it multiple means of contacting its Members, including for purposes of serving the notices specified in the BX Rule 9550 series by email or by facsimile. The Exchange proposes, in its introduction to Chapter 90, to state that cross references in the BX Rule 9000 Series to BX Rule 1160 should be read instead to refer to Exchange Rule 305(b), as modified herein.

To maintain consistency with the BX Rules, the Exchange also proposes to eliminate Existing Rule 305(d), which requires Members to maintain a current copy of the Exchange's governing documents and Rules in an accessible place and make them available for examination by customers, and to replace it with BX Rule 8110, which is materially equivalent.

Existing Rule 307 and its Supplementary Material govern the sale and transfer of market maker rights. Item .01 of the Supplementary Material presently provides that decisions by the Exchange (and specifically, by the Membership Department) to deny approval of such sales and transfers are appealable under Chapter 17 of the Existing Rules. The Exchange proposes to state instead that these decisions are appealable to the Exchange Review Council. The Exchange notes that no analogue exists to this proposal in the BX Rules, which do not provide for the sale and transfer of such rights or reviews of decisions to deny or condition such sales or transfers. Nevertheless, the Exchange believes that the Exchange Review Council is the logical and appropriate body for reviewing such determinations given its other responsibilities. The Exchange also proposes to replace the review procedures set forth in Chapter 17 of the Existing Rules with processes that are substantially the same as those set forth in BX Rules 1015 and 1016. To accomplish the foregoing, the Exchange proposes to eliminate Supplementary Material .01 and insert its substance into the body of Rule 307 as paragraphs (c) and (d). Proposed Rule 307(d) states that the Exchange Review Council will have jurisdiction to review Membership Department decisions to deny the sale and transfer of market maker rights. Proposed Rule 307(d)(1) states that anyone [sic] is an owner or an approved applicant that is a party to an executed transfer agreement that is denied approval may file a written request for review by the Exchange Review Council within 25 days after service of the Exchange's decision. The request must state specifically why the applicant believes that the Membership Department's decision is inconsistent with the permissible bases for denial set forth in Rule 307(c), or otherwise should be set aside and state whether a hearing is requested.[125] The request will be heard by a Subcommittee composed of two or more persons who are either current or past members of the Council or former Directors of the Exchange.[126] If a hearing is requested or directed, the hearing must be held within 45 days after the request for review is filed with the Exchange or service of the notice directing a hearing by the Subcommittee.[127] Applicants and the Membership Department may be represented by counsel at the hearing and formal rules of evidence will not apply during the hearing.[128] The Subcommittee must present a recommended decision in writing to the Exchange Review Council within 60 days after the date of the hearing, and not later than seven days before the meeting of the Exchange Review Council at which the proceeding shall be considered.[129] The Exchange Review Council must issue a proposed written decision that affirms, modifies, or reverses the Membership Department's decision, or remands the proceedings with instructions and provide it to the Exchange Board.[130] If the Exchange Board does not call the decision for review, it shall become final. If the Exchange Review Council does not serve its final written decision within the time period prescribed by Rule 307(d)(9)(C), then the applicant may file a written request with the Exchange Board for the Board to direct the Exchange Review Council to issue its decision immediately or show good cause why it needs additional time to issue its decision.[131] Proposed Rule 307(d)(10), which mirrors BX Rule 1016, grants the Exchange Board discretion, at the request of a Director, to review decisions of the Exchange Review Council.

Existing Rule 310 requires a Member to notify the Exchange upon its adoption of a plan of liquidation or dissolution. The Existing Rule also provides that upon receipt of such notice, the Member's trading privileges may be suspended in accordance with Chapter 15 of the Existing Rules. The Exchange proposes to replace this reference to Chapter 15 with a reference to BX Rule 9558. Again, no analogue to this proposal exists in the BX rules insofar as those rules do not expressly address suspensions for such reasons or reviews of suspension determinations. Nevertheless, the Exchange believes that the process set forth in BX Rule 9558 is most appropriate for reviewing suspension determinations in these circumstances given that they already apply in circumstances where a Member is experiencing extreme financial or operating difficulty such that the Exchange determines that the Member cannot safely continue to do business on the Exchange.

The Supplementary Material to Existing Rule 313 concerns the Exchange's authority to waive the applicable qualification examination requirements and accept other standards as evidence of an applicant's qualifications for registration. The Exchange is amending this Rule to specify that such requests are handled pursuant to the BX Rule 9600 Series process. The BX Rule 9600 Series concerns the procedures for requesting exemptions, and the appeal of adverse decisions regarding an exemptive request. The Exchange notes that the proposed revisions will render the text of the Supplementary Material to Existing Rule 313 consistent with BX Rule 1070(d).

Existing Rule 410 provides for the summary suspension of a Member that fails to perform on its contracts or is insolvent or is in such financial or operational condition or is otherwise conducting business in such a manner that it cannot be permitted to continue in business without compromising the safety of customers, creditors, or the Exchange. The Existing Rule provides for such suspensions to be administered in accordance with Chapter 15 of the Rules. The Exchange proposes to replace this reference to Chapter 15 with a reference to BX Rule 9558, which provides procedures for summary proceedings for actions authorized by Section 6(d)(3) under [sic] the Act.

Existing Rule 413(b)(1) states that decisions denying market makers exemptions from standard position

[125] *See* proposed Rule 307(d)(1).

[126] *See* proposed Rule 307(d)(3).

[127] *See* proposed Rule 307(d)(5)(A).

[128] *See* proposed Rule 307(d)(5)(B) & (C).

[129] *See* proposed Rule 307(d)(8).

[130] *See* proposed Rule 307(d)(9).

[131] *See* proposed Rule 307(d)(9)(D).

limits in options trading on the Exchange are not subject to appeal under Chapter 17 of the Existing Rules. The Exchange proposes to remove this reference to Chapter 17 as the Exchange proposes to delete it.

Existing Rule 720 concerns obvious and catastrophic errors. Existing Rule 720(k) currently references the OEP as the body responsible for reviewing determinations made by Options Exchange Officials pursuant to the Rule and it sets forth procedures to govern OEP review proceedings. In light of the fact that the OEP's responsibilities will be incorporated into those of the Exchange Review Council,[132] the amendments to the Rule remove references to the OEP and replaces [sic] them with references to a panel of the Exchange Review Council. The amended Rule also includes language grafted from the BX Rules prescribing the composition of panels convened for purposes of these reviews.[133]

Existing Rule 720A also provides for reviews by a ''Review Panel'' of decisions nullifying or adjusting transactions arising out of system disruptions or malfunctions. The Exchange proposes to eliminate the Review Panel in the Exchange's Rules and transfer its responsibility to a panel of the Exchange Review Council. The new Rule also includes language grafted from the BX Rules prescribing the composition of Exchange Review Council panels convened for purposes of these reviews.[134]

Existing Rule 804 permits a Primary Market Maker to apply to the Exchange to withdraw temporarily from its Primary Market Maker status in an options class. The Existing Rule does not presently authorize reviews of Exchange determinations to deny requests for temporary withdrawals or to impose conditions on the reentry of quotations. However, BX Rule 4619(f) does provide for such reviews. To provide consistency, the Exchange proposes to amend Existing Rule 804(f) to state that the Exchange Review Council will have authority conduct such reviews.

Existing Rule 1000 provides for the treatment of the options contracts of suspended Members. In discussing the nature of suspensions to which the Existing Rule applies, it references Chapter 15 several times. The Exchange proposes replacing this reference with a reference to the Chapter 90, which comprises the BX Rules that govern suspensions in lieu of Chapter 15.

Existing Rule 1406 states that no Member or Associated Person may refuse to appear or testify before another exchange or SRO in connection with a regulatory investigation, examination or disciplinary proceeding or refuse to furnish documentary materials or other information or otherwise impede or delay such investigation, examination or disciplinary proceeding if the Exchange requests such information or testimony in connection with an inquiry resulting from an agreement entered into by the Exchange. Existing Rule 1406(d) states that when Members and Associated Persons respond to such requests for appearance, testimony, documents, or information, they shall have the same rights and procedural protections as they would if they were responding to requests from the Exchange pursuant to Existing Rule 1601(b). The Exchange proposes to replace the reference to Existing Rule 1601(b), which is being deleted, with a reference to BX Rule 8210. BX Rule 8210(a) authorizes the Regulation Department, including FINRA staff, to require a Member or Associated Persons to provide information and testimony and to permit inspection and copying of their [sic] books, records, and accounts as to any matters involved in an investigation, complaint, examination, or proceeding. BX Rule 8210(b) provides that the Regulation Department and FINRA may exercise the aforementioned authority with respect to investigations, complaints, examinations, or proceedings conducted by other SROs. Lastly, BX Rule 8210(c) states that no Member or Associated Person may fail to provide information or testimony or to submit to inspection and copying of books, records, or accounts.

Existing Rule 1800 states that any Member or Associated Person that fails to honor an arbitration award shall be subject to disciplinary proceedings in accordance with Chapter 16. The Exchange proposes to replace this reference to Chapter 16 with a reference to BX Rule 9554, which is the BX Rule that governs such sanctions.

Proposed Introductory Paragraphs to Chapters 80 and 90

The Exchange proposes to include introductory paragraphs to both Chapters 80 and 90 which state that they incorporate by reference the BX Rule 8000 and 9000 Series, respectively, and that such BX Rules shall be applicable to Exchange Members, Associated Persons, and other persons subject to the Exchange's jurisdiction.

These proposed introductory paragraphs also list instances in which cross references in the BX Rule 8000 and 9000 Series to other BX rules should be read to refer instead to the Exchange Rules, and references to defined BX terms shall be read to refer to the Exchange-related meanings of those terms. For example, references in both the BX Rule 8000 and 9000 Series to the following defined terms shall be read to refer to the Exchange-specific meanings of those terms: ''Exchange'' or ''Nasdaq BX'' shall be read to refer to the Exchange; ''Rule'' or ''BX Rule'' shall be read to refer to the Exchange Rules; ''Board'' or ''Exchange Board'' shall be read to refer to the Exchange Board of Directors; ''Member'' shall be read to refer to an Exchange Member; ''Associated Person'' shall be read to refer to an Exchange Associated Person; ''BX Regulatory Department'' or ''Regulation Department'' shall be read to refer to the Exchange's Regulatory Department; ''BX Regulation'' shall be read to refer to Exchange Regulation; ''Chief Regulatory Officer'' shall be read to refer to the Chief Regulatory Officer of the Exchange; and ''Equity Rule'' shall be read to refer to an Exchange Rule.

Additionally, the proposed introduction to Chapter 80 states that cross references in the BX Rule 8000 Series to the term ''Rule 0120'' shall be read to refer to Exchange Rule 100 and cross references in the BX Rule 8000 Series to ''Rule 1015'' shall be read to refer to Exchange Rule 302. Similarly, the proposed introduction to Chapter 90 states that cross-references in the BX Rule 9000 Series to the following terms shall be read to refer to the following Exchange Rules: ''Rule 0120'' shall be read to refer to Exchange Rule 100; ''Rule 1013'' shall be read to refer to Exchange Rules 305 and 306; ''Rule 1070'' shall be read to refer to the Supplementary Material to Exchange Rule 313; ''Rule 1160'' shall be read to refer to Exchange Rule 305(b); ''Equity Rule 2110'' shall be read to refer to Exchange Rule 400; ''Equity Rule 2120'' shall be read to refer to Exchange Rule 405; ''Rule 2140'' shall be read to refer to Exchange Rule 312; ''Equity Rule 2150'' shall be read to refer to Exchange Rules Chapter 6; ''Rule 2170'' shall be read to refer to Exchange Rule 403; ''Rule 4110A'' shall be read to refer to Exchange Rules Chapter 13; ''Rule 4120A'' shall be read to refer to Exchange Rules Chapter 13; ''Rule 10000 Series'' shall be read to refer to Exchange Rules Chapter 18; and ''Chapter III, Section 16'' shall be read to refer to Exchange Rule 403.

Finally, as noted above, the introduction to Chapter 90 states that BX IM–9216 in the BX Rules shall not apply to the Exchange, its Members,

[132] *See* proposed Rule 100(a)(20A).

[133] *See* BX Options Rules Ch. V, Sec. 6(l).

[134] *See id.*

Associated Persons, or other persons subject to the jurisdiction of the Exchange and that instead, references to BX IM–9216 shall be read to refer to Exchange Rule 1614(b). Similarly, the introduction states that the Exchange's procedures set forth in BX Rule 9216(b) and 9143(e)(3), which govern its handling of MRVP violations and the issuance of MRVP violation letters, shall also apply to the Exchange's handling of minor rule violations and the issuance of minor rule violation letters, except that the Exchange shall promptly report any final disciplinary action to the Commission, in accordance with SEC Rule 19d–1(c)(1).

Conclusion

The changes proposed herein will allow the Exchange to harmonize its investigatory and disciplinary processes with the processes of BX, thus providing a uniform process for the investigation and discipline of Members and Associated Persons across all of the Nasdaq, Inc. SROs, as administered by FINRA pursuant to RSAs. Harmonizing the investigatory and disciplinary processes of all of the Nasdaq, Inc. SROs will bring efficiency to FINRA's administration of its responsibilities under the RSAs because the process [sic] it must follow are nearly identical, and are all based on the process that FINRA follows. Harmonized processes will bring consistency to investigations and adjudication of rule violations, and will reduce the number of disciplinary processes and requirements with which Members and Associated Persons, as well as their counsel, must be familiar.

The Exchange believes that the new investigatory and disciplinary processes are substantially similar to the existing process, and where there are differences between the new and old processes, the Exchange believes that the new process does not disadvantage its Members or Associated Persons. To the contrary, the Exchange believes that the new process will benefit all parties as it provides greater detail and specificity than the retired Rules, and that it is consequently more transparent.

The Exchange intends to announce the operative date of the new Rules at least 30 days in advance via a regulatory alert.[135] To facilitate an orderly transition from the Existing Rules to the new Rules, the Exchange is proposing to apply the Existing Rules to all Letters of Consent that the CRO has approved and which are pending approval of the BCC prior to the operative date. The Exchange also will apply the Existing Rules to any matter for which, prior to the operative date, the Exchange has provided notice to a Subject of its determination to impose an MRVP fine or a minor rule violation fine whereby the Subject may yet or has contested the determination pursuant to Existing Rule 1614(a). In terms of formal disciplinary matters, any matter that has been approved for the issuance of a statement of charges by the CRO will continue under the Existing Rules. Moreover, any appeal of a matter that is pending before an OEP pursuant to Existing Rule 720, a Review Panel pursuant to Existing Rule 720A, or the BCC pursuant to Existing Rule 302 or Supplementary Material .01 to Existing Rule 307, will continue under the Existing Rules. As a consequence of this transition process, the Exchange will retain the BCC, the OEP, the Review Panel, and the existing processes during the transition period until such time that there are no longer any matters proceeding under the Existing Rules. To facilitate this transition process, the Exchange will retain a transitional Rulebook that will contain the Exchange's Rules as they are at the time of that this proposal is filed with the Commission. This transitional Rulebook will apply only to matters initiated prior to the operational date of the changes proposed herein and it will be posted to the Exchange's public rules website. When the transition is complete and there are no longer any Members, Associated Persons or other persons subject to the existing disciplinary processes, the Exchange will remove the transitional Rulebook from its public rules website.

The Exchange furthermore notes that it expects the transition from the BCC to the Exchange Review Council to be smooth given that it expects to nominate the existing (and common) members of the BX, Nasdaq, and Phlx exchange review councils to also become members of the Exchange Review Council.[136] The Exchange does not expect that any existing members of the BCC will be nominated to become members of the Exchange Review Council; however, the Exchange will ensure that, in advance of the operative day, the members of the Exchange Review Council will familiarize themselves with the Rules and procedures of the Exchange so that they will be prepared to fulfill their responsibilities.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[137] in general, and furthers the objectives of Section 6(b)(5) of the Act,[138] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest, and are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange also believes that the proposal is consistent with Section 6(b)(6) of the Act,[139] which requires that the rules of an exchange provide that its members be appropriately disciplined for violations of the Act as well as the rules and regulations thereunder, or the rules of the Exchange, by expulsion, suspension, limitation of activities, functions, and operations, fine, censure, being suspended or barred from being associated with a member, or any other fitting sanction.

The Exchange believes that the proposed changes are consistent with these requirements because the changes harmonize the Exchange's investigative, disciplinary, and adjudicatory processes with the similar processes used by BX. The new processes are well-established as fair and designed to protect investors and the public interest, providing greater detail and transparency in the processes than is currently provided under the Existing Rules. Because the Exchange is adopting these Rules materially unchanged from the related BX Rules, with minor differences to account for the Exchange's unique MRVP and minor rule violation schedule of fines, the Exchange believes that the proposed changes should facilitate prompt, appropriate, and effective discipline of Members and Associated Persons consistent with the Act.

The proposed Rule change also makes miscellaneous changes to the Existing Rules to account for the adoption of the BX Rule 8000 and 9000 Series and the

[135] The Exchange notes that the proposed changes will not become operative unless and until the Commission approves the Exchange's request, which it has filed pursuant to Section 36 of the Exchange Act and SEC Rule 0–12 thereunder, for an exemption from the rule filing requirements of Section 19(b) of the Exchange Act as to changes to Chapters 80 and 90 that are effected solely by virtue of a change to the BX Rule 8000 or 9000 Series.

[136] The Exchange anticipates that the members of the Exchange Review Council will serve in a manner that is consistent with their tenures on the Nasdaq, BX, and Phlx review councils. That is, to the extent that the tenure of a member of these other review councils is due to expire on a particular date, then the same expiration date will apply to that member's tenure on the Exchange Review Council. All terms for members on the Exchange Review Council will comply with Article VI, Section 4 of the proposed By-Laws.

[137] 15 U.S.C. 78f(b).

[138] 15 U.S.C. 78f(b)(5).

[139] 15 U.S.C. 78f(b)(6).

replacement of the BCC with the Exchange Review Council. For example, subject to Chapter 90, proposed changes to Rule 302 re-assign responsibility to the Exchange Review Council to review decisions of the Exchange's Membership Department to deny or condition applications for membership and association with Exchange Members and to deny or condition continuing membership or association. The proposal also establishes a new process by which the Exchange Review Council will adjudicate such reviews. Likewise, the Exchange proposes to amend Rule 307 to re-assign responsibility to the Exchange Review Council to review decisions of the Exchange to deny sales or transfers of market maker rights. It also proposes to establish a new process by which the Exchange Review Council will adjudicate such reviews. The Exchange believes that these proposed changes to the Existing Rules are consistent with the Act because the new adjudicatory processes that the Exchange proposes to adopt in place of its existing processes are substantially similar to those that BX already utilizes. Moreover, the Exchange believes that the proposed processes will facilitate prompt, appropriate, and fair adjudications, consistent with the Act.

Additionally, the Exchange proposes to make minor updates, corrections, and conforming amendments to the Exchange's Rules, which are consistent with the Act because they are necessary to ensure that the Exchange's cross-references and terminology remain current and accurate.

The Exchange believes that harmonizing its investigative, disciplinary, and adjudicatory processes with those of BX will reduce the burden on Members and Associated Persons that are also members of BX, Nasdaq, Phlx, and/or FINRA. The Exchange notes that all but one of its Members are also members of BX, Nasdaq, Phlx, and/or FINRA. BX, Nasdaq, Phlx, and FINRA already have in place investigative, disciplinary, and adjudicatory processes that are the same or similar to those that the Exchange proposes to incorporate by reference.

As discussed above, the Exchange believes that the proposed Rules will benefit all parties involved in the Exchange's disciplinary and adjudicatory processes as they will include greater detail and specificity than do the Existing Rules. The proposal will render the Exchange's investigatory, disciplinary, and adjudicatory processes more transparent than the Existing Rules.

The Exchange also believes that adopting an Exchange Review Council is consistent with the Act because the Council's mandate is to, among other things, ensure consistent and fair application of the Exchange rules pertaining to discipline of Members and Associated Persons. The Exchange Review Council will be a body appointed by the Exchange Board of Directors and composed of representatives of the securities industry as well as persons from outside the securities industry. The broad membership of the new Exchange Review Council will ensure that the decisions and guidance it provides will be fair and balanced. The Exchange Review Council will be similar in structure and function to the BX exchange review council. In addition to reviewing appeals of disciplinary actions, the Exchange Review Council will also have jurisdiction to review membership decisions (proposed Rule 302) and appeals regarding limitations placed on Members or their employees that are subject to a statutory disqualification (BX Rule 9524). Additionally, the Exchange Review Council may consider and make recommendations to the Board on policy and rule changes relating to business and sales practices of Exchange Members and Associated Persons, and enforcement policies, including policies with respect to fines and other sanctions. Thus, the Exchange Review Council will provide the Exchange and market participants with a fair and impartial body overseeing disciplinary matters, as well as the rules and policies concerning the disciplinary process. For these reasons, the Exchange believes that adoption of the Exchange Review Council is consistent with the Act.

The Exchange believes that eliminating the BCC, the OEP (as provided for under Existing Rule 720), and the Review Panel (as provided for under Existing Rule 720A) is consistent with Sections 6(b)(5) and 6(b)(6) of the Act,[140] because the Exchange Review Council and the New Hearing Panels will assume the responsibilities of the BCC and the Panels. In particular, the functions of the Current Hearing Panels of the BCC will be handled by the New Hearing Panels, which the OHO shall convene. Going forward, the BCC's (and the CRO's) responsibility for approving settlements will be assumed by the Exchange Review Council and, in certain instances, the ODA. The BCC's responsibilities for hearing appeals of Exchange decisions on membership or association with a Member will be assumed by the Exchange Review Council. The responsibilities of the OEP and the Review Panel to hear appeals of Exchange determinations to nullify or adjust transactions that involve obvious errors or that result from system disruptions and malfunctions also will be assumed by the Exchange Review Council. The Exchange believes that the proposal will provide for the Exchange Review Council, the New Hearing Panels, and the ODA to execute the responsibilities of the BCC and the Panels in a manner that the Commission, within the context of the BX Rules, has already deemed to be consistent with the Act.[141] For example, the Exchange proposes to replace its existing process for handling appeals of membership decisions, as set forth in Existing Rule 302 and Chapter 17, with a process that BX already employs in BX Rules 1015 and 1016. Moreover, most Exchange Members and Associated Persons will already be familiar with the proposed responsibilities and procedures of the Exchange Review Council, the New Hearing Panels, and the ODA from their experiences as members of BX and other self-regulatory organizations whose rules provide for similar assignments of responsibilities and processes.

The Exchange believes that its proposal furthers the objectives of Section 6(b)(7) of the Act[142] in that it is designed to provide a fair procedure for the disciplining of members and Associated Persons, the denial of membership to any person seeking membership therein, the barring of any person from becoming associated with a Member thereof, and the prohibition or limitation by the Exchange of any person with respect to access to services offered by the Exchange or a Member thereof. Specifically, the Exchange believes that the proposed investigatory, disciplinary, and adjudicatory processes are consistent with Section 6(b)(7) of the Act[143] because they are based on the existing processes used by BX. The BX processes are well-established as consistent with the Act.[144]

Last, the Exchange believes that its proposal to phase-in the implementation of the new investigatory, disciplinary, and adjudicatory processes is consistent with Section 6(b)(7)[145] of the Act because both the current and proposed processes are consistent with the Act, providing fair procedures for investigating, disciplining, and

[140] 15 U.S.C. 78f(b)(5)–(6).

[141] *See* Securities Exchange Act Release No. 34–59154 (Dec. 23, 2008), 73 FR 80468 (Dec. 31, 2008) (SR–BSE–2008–048).

[142] 15 U.S.C. 78f(b)(7).

[143] *Id.*

[144] *See* n.141, *supra.*

[145] 15 U.S.C. 78f(b)(7).

adjudicating the rights of Members and Associated Persons. The Exchange is proposing to provide advanced notice of the implementation date of the new processes, and will apply the new processes to new matters that are initiated on or after that implementation date. Any matters initiated prior to the implementation date will be completed using the current processes. As a consequence, the Exchange will delete the applicable portions of Chapters 15–17 from the Exchange's Rulebook, but it will maintain a transitional Rulebook on the Exchange's public rules website (*http://nasdaqISE.cchwallstreet.com/*), which will contain the Exchange Rules as they are at the time of filing this rule change.[146] These transitional Rules will apply exclusively to the matters initiated prior to the implementation date. Upon conclusion of the last matter to which the transitional rules apply, the Exchange will remove the defunct transitional rules from its public rules website. Thus, the transition will be conducted in a fair, orderly, and transparent manner.

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, as amended [sic]. The proposed rule change is not intended to address competitive issues, but it should reduce burdens on Members, [sic] and Associated Persons. Specifically and as described in detail above, the Exchange believes that this change will bring efficiency and consistency in application of the investigative, disciplinary, and adjudicatory processes, thereby reducing the burden on Members and Associated Persons who are also members of BX.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[147] and subparagraph (f)(6) of Rule 19b–4 thereunder.[148]

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: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–ISE–2018–59 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–ISE–2018–59. 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–ISE–2018–59 and should be submitted on or before August 21, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[149]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–16271 Filed 7–30–18; 8:45 am]

BILLING CODE 8011–01–P

[146] The posting of the transitional rules on the public rules website will make it clear what disciplinary proceedings are governed by the transitional rules (*i.e.,* matters initiated prior to the implementation date).

[147] 15 U.S.C. 78s(b)(3)(A)(iii).

[148] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[149] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–83704; File No. SR–GEMX–2018–24]

Self-Regulatory Organizations; Nasdaq GEMX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Align Existing Investigatory and Disciplinary Processes and Related Rules With the Investigatory and Disciplinary Processes and Associated Rules of Nasdaq BX, Inc.

July 25, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 12, 2018, Nasdaq GEMX, LLC (''GEMX'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to align its existing investigatory and disciplinary processes and related rules with the investigatory and disciplinary processes and associated rules of Nasdaq BX, Inc. (''BX'').

The text of the proposed rule change is available on the Exchange's website at *http://nasdaqgemx.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.

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 new investigatory, disciplinary, and adjudicatory processes that are substantially the same as those of its sister exchange, BX. Specifically, the Exchange proposes to establish new Chapters 80 and 90 of its Rules [3] and then incorporate by reference into those Chapters the BX Rule 8000 and 9000 Series,[4] which set forth and govern the BX investigatory, disciplinary, and adjudicative processes.[5] The Exchange also proposes to amend its By-Laws to establish a new body to review disciplinary and certain other matters (the ''Exchange Review Council'') that is similar to the exchange review council that BX utilizes for such purposes.[6] These proposals, when coupled with certain changes to the Exchange's other Rules, including Rules that govern appeals of the Exchange's membership and other decisions, will render the Exchange's investigative, disciplinary, and adjudicatory processes substantially the same as those, not only of BX, but also of other Nasdaq, Inc. exchanges.[7] The proposal [sic] change will also further harmonize the work that the Financial Industry Regulatory Authority (''FINRA'') conducts for all these exchanges.

The Exchange's current investigatory, disciplinary, and adjudicatory processes are set forth in Chapters 15–17 of its Rules. Chapters 15–17 of the Exchange's Rules, in turn, incorporate by reference the investigatory, disciplinary, and adjudicatory processes of Nasdaq ISE, LLC (''Nasdaq ISE'') that are set forth in the corresponding chapters of the Nasdaq ISE rulebook. As part of a parallel Nasdaq ISE filing that also proposes to adopt the investigatory, disciplinary, and adjudicatory processes and rules of BX (and incorporate them by reference into new chapters 80 and 90 of the Nasdaq ISE rules), Nasdaq ISE proposes to eliminate chapters 15 and 17 of its rules, and to largely eliminate chapter 16.[8] These proposed changes to ISE chapters 15–17 will apply automatically to Chapters 15–17 of the Exchange's Rules. Accordingly, reference should be made to SR–ISE–2018–59 for a detailed explanation of the proposed changes to Chapters 15–17 and the purposes of those changes. Likewise, reference should be made to SR–ISE–2018–59 for a detailed discussion of the BX Rule 8000 and 9000 Series, which will largely replace Chapters 15–17 for both Nasdaq ISE and the Exchange. Lastly, reference should be made to SR–ISE–2018–59 for a discussion of proposed changes to certain other ISE rules that the Exchange also incorporates by reference and that are relevant to the Exchange's adoption of its new investigatory, disciplinary, and adjudicatory processes.[9]

The following is a discussion of proposed changes that are specific to the Rules of the Exchange and that are not otherwise addressed in or accomplished by the corresponding Nasdaq ISE filing. These changes include: (1) The elimination of the Exchange's BCC and its replacement with the Exchange Review Council; and (2) changes to Exchange Rules that are necessary to accommodate the new investigatory, disciplinary, and adjudicatory processes and rules and to harmonize those processes and rules with those of BX.

Elimination of the Business Conduct Committee and Establishment of the Exchange Review Council

The Exchange presently utilizes the BCC to help it enforce its Rules with respect to its members (''Members'') and persons associated with its members (''Associated Persons''). The BCC is a committee, established by the Board of Directors,[10] whose enforcement jurisdiction includes the following: (1) Ordering investigations of possible Rule violations; (2) considering letters of consent in expedited disciplinary actions; (3) making its members available to serve on Hearing Panels that adjudicate formal disciplinary proceedings; (4) imposing sanctions on Members or Associated Persons in disciplinary proceedings; (5) reviewing Exchange actions involving minor rule violations; (6) appointing panels to conduct hearings and reviews of Exchange actions that deny membership or Member association privileges; and (7) generally overseeing all matters relating to the conduct of disciplinary hearings and hearings for review of Exchange decisions, and providing the Exchange with advice for improving disciplinary procedures.[11]

The Exchange proposes to retire the BCC [12] and to amend its By-Laws to

[3] The Exchange proposes to add Chapters 23–79 and Chapters 81–89 to its Rules, but reserve such Chapters for future use.

[4] Citation herein to rules of the proposed Chapters 80 and 90 will be preceded by the term ''BX Rule'' to reflect incorporation of the BX Rule 8000 and 9000 Series. References to current rules will be preceded by the term ''Existing Rule.''

[5] The Exchange proposes to separately request an exemption from the rule filing requirements of Section 19(b) of the Act for changes to Chapters 80 and 90 to the extent such rules are effected solely by virtue of a change to the BX Rule 8000 and 9000 Series.

[6] As discussed below, the Exchange Review Council will assume responsibilities that presently reside with the Business Conduct Committee (the ''BCC''). The Exchange also proposes to eliminate the BCC.

[7] The Exchange notes that the BX Rule 8000 and 9000 Series are substantially similar to corresponding rules of The Nasdaq Stock Market, LLC (''Nasdaq'') and Nasdaq PHLX, LLC (''Phlx''). Moreover, the Exchange notes that Nasdaq ISE, LLC and Nasdaq MRX, LLC will propose similar changes to their respective investigatory, disciplinary, and adjudicatory processes and associated rules that will render them substantially similar to those of BX.

[8] *See* SR–ISE–2018–59. Nasdaq ISE proposes to retain Rule 1600, which sets forth the general jurisdiction of the Exchange with respect to disciplinary matters. It also proposes to retain Existing Rule 1614(a), which sets forth its authority to impose fines of up to $2,500 for violations of the Exchange's Minor Rule Violation Plan (''MRVP'') and up to $5,000 for minor rule violations (other than those subject to an MRVP). Nasdaq ISE also proposes to retain Existing Rule 1614(d) (to be renumbered as Rule 1614(b)), which sets forth the Exchange's schedule of MRVP violations and minor rule violations and their associated fines.

[9] The proposed changes involve Nasdaq ISE Rules 410, 413(b)(1), 1000, 1406, and 1800.

[10] *See* Resolution of the Board of Directors of the ISE Gemini Delegating Authority, dated July 30, 2013.

[11] *See* GEMX Business Conduct Committee Charter, as amended, May 1, 2003.

[12] In a February 4, 2016 resolution, the Exchange Board delegated its authority to the President of the Exchange to establish a BCC to, among other things, conduct disciplinary hearings under Chapter 16 of the Existing Rules and conduct other hearings and

Continued

establish in its place the Exchange Review Council. The amended By-Laws that the Exchange proposes to adopt in this regard are substantially the same as those that BX adopted to establish the BX Exchange Review Council.[13] Thus, the By-Laws provide for the Exchange Review Council to have the same general structure and powers as does the BX Exchange Review Council.[14] The proposed By-Laws will authorize the Exchange Review Council to adjudicate disciplinary actions and approve settlements thereof as well as make recommendations to the Board on certain policy matters and rule changes. Such policy functions of the Exchange Review Council render its jurisdiction broader than that of the BCC.

Specifically, proposed Article VI, Section 1 of the proposed By-Laws provides that the Exchange Review Council may be authorized to act for the Board with respect to: An appeal or review of a disciplinary proceeding, a statutory disqualification proceeding, or a membership proceeding; a review of an offer of settlement, a letter of acceptance, waiver, and consent, and a minor rule violation plan letter; the exercise of exemptive authority; and such other proceedings or actions as may be authorized by the Exchange rules. The Exchange Review Council also may consider and make recommendations to the Board on policy and rule changes relating to business and sales practices of Exchange Members and Associated Persons and enforcement policies, including policies with respect to fines and other sanctions. It may advise the Board on regulatory proposals and industry initiatives relating to quotations, execution, trade reporting, and trading practices and it may advise the Board in its administration of programs and systems for the surveillance and enforcement of rules governing Exchange Members' conduct and trading activities in the Exchange.

Proposed Article VI, Section 2 states that the Exchange Review Council would consist of no fewer than eight and no more than 12 members. The Exchange Review Council must include a number of Member Representative members [15] that is equal to at least 20% of the total number of members of the Exchange Review Council. The number of Non-Industry members,[16] including at least three Public members,[17] shall equal or exceed the sum of the number of Industry members [18] and Member Representative members. As soon as practicable, following the appointment of members, the Exchange Review Council shall elect a Chair from among its members. The Chair shall have such powers and duties as may be determined from time to time by the Exchange Review Council. The Board, by resolution adopted by a majority of Directors then in office, may remove the Chair from such position at any time for refusal, failure, neglect, or inability to discharge the duties of Chair. No more than 50% of the members of the Exchange Review Council shall be engaged in market making activity or employed by an Exchange Member firm whose revenues from market making activity exceed 10 percent of its total revenues.

Proposed Article VI, Section 3 requires the Exchange's Secretary to collect from each nominee for the office of member of the Exchange Review Council such information as is reasonably necessary to serve as the basis for a determination of the nominee's qualifications and classification as an Industry, Member Representative, Non-Industry, or Public member. The Secretary must also certify to the Nominating Committee or the Member Nominating Committee [19] (as applicable) each nominee's qualifications and classification. After appointment to the Exchange Review Council, each member must update such information at least annually and upon request of the Exchange's Secretary, and must report immediately to the Secretary any change in such information.

Proposed Article VI, Section 4 provides that Exchange Review Council members shall serve three-year terms, or until a successor is duly appointed and qualified, except in the event of earlier termination from office by reason by death, resignation, removal, disqualification, or other reason. Members are term limited out after two consecutive terms. Proposed Article VI, Section 5 sets forth the procedures for resigning as a member of the Exchange Review Council and provides that an Exchange Review Council member may resign at any time upon written notice to the Board. Under proposed Article VI, Section 6, any member of the Exchange Review Council may be removed from office at any time for refusal, failure, neglect, or inability to discharge the duties of such office by majority vote of the Board.

Under proposed Article VI, Section 7, an Exchange Review Council member would be disqualified and removed immediately upon a determination by the Board, by a majority vote, (a) that the member no longer satisfies the classification (Industry, Member Representative, Non-Industry, or Public) for which the member was elected; and (b) that the member's continued service as such would violate the compositional requirements of the Exchange Review Council set forth in Article VI, Section 2. If the term of office of an Exchange Review Council member terminates under this Section, and the remaining term of office of such member at the time of termination is not more than six months, during the period of vacancy the Exchange Review Council shall not be deemed to be in violation of Article VI, Section 2 by virtue of such vacancy. Proposed Article VI, Section 8 contains provisions for the filling of vacancies on the Exchange Review Council and states that if a position on the Exchange Review Council becomes vacant, the Nominating Committee or the Member Nominating Committee (as applicable) shall nominate, and the Board shall appoint a person satisfying the qualifications for the position as provided in Article VI, Section 2 to fill

reviews as set forth in Chapter 17 of the Existing Rules. On February 1, 2017, the Board passed a resolution that both revoked the President's authority to establish a BCC and authorized the establishment of an Exchange Review Council, effective upon the date when this rule filing becomes operative.

[13] The BX by-laws differ from the proposed Exchange By-Laws because the BX by-laws have a different numbering convention from the Exchange's By-Laws and, in various places, the BX by-laws refer to a Listing and Hearing Review Council, which has no analogue with respect to the Exchange.

[14] The BX by-laws do not describe in detail the process of the proceedings over which the BX Exchange Review Council presides. However, Section 7.9 of the BX by-laws state [sic] that a quorum of three BX Exchange Review Council members is necessary to adjudicate appeals of determinations made under BX Rules 4612 (appeal of denial of registration as an Equities Market Maker), 4619 (review of denial of an excused withdrawal of Equities Market Maker quotation), 4620 (appeal of denial of reinstatement of Equities Market Maker that accidentally withdraws), 11890 (appeal of clearly erroneous transaction determination), and BX Options Chapter V, Section 6 (appeal of obvious error determination). *See* BX by-laws, Article VII, Section 9. The Exchange's Rules do not have analogues to BX Rules 4612, 4620, and 11890 and, as such, the corresponding provision of the Exchange's proposed By-Laws (Article VII, Section 9) provides only that a quorum of three Exchange Review Council members is necessary for it to adjudicate appeals involving determinations made under Rules 720 (appeal of obvious error determination), 720A (appeal of determinations of erroneous trades due to system malfunctions and disruptions), and 804 (review of denial of an excused withdrawal of market maker quotation).

[15] *See* n.20, *infra.*

[16] *See id.*

[17] *See id.*

[18] *See id.*

[19] The terms ''Nominating Committee'' and ''Member Nominating Committee'' are defined in Exchange By-Laws, Article I.

such vacancy, except that if the remaining term of office for the vacant position is not more than six months, no replacement shall be required.

Proposed Article VI, Section 9 provides that a quorum of the Exchange Review Council will consist of a majority of its members, including not less than 50% of its Non-Industry members and one Member Representative member. Proposed Article VI, Section 10 contains provisions related to the meetings of the Exchange Review Council.

Under proposed Article VI, Section 11, the Exchange Review Council is required to establish a Review Subcommittee to determine whether disciplinary and membership proceedings decisions should be called for review by the Exchange Review Council under the disciplinary and membership rules to be proposed for the Exchange. The Review Subcommittee shall be composed of no fewer than two and no more than four members of the Exchange Review Council. The number of Non-Industry members of the Review Subcommittee shall equal or exceed the sum of the number of Industry members and Member Representative members of the Review Subcommittee, and the subcommittee must include at least one Member Representative member. At all meetings of the Review Subcommittee, a quorum for the transaction of business shall consist of not less than 50 percent of the members of the Review Subcommittee, including not less than 50 percent of the Non-Industry members of the Review Subcommittee and one Member Representative member of the Review Subcommittee.[20]

The BX Rules implement the foregoing responsibilities of the Exchange Review Council by establishing various procedures to govern its reviews. As the Exchange describes in further detail below, the Exchange proposes to transfer to the Exchange Review Council (or panels thereof) certain responsibilities currently vested in other Exchange committees or the Board. For example, pursuant to Existing Rule 720, an Obvious Error Panel (''OEP'') is presently responsible for reviewing determinations regarding obvious and catastrophic errors. Pursuant to Existing Rule 720A, a ''Review Panel'' is responsible for reviewing determinations to nullify or adjust transactions that arise from system disruptions and malfunctions. The Exchange is proposing to eliminate the OEP and the Review Panel and to transfer their responsibilities to a panel of the new Exchange Review Council, which corresponds to the practice of BX. Subject to Chapter 90, the Exchange also proposes to transfer responsibility to the Exchange Review Council to review denials or conditions imposed upon those that seek to become or remain a Member of the Exchange or become or remain associated with a Member of the Exchange, as set forth in Existing Rule 303.[21] In addition, the Exchange proposes to amend Existing Rule 804 to provide for the Exchange Review Council to review determinations regarding temporary withdrawals of quotations, which are not reviewable under the Existing Rules. The Exchange notes that BX vests in its Exchange Review Council responsibility for reviewing similar types of matters.[22]

Other Conforming Rule Changes

The Exchange proposes to amend or delete certain other Existing Rules, which are either not needed, duplicated elsewhere, or reference the deleted Existing Rules. Below is a description of the specific changes the Exchange proposes to make to its Existing Rules.

Existing Rule 100 provides definitions for purposes of the Existing Rules. The Exchange is proposing to amend this Existing Rule to include definitions for several new terms. For example, the proposed Rules will define the new term ''Code of Procedure'' as the procedural rules contained in Chapter 90. The Exchange also defines the new term ''Exchange Review Council,'' which is largely copied from BX Rule 0120(m). The Exchange notes that item (6) of the new definition differs from the BX item (6) in that it cites the analogous rules of the Exchange, which have different rule numbers. Finally, the Exchange proposes to amend the definition of ''SEC'' so that it also includes the word ''Commission.''

Existing Rule 206 concerns the consequences of a Member's or an Associated Person's failure to pay dues, fees and other charges. The Exchange proposes to delete this Existing Rule in favor of BX Rule 9553, which is more comprehensive than the Existing Rule and differs from it in several respects. Existing Rule 206 provides that instances of nonpayment shall be reported to the Exchange's Chief Executive Officer and President when they are 30 days past due, and that the Chief Executive Officer and President thereafter shall provide reasonable notice to the delinquent Member that continued non-payment will result in suspension of trading privileges. An Associated Person that fails to pay may be suspended from association with a Member. By contrast, BX Rule 9553 states that the Exchange's Regulation Department, within an unspecified period of time period [sic] after the onset of a delinquency, may issue a written notice to the delinquent Member or Associated Person that failure to comply within 21 days of service of the notice will result in suspension or cancellation of membership or suspension or bar of association with a Member, as applicable. BX Rule 9553 also provides for detailed provisions for serving such notice, a provision for requesting a hearing with respect to such a notice, a provision declaring the effectiveness of such notices (21 days after service) when no hearing is requested, and a means to request termination of a suspension, which may be granted for good cause shown.

Existing Rule 303 sets forth circumstances in which the Exchange may deny or condition approval of membership applications or applications to associate with Members. Existing Rule 303(c) also sets forth circumstances in which the Exchange may determine not to permit a Member or Associated Person from continuing their [sic] membership or association with a Member, including because they become [sic] subject to [sic] statutory disqualification under the Act. Existing Rule 303(f) furthermore permits a Member or Associated Person that becomes subject to [sic] statutory disqualification under the Act to apply to the Exchange to continue as a Member or as an Associated Person, within 30 days of becoming subject to the statutory disqualification. Existing

[20] In addition to adding Article VI to the By-Laws, the Exchange proposes to make changes to other articles of the By-Laws to accommodate the existence of the Exchange Review Council. For example, the Exchange proposes to amend Article I, which defines the terms that the Exchange uses in the By-Laws, to provide that the terms ''Industry member,'' ''Member representative member,'' ''Non-industry member,'' and ''Public member'' mean, in part, members of the Exchange Review Council. The Exchange also proposes to amend Article III, Section 6, to add a new subsection (a) that directs the Board to appoint an Exchange Review Council, as provided in Article VI. It also proposes to amend Article III, Section 6(b) to state that the Nominating Committee and the Member Nominating Committee of the Board shall have responsibility for nominating members of the Exchange Review Council. Finally, the Exchange proposes to amend Sections 7 and 8 of Article III, which deal with Director conflicts-of-interest/self-interested transactions and Director compensation, respectively, to ensure that the restrictions and benefits that these provisions provide apply to Exchange Review Council members.

[21] The Exchange notes that it proposes to establish procedures in Existing Rule 303 to govern the review by the Exchange Review Council of adverse membership and association determinations. The Exchange proposes to base these procedures upon those set forth BX Rules 1015 and 1016.

[22] *See* Securities Exchange Act Release No. 72149 (May 12, 2014), 79 FR 28564 (May 16, 2014) (SR–BX–2014–024).

Rule 303(g) states that, subject to the summary suspension rules in Chapter 15, any applicant for membership or association with a Member whose application is denied or conditioned or who is not permitted to continue as a Member or Associated Person may appeal such determinations under Chapter 17 of the Existing Rules.

The Exchange proposes to modify Existing Rule 303(f) so that it refers to new and more robust procedures, set forth in the BX Rule 9520 series, by which a Member or an Associated Person may obtain relief from disqualification or ineligibility determinations (BX Rule 9522).

The Exchange also proposes to amend Existing Rule 303(g), which states that subject to Chapter 15, the BCC may review, in part, Exchange determinations to deny membership or association with a Member pursuant to Chapter 17 of the Existing Rules. The Exchange proposes to re-assign responsibility for these reviews from the BCC to the Exchange Review Council and replace the review process presently set forth in Chapter 17 of the Existing Rules with processes that are substantially the same as those set forth in BX Rules 1015 and 1016. Specifically, the proposed amendments to Exchange Rule 303(g) state that, subject to Chapter 90, the Exchange Review Council will have jurisdiction to review these decisions. Proposed Rule 303(g) states that anyone whose application for membership on the Exchange, association with an Exchange Member, or whose continuing membership or association is denied or conditioned by the Exchange's Membership Department, may file a written request for review by the Exchange Review Council within 25 days after service of the Exchange's decision.[23] The request must state specifically why the applicant believes that the Membership Department's decision is inconsistent with the permissible bases for denial set forth in Rule 303, or otherwise should be set aside and state whether a hearing is requested.[24] The request will be heard by a Subcommittee appointed by the Exchange Review Council or the Review Subcommittee composed of two or more persons who are either current or past members of the Council or former Directors of the Exchange.[25] If a hearing is requested or directed, it must be held within 45 days after the request for review is filed with the Exchange or service of the notice by the Subcommittee.[26] Applicants and the Membership Department may be represented by counsel at the hearing and formal rules of evidence will not apply during the hearing.[27] The Subcommittee must present a recommended decision in writing to the Exchange Review Council within 60 days after the date of the hearing, and not later than seven days before the meeting of the Exchange Review Council at which the proceeding shall be considered.[28] The Exchange Review Council must issue a proposed written decision that affirms, modifies, or reverses the Membership Department's decision, or remands the proceedings with instructions and provide the proposed decision to the Exchange Board.[29] If the Exchange Board does not call the decision for review, it shall become final. If the Exchange Review Council does not serve its final written decision within the time period prescribed by Rule 303(g)(10)(C), then the Applicant may file a written request with the Exchange Board for the Board to direct the Exchange Review Council to issue its decision immediately or show good cause why it needs additional time to issue its decision.[30] Proposed Rule 303(h), which mirrors BX Rule 1016, grants the Exchange Board discretion, at the request of a Director, to review decisions of the Exchange Review Council.[31]

Existing Rule 307(b) requires Members to file with the Exchange and keep current their addresses at which notices may be served. The Exchange proposes to amend this Existing Rule to incorporate the language set forth in BX Rule 1160. Rather than merely requiring Members to provide the Exchange with their current address, the proposed amendment more broadly requires Members to report to the Exchange, through the FINRA Contact System, all of their contact information, including their mailing addresses, email addresses, facsimile numbers, and other information. It also requires members to update such contact information in the FINRA System within 30 days of any changes thereto, and to generally verify that such information remains accurate within 17 business days after the end of each calendar year. This proposed amendment to the Existing Rule will ensure that the Exchange has available to it multiple means of contacting its Members, including for purposes of serving the notices specified in the BX Rule 9550 series by email or by facsimile. The Exchange proposes, in its introduction to Chapter 90, to state that cross references in the BX Rule 9000 Series to BX Rule 1160 should be read instead to refer to Exchange Rule 307(b), as modified herein.

To maintain consistency with the BX Rules, the Exchange also proposes to eliminate Existing Rule 307(d), which requires Members to maintain a current copy of the Exchange's governing documents and Rules in an accessible place and make them available for examination by customers, and to replace it with BX Rule 8110, which is materially equivalent.

Existing Rule 308 requires a Member to notify the Exchange upon its adoption of a plan of liquidation or dissolution. The Existing Rule also provides that upon receipt of such notice, the Member's trading privileges may be suspended in accordance with Chapter 15 of the Existing Rules. The Exchange proposes to replace this reference to Chapter 15 with a reference to BX Rule 9558. Again, no analogue to this proposal exists in the BX rules insofar as those rules do not expressly address suspensions for such reasons or reviews of suspension determinations. Nevertheless, the Exchange believes that the process set forth in BX Rule 9558 is most appropriate for reviewing suspension determinations in these circumstances given that they already apply in circumstances where a Member is experiencing extreme financial or operating difficulty such that the Exchange determines that the Member cannot safely continue to do business on the Exchange.

The Supplementary Material to Existing Rule 306 concerns the Exchange's authority to waive the applicable qualification examination requirements and accept other standards as evidence of an applicant's qualifications for registration. The

[23] *See* proposed Rule 303(g)(1). The Exchange notes that the deadline for filing petitions for BCC review of an Exchange action under Existing Rule 1701(a) is 30 days from the date of such action. The Existing Rules pertaining to membership do not reference or define the terms ''Membership Department'' or ''Department.'' As part of this proposal, the Exchange proposes to amend Rule 303(g) to specify that the Exchange's Membership Department—rather than simply the ''Exchange''—makes determinations as to whether to grant, deny, or conditionally grant applications for membership or association or to continue as a Member or an Associated Person.

[24] *See* proposed Rule 303(g)(1).

[25] *See* proposed Rule 303(g)(4). The Exchange notes that Existing Rule 1702 provides for review by a BCC panel composed of two or more of its members.

[26] *See* proposed Rule 303(g)(6)(A).

[27] *See* proposed Rule 303(g)(6)(B) & (C). Unlike Existing Rule 1703, proposed Rule 303(g) does not provide for intervention in proceedings by interested non-parties.

[28] *See* proposed Rule 303(g)(9).

[29] *See* proposed Rule 303(g)(10)(A).

[30] *See* proposed Rule 303(g)(10)(D).

[31] Unlike Existing Rule 1704, proposed Rule 303(h) does not authorize the applicant or the President of the Exchange to request that the Board review the decision of the Exchange Review Council.

Exchange is amending this Rule to specify that such requests are handled pursuant to the BX Rule 9600 Series process. The BX Rule 9600 Series concerns the procedures for requesting exemptions, and the appeal of adverse decisions regarding an exemptive request. The Exchange notes that the proposed revisions will render the text of the Supplementary Material to Existing Rule 306 consistent with BX Rule 1070(d).

Existing Rule 720 concerns obvious and catastrophic errors. Existing Rule 720(k) currently references the OEP as the body responsible for reviewing determinations made by Options Exchange Officials pursuant to the Rule and it sets forth procedures to govern OEP review proceedings. In light of the fact that the OEP's responsibilities will be incorporated into those of the Exchange Review Council,[32] the amendments to the Rule remove references to the OEP and replaces [sic] them with references to a panel of the Exchange Review Council. The amended Rule also includes language grafted from the BX Rules prescribing the composition of panels convened for purposes of these reviews.[33]

Existing Rule 720A also provides for reviews by a ''Review Panel'' of decisions nullifying or adjusting transactions arising out of system disruptions or malfunctions. The Exchange proposes to eliminate the Review Panel in the Exchange's Rules and transfer its responsibility to a panel of the Exchange Review Council. The new Rule also includes language grafted from the BX Rules prescribing the composition of Exchange Review Council panels convened for purposes of these reviews.[34]

Existing Rule 804 permits a Primary Market Maker to apply to the Exchange to withdraw temporarily from its Primary Market Maker status in an options class. The Existing Rule does not presently authorize reviews of Exchange determinations to deny requests for temporary withdrawals or to impose conditions on the reentry of quotations. However, BX Rule 4619(f) does provide for such reviews. To provide consistency, the Exchange proposes to amend Existing Rule 804(f) to state that the Exchange Review Council will have authority conduct such reviews.

As discussed above, Chapter 16 of the Exchange's Rules incorporates by reference Chapter 16 of the ISE rules. However, Chapter 16 of the Exchange's Rules contains an introductory paragraph that references the incorporation by reference and provides instructions for cross-references. The Exchange proposes to delete the last line of this introductory paragraph, which specifies that a reference in the ISE Rule 1615 to Nasdaq ISE's contract with FINRA shall be read to refer to the Exchange's contract with FINRA. The Exchange proposes to delete this sentence because Nasdaq ISE is proposing to delete its Rule 1615, such that this sentence will no longer be necessary. The Exchange also proposes to change the title of Chapter 16 from ''Discipline'' to ''Disciplinary Jurisdiction and Minor Rule Violation Fines'' so that it conforms to the new title of Chapter 16 of the Nasdaq ISE Rules and to the content of that Chapter that Nasdaq ISE proposes to revise.[35]

Proposed Introductory Paragraphs to Chapters 80 and 90

The Exchange proposes to include introductory paragraphs to both Chapters 80 and 90 which state that they incorporate by reference the BX Rule 8000 and 9000 Series, respectively, and that such BX Rules shall be applicable to Exchange Members, Associated Persons, and other persons subject to the Exchange's jurisdiction.

These proposed introductory paragraphs also list instances in which cross references in the BX Rule 8000 and 9000 Series to other BX rules should be read to refer instead to the Exchange Rules, and references to defined BX terms shall be read to refer to the Exchange-related meanings of those terms. For example, references in both the BX Rule 8000 and 9000 Series to the following defined terms shall be read to refer to the Exchange-specific meanings of those terms: ''Exchange'' or ''Nasdaq BX'' shall be read to refer to the Exchange; ''Rule'' or ''BX Rule'' shall be read to refer to the Exchange Rules; ''Board'' or ''Exchange Board'' shall be read to refer to the Exchange Board of Directors; ''Member'' shall be read to refer to an Exchange Member; ''Associated Person'' shall be read to refer to an Exchange Associated Person; ''BX Regulatory Department'' or ''Regulation Department'' shall be read to refer to the Exchange's Regulatory Department; ''BX Regulation'' shall be read to refer to Exchange Regulation; ''Chief Regulatory Officer'' shall be read to refer to the Chief Regulatory Officer of the Exchange; and ''Equity Rule'' shall be read to refer to an Exchange Rule.

Additionally, the proposed introduction to Chapter 80 states that cross references in the BX Rule 8000 Series to the term ''Rule 0120'' shall be read to refer to Exchange Rule 100 and cross references in the BX Rule 8000 Series to ''Rule 1015'' shall be read to refer to Exchange Rule 303. Similarly, the proposed introduction to Chapter 90 states that cross-references in the BX Rule 9000 Series to the following terms shall be read to refer to the following Exchange Rules: ''Rule 0120'' shall be read to refer to Exchange Rule 100; ''Rule 1013'' shall be read to refer to Exchange Rules 302 and 307; ''Rule 1070'' shall be read to refer to the Supplementary Material to Exchange Rule 306; ''Rule 1160'' shall be read to refer to Exchange Rule 307(b); ''Equity Rule 2110'' shall be read to refer to Exchange Rule 400; ''Equity Rule 2120'' shall be read to refer to Exchange Rule 405; ''Rule 2140'' shall be read to refer to Exchange Rule 309; ''Equity Rule 2150'' shall be read to refer to Exchange Rules Chapter 6; ''Rule 2170'' shall be read to refer to Exchange Rule 403; ''Rule 4110A'' shall be read to refer to Exchange Rules Chapter 13; ''Rule 4120A'' shall be read to refer to Exchange Rules Chapter 13; ''Rule 10000 Series'' shall be read to refer to Exchange Rules Chapter 18; and ''Chapter III, Section 16'' shall be read to refer to Exchange Rule 403.

Finally, the introduction to Chapter 90 states that BX IM–9216 in the BX Rules shall not apply to the Exchange, its Members, Associated Persons, or other persons subject to the jurisdiction of the Exchange and that instead, references to BX IM–9216 shall be read to refer to Exchange Rule 1614(b). Similarly, the introduction states that the procedures set forth in BX Rule 9216(b) and 9143(e)(3), which govern the handling of violations of rules subject to the MRVP (''MRVP violations'') and the issuance of MRVP violation letters, shall also apply to the Exchange's handling of other violations of Rules listed in Rule 1614(b) that are not subject to the MRVP (''minor rule violations'') and the issuance of minor rule violation letters, except that the Exchange shall promptly report any final disciplinary action to the Commission, in accordance with SEC Rule 19d–1(c)(1). These proposed references are necessary to account for Nasdaq ISE's proposed revisions to Chapter 16 of its rules, which will retain the Exchange's existing authority to impose fines of up to $2,500 for MRVP violations and up to $5,000 for minor rule violations, as well as the Exchange's existing fine schedule for

[32] *See* proposed Rule 100(a)(21A).

[33] *See* BX Options Rules Ch. V, Sec. 6(l).

[34] *See id.*

[35] *See* SR–ISE–2018–59.

such violations, which will be set forth in Rule 1614(b).

Conclusion

The changes proposed herein will allow the Exchange to harmonize its investigatory and disciplinary processes with the processes of BX, thus providing a uniform process for the investigation and discipline of Members and Associated Persons across all of the Nasdaq, Inc. exchanges, as administered by FINRA pursuant to Regulatory Services Agreements. Harmonizing the investigatory and disciplinary processes of all of the Nasdaq, Inc. exchanges will bring efficiency to FINRA's administration of its responsibilities under the RSAs because the process [sic] it must follow are nearly identical, and are all based on the process that FINRA follows. Harmonized processes will bring consistency to investigations and adjudication of rule violations, and will reduce the number of disciplinary processes and requirements with which Members and Associated Persons, as well as their counsel, must be familiar.

The Exchange believes that the new investigatory and disciplinary processes are substantially similar to the existing process, and where there are differences between the new and old processes, the Exchange believes that the new process does not disadvantage its Members or Associated Persons. To the contrary, the Exchange believes that the new process will benefit all parties as it provides greater detail and specificity than the retired Rules, and that it is consequently more transparent.

The Exchange intends to announce the operative date of the new Rules at least 30 days in advance via a regulatory alert.[36] To facilitate an orderly transition from the Existing Rules to the new Rules, the Exchange is proposing to apply the Existing Rules to all Letters of Consent[37] that the Chief Regulatory Officer of the Exchange has approved and which are pending approval of the BCC prior to the operative date. The Exchange also will apply the Existing Rules to any matter for which, prior to the operative date, the Exchange has provided notice to a subject of its determination to impose an MRVP violation fine or a minor rule violation fine whereby the subject may yet or has contested the determination pursuant to Existing Rule 1614(a). In terms of formal disciplinary matters, any matter that has been approved for the issuance of a statement of charges[38] by the CRO will continue under the Existing Rules. Moreover, any appeal of a matter that is pending before an OEP pursuant to Existing Rule 720, a Review Panel pursuant to Existing Rule 720A, or the BCC pursuant to Existing Rule 303 will continue under the Existing Rules. As a consequence of this transition process, the Exchange will retain the BCC, the OEP, the Review Panel, and the existing processes during the transition period until such time that there are no longer any matters proceeding under the Existing Rules. To facilitate this transition process, the Exchange will retain a transitional Rulebook that will contain the Exchange's Rules as they are at the time of that this proposal is filed with the Commission. This transitional Rulebook will apply only to matters initiated prior to the operational date of the changes proposed herein and it will be posted to the Exchange's public rules website. When the transition is complete and there are no longer any Members, Associated Persons, or other persons subject to the existing disciplinary processes, the Exchange will remove the transitional Rulebook from its public rules website.

The Exchange furthermore notes that it expects the transition from the BCC to the Exchange Review Council to be smooth given that it expects to nominate the existing (and shared) membership of the BX, Nasdaq, and Phlx Review Councils to also become members of the Exchange Review Council.[39] The Exchange does not expect that any existing members of the BCC will be nominated to become members of the Exchange Review Council; however, the Exchange will ensure that, in advance of the operative day, the members of the Exchange Review Council will familiarize themselves with the Rules and procedures of the Exchange so that they will be prepared to fulfill their responsibilities.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[40] in general, and furthers the objectives of Section 6(b)(5) of the Act,[41] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest, and are [sic] not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange also believes that the proposal is consistent with Section 6(b)(6) of the Act,[42] which requires that the rules of an exchange provide that its members be appropriately disciplined for violations of the Act as well as the rules and regulations thereunder, or the rules of the Exchange, by expulsion, suspension, limitation of activities, functions, and operations, fine, censure, being suspended or barred from being associated with a member, or any other fitting sanction.

First, the Exchange's proposals are consistent with the Act to [sic] make miscellaneous changes to the Existing Rules to account for the adoption of the BX Rule 8000 and 9000 Series and the replacement of the BCC with the Exchange Review Council. For example, subject to Chapter 90, proposed changes to Rule 303 re-assign responsibility to the Exchange Review Council to review decisions of the Exchange's Membership Department to deny or condition applications for membership and association with Exchange Members and to deny or condition continuing membership or association. The proposal also establishes a new process by which the Exchange Review Council will adjudicate such reviews. The Exchange believes that these proposed changes to the Existing Rules are consistent with the Act because the new adjudicatory processes that the Exchange proposes to adopt in place of its existing processes are substantially similar to those that BX already utilizes. Moreover, the Exchange believes that the proposed processes will facilitate prompt, appropriate, and fair adjudications, consistent with the Act.

Second, the Exchange's proposals are consistent with the Act to [sic] make minor updates, corrections, and conforming amendments to the Exchange's Rules because they are necessary to ensure that the Exchange's

[36] The Exchange notes that the proposed changes will not become operative unless and until the Commission approves the Exchange's request, which it has filed pursuant to Section 36 of the Exchange Act and SEC Rule 0–12 thereunder, for an exemption from the rule filing requirements of Section 19(b) of the Exchange Act as to changes to Chapters 80 and 90 that are effected solely by virtue of a change to the BX Rule 8000 or 9000 Series.

[37] A ''Letter of Consent'' is a means by which the Exchange may consensually address a violation of its Rules without resort to the formal disciplinary process. *See* Existing Rule 1603.

[38] A ''statement of charges'' is formal disciplinary complaint. *See* Existing Rule 1604.

[39] The Exchange anticipates that the members of the Exchange Review Council will serve in a manner that is consistent with their tenures on the Nasdaq, BX, and Phlx review councils. That is, to the extent that the tenure of a member of these other review councils is due to expire on a particular date, then the same expiration date will apply to that member's tenure on the Exchange Review Council. All terms for members on the Exchange Review Council will comply with Article VI, Section 4 of the proposed By-Laws.

[40] 15 U.S.C. 78f(b).

[41] 15 U.S.C. 78f(b)(5).

[42] 15 U.S.C. 78f(b)(6).

cross-references and terminology remain current and accurate.

Third, the proposed rule change is necessary to ensure that the Exchange maintains a disciplinary process, in accordance with Section 6(b)(5) and (6) of the Act,[43] once Nasdaq ISE deletes its disciplinary rules from chapters 15–17 of the Nasdaq ISE rulebook, which the Exchange presently incorporates by reference. The proposed rule change will also ensure that going forward, the Exchange's disciplinary rules will continue to exist in harmony with those of Nasdaq ISE. As noted earlier, Nasdaq ISE is similarly proposing to incorporate by reference the BX Rule 8000 and 9000 Series into new chapters 80 and 90 of its rulebook as to well make similar conforming changes to its other rules.

The Exchange believes that harmonizing its investigative, disciplinary, and adjudicatory processes with those of BX will reduce the burden on Members and Associated Persons that are also members of BX, Nasdaq, Phlx, and/or FINRA. The Exchange notes that all of its Members are also members of BX, Nasdaq, Phlx, and/or FINRA. BX, Nasdaq, Phlx, and FINRA already have in place investigative, disciplinary, and adjudicatory processes that are the same or similar to those that the Exchange proposes to incorporate by reference.

As discussed above, the Exchange believes that the proposed Rules will benefit all parties involved in the Exchange's disciplinary and adjudicatory processes as they will include greater detail and specificity than do the Existing Rules. The proposal will render the Exchange's investigatory, disciplinary, and adjudicatory processes more transparent than the Existing Rules.

The Exchange also believes that adopting an Exchange Review Council is consistent with the Act because the Council's mandate is to, among other things, ensure consistent and fair application of the Exchange rules pertaining to discipline of Members and Associated Persons. The Exchange Review Council will be a body appointed by the Exchange Board of Directors and composed of representatives of the securities industry as well as persons from outside the securities industry. The broad membership of the new Exchange Review Council will ensure that the decisions and guidance it provides will be fair and balanced. The Exchange Review Council will be similar in structure and function to the BX exchange review council. In addition to reviewing appeals of disciplinary actions, the Exchange Review Council will also have jurisdiction to review membership decisions (proposed Rule 303), and appeals regarding limitations placed on Members or their employees that are subject to a statutory disqualification (BX Rule 9524). Additionally, the Exchange Review Council may consider and make recommendations to the Board on policy and rule changes relating to business and sales practices of Exchange Members and Associated Persons, and enforcement policies, including policies with respect to fines and other sanctions. Thus, the Exchange Review Council will provide the Exchange and market participants with a fair and impartial body overseeing disciplinary matters, as well as the rules and policies concerning the disciplinary process. For these reasons, the Exchange believes that adoption of the Exchange Review Council is consistent with the Act.

The Exchange believes that eliminating the BCC, the OEP (as provided for under Existing Rule 720), and the Review Panel (as provided for under Existing Rule 720A) is consistent with Sections 6(b)(5) and 6(b)(6) of the Act,[44] because the Exchange Review Council and the New Hearing Panels will assume the responsibilities of the BCC and the Panels. In particular, the functions of the current Hearing Panels of the BCC (''Current Hearing Panels'')—which include adjudicating disciplinary actions—will be handled by new Hearing Panels, which FINRA's Office of Hearing Officers (''OHO'') shall convene (''New Hearing Panels'').[45] Going forward, the BCC's (and the CRO's) responsibility for approving settlements will be assumed by the Exchange Review Council and, in certain instances, FINRA's Office of Disciplinary Affairs (the ''ODA'').[46] The BCC's responsibilities for hearing appeals of Exchange decisions on membership or association with a Member will be assumed by the Exchange Review Council. The responsibilities of the OEP and the Review Panel to hear appeals of Exchange determinations to nullify or adjust transactions that involve obvious errors or that result from system disruptions and malfunctions also will be assumed by the Exchange Review Council. The Exchange believes that the proposal will provide for the Exchange Review Council, the New Hearing Panels, and the ODA to execute the responsibilities of the BCC and the Panels in a manner that the Commission, within the context of the BX Rules, has already deemed to be consistent with the Act.[47] For example, the Exchange proposes to replace its existing process for handling appeals of membership decisions, as set forth in Existing Rule 303 and Chapter 17, with a process that BX already employs in BX Rules 1015 and 1016. Moreover, Exchange Members and Associated Persons will already be familiar with the proposed responsibilities and procedures of the Exchange Review Council, the New Hearing Panels, and the ODA from their experiences as members of BX and other SROs whose rules provide for similar assignments of responsibilities and processes.

The Exchange believes that its proposal furthers the objectives of Section 6(b)(7) of the Act[48] in that it is designed to provide a fair procedure for the disciplining of Members and Associated Persons, the denial of membership to any person seeking membership therein, the barring of any person from becoming associated with a Member thereof, and the prohibition or limitation by the Exchange of any person with respect to access to services offered by the Exchange or a Member thereof. Specifically, the Exchange believes that the proposed investigatory, disciplinary, and adjudicatory processes are consistent with Section 6(b)(7) of the Act[49] because they are based on the existing processes used by BX. The BX processes are well-established as consistent with the Act.[50]

Last, the Exchange believes that its proposal to phase-in the implementation of the new investigatory, disciplinary, and adjudicatory processes is consistent with Section 6(b)(7)[51] of the Act because both the current and proposed processes are consistent with the Act, providing fair procedures for investigating, disciplining, and adjudicating the rights of Members and Associated Persons. The Exchange is proposing to provide advanced notice of the implementation date of the new processes, and will apply the new

[43] 15 U.S.C. 78f(b)(5)–(6).

[44] *Id.*

[45] The OHO is an office within FINRA that is independent of the FINRA enforcement function and not involved in investigating or litigating cases.

[46] Pursuant to BX Rule 9270, proposed settlements must be submitted to and accepted by the Exchange Review Council, except that proposed settlements involving an affiliate of the Exchange must be reviewed by the ODA. Like the OHO, the ODA is an office within FINRA that is independent of the FINRA enforcement function and not involved in investigating or litigating cases.

[47] *See* Securities Exchange Act Release No. 34–59154 (Dec. 23, 2008), 73 FR 80468 (Dec. 31, 2008) (SR–BSE–2008–048).

[48] 15 U.S.C. 78f(b)(7).

[49] *Id.*

[50] *See* n.46, *supra.*

[51] 15 U.S.C. 78f(b)(7).

processes to new matters that are initiated on or after that implementation date. Any matters initiated prior to the implementation date will be completed using the current processes. As a consequence, the Exchange will delete the applicable portions of Chapters 15–17 from the Exchange's Rulebook, but it will maintain a transitional Rulebook on the Exchange's public rules website (*http://http://nasdaqgemx.cchwallstreet.com/*), which will contain the Exchange Rules as they are at the time of filing this rule change.[52] These transitional Rules will apply exclusively to the matters initiated prior to the implementation date. Upon conclusion of the last matter to which the transitional rules apply, the Exchange will remove the defunct transitional rules from its public rules website. Thus, the transition will be conducted in a fair, orderly, and transparent manner.

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, as amended [sic]. The proposed rule change is not intended to address competitive issues, but it should reduce burdens on Members, [sic] and Associated Persons. Specifically and as described in detail above, the Exchange believes that this change will bring efficiency and consistency in application of the investigative, disciplinary, and adjudicatory processes, thereby reducing the burden on Members and Associated Persons who are also members of BX and the other Nasdaq, Inc. Exchanges.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[53] and subparagraph (f)(6) of Rule 19b–4 thereunder.[54]

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: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–GEMX–2018–24 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–GEMX–2018–24. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–GEMX–2018–24 and should be submitted on or before August 21, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[55]

Eduardo A. Aleman,

Assistant Secretary.

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[52] The posting of the transitional rules on the public rules website will make it clear what disciplinary proceedings are governed by the transitional rules (*i.e.,* matters initiated prior to the implementation date).

[53] 15 U.S.C. 78s(b)(3)(A)(iii).

[54] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[55] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–83705; File No. SR–MRX–2018–23]

Self-Regulatory Organizations; Nasdaq MRX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Align Existing Investigatory and Disciplinary Processes and Related Rules With the Investigatory and Disciplinary Processes and Associated Rules of Nasdaq BX, Inc.

July 25, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 16, 2018, Nasdaq MRX, LLC (''MRX'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to align its existing investigatory and disciplinary processes and related rules with the investigatory and disciplinary processes and associated rules of Nasdaq BX, Inc. (''BX'').

The text of the proposed rule change is available on the Exchange's website at *http://nasdaqmrx.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.

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 new investigatory, disciplinary, and adjudicatory processes that are substantially the same as those of its sister exchange, BX. Specifically, the Exchange proposes to establish new Chapters 80 and 90 of its Rules [3] and then incorporate by reference into those Chapters the BX Rule 8000 and 9000 Series,[4] which set forth and govern the BX investigatory, disciplinary, and adjudicative processes.[5] The Exchange also proposes to amend its By-Laws to establish a new body to review disciplinary and certain other matters (the ''Exchange Review Council'') that is similar to the exchange review council that BX utilizes for such purposes.[6] These proposals, when coupled with certain changes to the Exchange's other Rules, including Rules that govern appeals of the Exchange's membership and other decisions, will render the Exchange's investigative, disciplinary, and adjudicatory processes substantially the same as those, not only of BX, but also of other Nasdaq, Inc. exchanges.[7] The proposal [sic] change will also further harmonize the work that the Financial Industry Regulatory Authority (''FINRA'') conducts for all these exchanges.

The Exchange's current investigatory, disciplinary, and adjudicatory processes are set forth in Chapters 15–17 of its Rules. Chapters 15–17 of the Exchange's Rules, in turn, incorporate by reference the investigatory, disciplinary, and adjudicatory processes of Nasdaq ISE, LLC (''Nasdaq ISE'') that are set forth in the corresponding chapters of the Nasdaq ISE rulebook. As part of a parallel Nasdaq ISE filing that also proposes to adopt the investigatory, disciplinary, and adjudicatory processes and rules of BX (and incorporate them by reference into new chapters 80 and 90 of the Nasdaq ISE rules), Nasdaq ISE proposes to eliminate chapters 15 and 17 of its rules, and to largely eliminate chapter 16.[8] These proposed changes to ISE chapters 15–17 will apply automatically to Chapters 15–17 of the Exchange's Rules. Accordingly, reference should be made to SR–ISE–2018–59 for a detailed explanation of the proposed changes to Chapters 15–17 and the purposes of those changes. Likewise, reference should be made to SR–ISE–2018–59 for a detailed discussion of the BX Rule 8000 and 9000 Series, which will largely replace Chapters 15–17 for both Nasdaq ISE and the Exchange. Lastly, reference should be made to SR–ISE–2018–59 for a discussion of proposed changes to certain other ISE rules that the Exchange also incorporates by reference and that are relevant to the Exchange's adoption of its new investigatory, disciplinary, and adjudicatory processes.[9]

The following is a discussion of proposed changes that are specific to the Rules of the Exchange and that are not otherwise addressed in or accomplished by the corresponding Nasdaq ISE filing. These changes include: (1) The elimination of the Exchange's BCC and its replacement with the Exchange Review Council; and (2) changes to Exchange Rules that are necessary to accommodate the new investigatory, disciplinary, and adjudicatory processes and rules and to harmonize those processes and rules with those of BX.

Elimination of the Business Conduct Committee and Establishment of the Exchange Review Council

The Exchange presently utilizes the BCC to help it enforce its Rules with respect to its members (''Members'') and persons associated with its members (''Associated Persons''). The BCC is a committee, established by the Board of Directors,[10] whose enforcement jurisdiction includes the following: (1) Ordering investigations of possible Rule violations; (2) considering letters of consent in expedited disciplinary actions; (3) making its members available to serve on Hearing Panels that adjudicate formal disciplinary proceedings; (4) imposing sanctions on Members or Associated Persons in disciplinary proceedings; (5) reviewing Exchange actions involving minor rule violations; (6) appointing panels to conduct hearings and reviews of Exchange actions that deny membership or Member association privileges; and (7) generally overseeing all matters relating to the conduct of disciplinary hearings and hearings for review of Exchange decisions, and providing the Exchange with advice for improving disciplinary procedures.[11]

The Exchange proposes to retire the BCC [12] and to amend its By-Laws to

[3] The Exchange proposes to add Chapters 23–79 and Chapters 81–89 to its Rules, but reserve such Chapters for future use.

[4] Citation herein to rules of the proposed Chapters 80 and 90 will be preceded by the term ''BX Rule'' to reflect incorporation of the BX Rule 8000 and 9000 Series. References to current rules will be preceded by the term ''Existing Rule.''

[5] The Exchange proposes to separately request an exemption from the rule filing requirements of Section 19(b) of the Act for changes to Chapters 80 and 90 to the extent such rules are effected solely by virtue of a change to the BX Rule 8000 and 9000 Series.

[6] As discussed below, the Exchange Review Council will assume responsibilities that presently reside with the Business Conduct Committee (the ''BCC''). The Exchange also proposes to eliminate the BCC.

[7] The Exchange notes that the BX Rule 8000 and 9000 Series are substantially similar to corresponding rules of The Nasdaq Stock Market, LLC (''Nasdaq'') and Nasdaq PHLX, LLC (''Phlx''). Moreover, the Exchange notes that Nasdaq ISE, LLC and Nasdaq GEMX, LLC will propose similar changes to their respective investigatory, disciplinary, and adjudicatory processes and associated rules that will render them substantially similar to those of BX.

[8] *See* SR–ISE–2018–59. Nasdaq ISE proposes to retain Rule 1600, which sets forth the general jurisdiction of the Exchange with respect to disciplinary matters. It also proposes to retain Existing Rule 1614(a), which sets forth its authority to impose fines of up to $2,500 for violations of the Exchange's Minor Rule Violation Plan (''MRVP'') and up to $5,000 for minor rule violations (other than those subject to an MRVP). Nasdaq ISE also proposes to retain Existing Rule 1614(d) (to be renumbered as Rule 1614(b)), which sets forth the Exchange's schedule of MRVP violations and minor rule violations and their associated fines.

[9] The proposed changes involve Nasdaq ISE Rules 410, 413(b)(1), 1000, 1406, and 1800.

[10] *See* Resolution of the Board of Directors of the ISE Mercury Delegating Authority, dated February 4, 2016.

[11] *See* MRX Business Conduct Committee Charter, dated May 22, 2018.

[12] In a February 4, 2016 resolution, the Exchange Board delegated its authority to the President of the Exchange to establish a BCC to, among other things, conduct disciplinary hearings under Chapter 16 of the Existing Rules and conduct other hearings and

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establish in its place the Exchange Review Council. The amended By-Laws that the Exchange proposes to adopt in this regard are substantially the same as those that BX adopted to establish the BX Exchange Review Council.[13] Thus, the By-Laws provide for the Exchange Review Council to have the same general structure and powers as does the BX Exchange Review Council.[14] The proposed By-Laws will authorize the Exchange Review Council to adjudicate disciplinary actions and approve settlements thereof as well as make recommendations to the Board on certain policy matters and rule changes. Such policy functions of the Exchange Review Council render its jurisdiction broader than that of the BCC.

Specifically, proposed Article VI, Section 1 of the proposed By-Laws provides that the Exchange Review Council may be authorized to act for the Board with respect to: an appeal or review of a disciplinary proceeding, a statutory disqualification proceeding, or a membership proceeding; a review of an offer of settlement, a letter of acceptance, waiver, and consent, and a minor rule violation plan letter; the exercise of exemptive authority; and such other proceedings or actions as may be authorized by the Exchange rules. The Exchange Review Council also may consider and make recommendations to the Board on policy and rule changes relating to business and sales practices of Exchange Members and Associated Persons and enforcement policies, including policies with respect to fines and other sanctions. It may advise the Board on regulatory proposals and industry initiatives relating to quotations, execution, trade reporting, and trading practices and it may advise the Board in its administration of programs and systems for the surveillance and enforcement of rules governing Exchange Members' conduct and trading activities in the Exchange.

Proposed Article VI, Section 2 states that the Exchange Review Council would consist of no fewer than eight and no more than 12 members. The Exchange Review Council must include a number of Member Representative members [15] that is equal to at least 20% of the total number of members of the Exchange Review Council. The number of Non-Industry members,[16] including at least three Public members,[17] shall equal or exceed the sum of the number of Industry members [18] and Member Representative members. As soon as practicable, following the appointment of members, the Exchange Review Council shall elect a Chair from among its members. The Chair shall have such powers and duties as may be determined from time to time by the Exchange Review Council. The Board, by resolution adopted by a majority of Directors then in office, may remove the Chair from such position at any time for refusal, failure, neglect, or inability to discharge the duties of Chair. No more than 50% of the members of the Exchange Review Council shall be engaged in market making activity or employed by an Exchange Member firm whose revenues from market making activity exceed 10 percent of its total revenues.

Proposed Article VI, Section 3 requires the Exchange's Secretary to collect from each nominee for the office of member of the Exchange Review Council such information as is reasonably necessary to serve as the basis for a determination of the nominee's qualifications and classification as an Industry, Member Representative, Non-Industry, or Public member. The Secretary must also certify to the Nominating Committee or the Member Nominating Committee [19] (as applicable) each nominee's qualifications and classification. After appointment to the Exchange Review Council, each member must update such information at least annually and upon request of the Exchange's Secretary, and must report immediately to the Secretary any change in such information.

Proposed Article VI, Section 4 provides that Exchange Review Council members shall serve three-year terms, or until a successor is duly appointed and qualified, except in the event of earlier termination from office by reason by death, resignation, removal, disqualification, or other reason. Members are term limited out after two consecutive terms. Proposed Article VI, Section 5 sets forth the procedures for resigning as a member of the Exchange Review Council and provides that an Exchange Review Council member may resign at any time upon written notice to the Board. Under proposed Article VI, Section 6, any member of the Exchange Review Council may be removed from office at any time for refusal, failure, neglect, or inability to discharge the duties of such office by majority vote of the Board.

Under proposed Article VI, Section 7, an Exchange Review Council member would be disqualified and removed immediately upon a determination by the Board, by a majority vote, (a) that the member no longer satisfies the classification (Industry, Member Representative, Non-Industry, or Public) for which the member was elected; and (b) that the member's continued service as such would violate the compositional requirements of the Exchange Review Council set forth in Article VI, Section 2. If the term of office of an Exchange Review Council member terminates under this Section, and the remaining term of office of such member at the time of termination is not more than six months, during the period of vacancy the Exchange Review Council shall not be deemed to be in violation of Article VI, Section 2 by virtue of such vacancy. Proposed Article VI, Section 8 contains provisions for the filling of vacancies on the Exchange Review Council and states that if a position on the Exchange Review Council becomes vacant, the Nominating Committee or the Member Nominating Committee (as applicable) shall nominate, and the Board shall appoint a person satisfying the qualifications for the position as provided in Article VI, Section 2 to fill

reviews as set forth in Chapter 17 of the Existing Rules. On February 1, 2017, the Board passed a resolution that both revoked the President's authority to establish a BCC and authorized the establishment of an Exchange Review Council, effective upon the date when this rule filing becomes operative.

[13] The BX by-laws differ from the proposed Exchange By-Laws because the BX by-laws have a different numbering convention from the Exchange's By-Laws and, in various places, the BX by-laws refer to a Listing and Hearing Review Council, which has no analogue with respect to the Exchange.

[14] The BX by-laws do not describe in detail the process of the proceedings over which the BX Exchange Review Council presides. However, Section 7.9 of the BX by-laws state [sic] that a quorum of three BX Exchange Review Council members is necessary to adjudicate appeals of determinations made under BX Rules 4612 (appeal of denial of registration as an Equities Market Maker), 4619 (review of denial of an excused withdrawal of Equities Market Maker quotation), 4620 (appeal of denial of reinstatement of Equities Market Maker that accidentally withdraws), 11890 (appeal of clearly erroneous transaction determination), and BX Options Chapter V, Section 6 (appeal of obvious error determination). *See* BX by-laws, Article VII, Section 9. The Exchange's Rules do not have analogues to BX Rules 4612, 4620, and 11890 and, as such, the corresponding provision of the Exchange's proposed By-Laws (Article VII, Section 9) provides only that a quorum of three Exchange Review Council members is necessary for it to adjudicate appeals involving determinations made under Rules 720 (appeal of obvious error determination), 720A (appeal of determinations of erroneous trades due to system malfunctions and disruptions), and 804 (review of denial of an excused withdrawal of market maker quotation).

[15] *See* n.20, *infra.*

[16] *See id.*

[17] *See id.*

[18] *See id.*

[19] The terms ''Nominating Committee'' and ''Member Nominating Committee'' are defined in Exchange By-Laws, Article I.

such vacancy, except that if the remaining term of office for the vacant position is not more than six months, no replacement shall be required.

Proposed Article VI, Section 9 provides that a quorum of the Exchange Review Council will consist of a majority of its members, including not less than 50% of its Non-Industry members and one Member Representative member. Proposed Article VI, Section 10 contains provisions related to the meetings of the Exchange Review Council.

Under proposed Article VI, Section 11, the Exchange Review Council is required to establish a Review Subcommittee to determine whether disciplinary and membership proceedings decisions should be called for review by the Exchange Review Council under the disciplinary and membership rules to be proposed for the Exchange. The Review Subcommittee shall be composed of no fewer than two and no more than four members of the Exchange Review Council. The number of Non-Industry members of the Review Subcommittee shall equal or exceed the sum of the number of Industry members and Member Representative members of the Review Subcommittee, and the subcommittee must include at least one Member Representative member. At all meetings of the Review Subcommittee, a quorum for the transaction of business shall consist of not less than 50 percent of the members of the Review Subcommittee, including not less than 50 percent of the Non-Industry members of the Review Subcommittee and one Member Representative member of the Review Subcommittee.[20]

The BX Rules implement the foregoing responsibilities of the Exchange Review Council by establishing various procedures to govern its reviews. As the Exchange describes in further detail below, the Exchange proposes to transfer to the Exchange Review Council (or panels thereof) certain responsibilities currently vested in other Exchange committees or the Board. For example, pursuant to Existing Rule 720, an Obvious Error Panel (''OEP'') is presently responsible for reviewing determinations regarding obvious and catastrophic errors. Pursuant to Existing Rule 720A, a ''Review Panel'' is responsible for reviewing determinations to nullify or adjust transactions that arise from system disruptions and malfunctions. The Exchange is proposing to eliminate the OEP and the Review Panel and to transfer their responsibilities to a panel of the new Exchange Review Council, which corresponds to the practice of BX. Subject to Chapter 90, the Exchange also proposes to transfer responsibility to the Exchange Review Council to review denials or conditions imposed upon those that seek to become or remain a Member of the Exchange or become or remain associated with a Member of the Exchange, as set forth in Existing Rule 303.[21] In addition, the Exchange proposes to amend Existing Rule 804 to provide for the Exchange Review Council to review determinations regarding temporary withdrawals of quotations, which are not reviewable under the Existing Rules. The Exchange notes that BX vests in its Exchange Review Council responsibility for reviewing similar types of matters.[22]

Other Conforming Rule Changes

The Exchange proposes to amend or delete certain other Existing Rules, which are either not needed, duplicated elsewhere, or reference the deleted Existing Rules. Below is a description of the specific changes the Exchange proposes to make to its Existing Rules.

Existing Rule 100 provides definitions for purposes of the Existing Rules. The Exchange is proposing to amend this Existing Rule to include definitions for several new terms. For example, the proposed Rules will define the new term ''Code of Procedure'' as the procedural rules contained in Chapter 90. The Exchange also defines the new term ''Exchange Review Council,'' which is largely copied from BX Rule 0120(m). The Exchange notes that item (6) of the new definition differs from the BX item (6) in that it cites the analogous rules of the Exchange, which have different rule numbers. Finally, the Exchange proposes to amend the definition of ''SEC'' so that it also includes the word ''Commission.''

Existing Rule 206 concerns the consequences of a Member's or an Associated Person's failure to pay dues, fees and other charges. The Exchange proposes to delete this Existing Rule in favor of BX Rule 9553, which is more comprehensive than the Existing Rule and differs from it in several respects. Existing Rule 206 provides that instances of nonpayment shall be reported to the Exchange's Chief Executive Officer and President when they are 30 days past due, and that the Chief Executive Officer and President thereafter shall provide reasonable notice to the delinquent Member that continued non-payment will result in suspension of trading privileges. An Associated Person that fails to pay may be suspended from association with a Member. By contrast, BX Rule 9553 states that the Exchange's Regulation Department, within an unspecified period of time period [sic] after the onset of a delinquency, may issue a written notice to the delinquent Member or Associated Person that failure to comply within 21 days of service of the notice will result in suspension or cancellation of membership or suspension or bar of association with a Member, as applicable. BX Rule 9553 also provides for detailed provisions for serving such notice, a provision for requesting a hearing with respect to such a notice, a provision declaring the effectiveness of such notices (21 days after service) when no hearing is requested, and a means to request termination of a suspension, which may be granted for good cause shown.

Existing Rule 303 sets forth circumstances in which the Exchange may deny or condition approval of membership applications or applications to associate with Members. Existing Rule 303(c) also sets forth circumstances in which the Exchange may determine not to permit a Member or Associated Person from continuing their [sic] membership or association with a Member, including because they become [sic] subject to [sic] statutory disqualification under the Act. Existing Rule 303(f) furthermore permits a Member or Associated Person that becomes subject to [sic] statutory disqualification under the Act to apply to the Exchange to continue as a Member or as an Associated Person, within 30 days of becoming subject to the statutory disqualification. Existing

[20] In addition to adding Article VI to the By-Laws, the Exchange proposes to make changes to other articles of the By-Laws to accommodate the existence of the Exchange Review Council. For example, the Exchange proposes to amend Article I, which defines the terms that the Exchange uses in the By-Laws, to provide that the terms ''Industry member,'' ''Member representative member,'' ''Non-industry member,'' and ''Public member'' mean, in part, members of the Exchange Review Council. The Exchange also proposes to amend Article III, Section 6, to add a new subsection (a) that directs the Board to appoint an Exchange Review Council, as provided in Article VI. It also proposes to amend Article III, Section 6(b) to state that the Nominating Committee and the Member Nominating Committee of the Board shall have responsibility for nominating members of the Exchange Review Council. Finally, the Exchange proposes to amend Sections 7 and 8 of Article III, which deal with Director conflicts-of-interest/self-interested transactions and Director compensation, respectively, to ensure that the restrictions and benefits that these provisions provide apply to Exchange Review Council members.

[21] The Exchange notes that it proposes to establish procedures in Existing Rule 303 to govern the review by the Exchange Review Council of adverse membership and association determinations. The Exchange proposes to base these procedures upon those set forth BX Rules 1015 and 1016.

[22] *See* Securities Exchange Act Release No. 72149 (May 12, 2014), 79 FR 28564 (May 16, 2014) (SR–BX–2014–024).

Rule 303(g) states that, subject to the summary suspension rules in Chapter 15, any applicant for membership or association with a Member whose application is denied or conditioned or who is not permitted to continue as a Member or Associated Person may appeal such determinations under Chapter 17 of the Existing Rules.

The Exchange proposes to modify Existing Rule 303(f) so that it refers to new and more robust procedures, set forth in the BX Rule 9520 series, by which a Member or an Associated Person may obtain relief from disqualification or ineligibility determinations (BX Rule 9522).

The Exchange also proposes to amend Existing Rule 303(g), which states that subject to Chapter 15, the BCC may review, in part, Exchange determinations to deny membership or association with a Member pursuant to Chapter 17 of the Existing Rules. The Exchange proposes to re-assign responsibility for these reviews from the BCC to the Exchange Review Council and replace the review process presently set forth in Chapter 17 of the Existing Rules with processes that are substantially the same as those set forth in BX Rules 1015 and 1016. Specifically, the proposed amendments to Exchange Rule 303(g) state that, subject to Chapter 90, the Exchange Review Council will have jurisdiction to review these decisions. Proposed Rule 303(g) states that anyone whose application for membership on the Exchange, association with an Exchange Member, or whose continuing membership or association is denied or conditioned by the Exchange's Membership Department, may file a written request for review by the Exchange Review Council within 25 days after service of the Exchange's decision.[23] The request must state specifically why the applicant believes that the Membership Department's decision is inconsistent with the permissible bases for denial set forth in Rule 303, or otherwise should be set aside and state whether a hearing is requested.[24] The request will be heard by a Subcommittee appointed by the Exchange Review Council or the Review Subcommittee composed of two or more persons who are either current or past members of the Council or former Directors of the Exchange.[25] If a hearing is requested or directed, it must be held within 45 days after the request for review is filed with the Exchange or service of the notice by the Subcommittee.[26] Applicants and the Membership Department may be represented by counsel at the hearing and formal rules of evidence will not apply during the hearing.[27] The Subcommittee must present a recommended decision in writing to the Exchange Review Council within 60 days after the date of the hearing, and not later than seven days before the meeting of the Exchange Review Council at which the proceeding shall be considered.[28] The Exchange Review Council must issue a proposed written decision that affirms, modifies, or reverses the Membership Department's decision, or remands the proceedings with instructions and provide the proposed decision to the Exchange Board.[29] If the Exchange Board does not call the decision for review, it shall become final. If the Exchange Review Council does not serve its final written decision within the time period prescribed by Rule 303(g)(10)(C), then the Applicant may file a written request with the Exchange Board for the Board to direct the Exchange Review Council to issue its decision immediately or show good cause why it needs additional time to issue its decision.[30] Proposed Rule 303(h), which mirrors BX Rule 1016, grants the Exchange Board discretion, at the request of a Director, to review decisions of the Exchange Review Council.[31]

Existing Rule 307(b) requires Members to file with the Exchange and keep current their addresses at which notices may be served. The Exchange proposes to amend this Existing Rule to incorporate the language set forth in BX Rule 1160. Rather than merely requiring Members to provide the Exchange with their current address, the proposed amendment more broadly requires Members to report to the Exchange, through the FINRA Contact System, all of their contact information, including their mailing addresses, email addresses, facsimile numbers, and other information. It also requires members to update such contact information in the FINRA System within 30 days of any changes thereto, and to generally verify that such information remains accurate within 17 business days after the end of each calendar year. This proposed amendment to the Existing Rule will ensure that the Exchange has available to it multiple means of contacting its Members, including for purposes of serving the notices specified in the BX Rule 9550 series by email or by facsimile. The Exchange proposes, in its introduction to Chapter 90, to state that cross references in the BX Rule 9000 Series to BX Rule 1160 should be read instead to refer to Exchange Rule 307(b), as modified herein.

To maintain consistency with the BX Rules, the Exchange also proposes to eliminate Existing Rule 307(d), which requires Members to maintain a current copy of the Exchange's governing documents and Rules in an accessible place and make them available for examination by customers, and to replace it with BX Rule 8110, which is materially equivalent.

Existing Rule 308 requires a Member to notify the Exchange upon its adoption of a plan of liquidation or dissolution. The Existing Rule also provides that upon receipt of such notice, the Member's trading privileges may be suspended in accordance with Chapter 15 of the Existing Rules. The Exchange proposes to replace this reference to Chapter 15 with a reference to BX Rule 9558. Again, no analogue to this proposal exists in the BX rules insofar as those rules do not expressly address suspensions for such reasons or reviews of suspension determinations. Nevertheless, the Exchange believes that the process set forth in BX Rule 9558 is most appropriate for reviewing suspension determinations in these circumstances given that they already apply in circumstances where a Member is experiencing extreme financial or operating difficulty such that the Exchange determines that the Member cannot safely continue to do business on the Exchange.

The Supplementary Material to Existing Rule 306 concerns the Exchange's authority to waive the applicable qualification examination requirements and accept other standards as evidence of an applicant's qualifications for registration. The

[23] *See* proposed Rule 303(g)(1). The Exchange notes that the deadline for filing petitions for BCC review of an Exchange action under Existing Rule 1701(a) is 30 days from the date of such action. The Existing Rules pertaining to membership do not reference or define the terms ''Membership Department'' or ''Department.'' As part of this proposal, the Exchange proposes to amend Rule 303(g) to specify that the Exchange's Membership Department—rather than simply the ''Exchange''—makes determinations as to whether to grant, deny, or conditionally grant applications for membership or association or to continue as a Member or an Associated Person.

[24] *See* proposed Rule 303(g)(1).

[25] *See* proposed Rule 303(g)(4). The Exchange notes that Existing Rule 1702 provides for review by a BCC panel composed of two or more of its members.

[26] *See* proposed Rule 303(g)(6)(A).

[27] *See* proposed Rule 303(g)(6)(B) & (C). Unlike Existing Rule 1703, proposed Rule 303(g) does not provide for intervention in proceedings by interested non-parties.

[28] *See* proposed Rule 303(g)(9).

[29] *See* proposed Rule 303(g)(10)(A).

[30] *See* proposed Rule 303(g)(10)(D).

[31] Unlike Existing Rule 1704, proposed Rule 303(h) does not authorize the applicant or the President of the Exchange to request that the Board review the decision of the Exchange Review Council.

Exchange is amending this Rule to specify that such requests are handled pursuant to the BX Rule 9600 Series process. The BX Rule 9600 Series concerns the procedures for requesting exemptions, and the appeal of adverse decisions regarding an exemptive request. The Exchange notes that the proposed revisions will render the text of the Supplementary Material to Existing Rule 306 consistent with BX Rule 1070(d).

Existing Rule 720 concerns obvious and catastrophic errors. Existing Rule 720(k) currently references the OEP as the body responsible for reviewing determinations made by Options Exchange Officials pursuant to the Rule and it sets forth procedures to govern OEP review proceedings. In light of the fact that the OEP's responsibilities will be incorporated into those of the Exchange Review Council,[32] the amendments to the Rule remove references to the OEP and replaces [sic] them with references to a panel of the Exchange Review Council. The amended Rule also includes language grafted from the BX Rules prescribing the composition of panels convened for purposes of these reviews.[33]

Existing Rule 720A also provides for reviews by a ''Review Panel'' of decisions nullifying or adjusting transactions arising out of system disruptions or malfunctions. The Exchange proposes to eliminate the Review Panel in the Exchange's Rules and transfer its responsibility to a panel of the Exchange Review Council. The new Rule also includes language grafted from the BX Rules prescribing the composition of Exchange Review Council panels convened for purposes of these reviews.[34]

Existing Rule 804 permits a Primary Market Maker to apply to the Exchange to withdraw temporarily from its Primary Market Maker status in an options class. The Existing Rule does not presently authorize reviews of Exchange determinations to deny requests for temporary withdrawals or to impose conditions on the reentry of quotations. However, BX Rule 4619(f) does provide for such reviews. To provide consistency, the Exchange proposes to amend Existing Rule 804(f) to state that the Exchange Review Council will have authority conduct such reviews.

As discussed above, Chapter 16 of the Exchange's Rules incorporates by reference Chapter 16 of the ISE rules. However, Chapter 16 of the Exchange's Rules contains an introductory paragraph that references the incorporation by reference and provides instructions for cross-references. The Exchange proposes to delete the last line of this introductory paragraph, which specifies that a reference in the ISE Rule 1615 to Nasdaq ISE's contract with FINRA shall be read to refer to the Exchange's contract with FINRA. The Exchange proposes to delete this sentence because Nasdaq ISE is proposing to delete its Rule 1615, such that this sentence will no longer be necessary. The Exchange also proposes to change the title of Chapter 16 from ''Discipline'' to ''Disciplinary Jurisdiction and Minor Rule Violation Fines'' so that it conforms to the new title of Chapter 16 of the Nasdaq ISE Rules and to the content of that Chapter that Nasdaq ISE proposes to revise.[35]

Proposed Introductory Paragraphs to Chapters 80 and 90

The Exchange proposes to include introductory paragraphs to both Chapters 80 and 90 which state that they incorporate by reference the BX Rule 8000 and 9000 Series, respectively, and that such BX Rules shall be applicable to Exchange Members, Associated Persons, and other persons subject to the Exchange's jurisdiction.

These proposed introductory paragraphs also list instances in which cross references in the BX Rule 8000 and 9000 Series to other BX rules should be read to refer instead to the Exchange Rules, and references to defined BX terms shall be read to refer to the Exchange-related meanings of those terms. For example, references in both the BX Rule 8000 and 9000 Series to the following defined terms shall be read to refer to the Exchange-specific meanings of those terms: ''Exchange'' or ''Nasdaq BX'' shall be read to refer to the Exchange; ''Rule'' or ''BX Rule'' shall be read to refer to the Exchange Rules; ''Board'' or ''Exchange Board'' shall be read to refer to the Exchange Board of Directors; ''Member'' shall be read to refer to an Exchange Member; ''Associated Person'' shall be read to refer to an Exchange Associated Person; ''BX Regulatory Department'' or ''Regulation Department'' shall be read to refer to the Exchange's Regulatory Department; ''BX Regulation'' shall be read to refer to Exchange Regulation; ''Chief Regulatory Officer'' shall be read to refer to the Chief Regulatory Officer of the Exchange; and ''Equity Rule'' shall be read to refer to an Exchange Rule.

Additionally, the proposed introduction to Chapter 80 states that cross references in the BX Rule 8000 Series to the term ''Rule 0120'' shall be read to refer to Exchange Rule 100 and cross references in the BX Rule 8000 Series to ''Rule 1015'' shall be read to refer to Exchange Rule 303. Similarly, the proposed introduction to Chapter 90 states that cross-references in the BX Rule 9000 Series to the following terms shall be read to refer to the following Exchange Rules: ''Rule 0120'' shall be read to refer to Exchange Rule 100; ''Rule 1013'' shall be read to refer to Exchange Rules 302 and 307; ''Rule 1070'' shall be read to refer to the Supplementary Material to Exchange Rule 306; ''Rule 1160'' shall be read to refer to Exchange Rule 307(b); ''Equity Rule 2110'' shall be read to refer to Exchange Rule 400; ''Equity Rule 2120'' shall be read to refer to Exchange Rule 405; ''Rule 2140'' shall be read to refer to Exchange Rule 309; ''Equity Rule 2150'' shall be read to refer to Exchange Rules Chapter 6; ''Rule 2170'' shall be read to refer to Exchange Rule 403; ''Rule 4110A'' shall be read to refer to Exchange Rules Chapter 13; ''Rule 4120A'' shall be read to refer to Exchange Rules Chapter 13; ''Rule 10000 Series'' shall be read to refer to Exchange Rules Chapter 18; and ''Chapter III, Section 16'' shall be read to refer to Exchange Rule 403.

Finally, the introduction to Chapter 90 states that BX IM–9216 in the BX Rules shall not apply to the Exchange, its Members, Associated Persons, or other persons subject to the jurisdiction of the Exchange and that instead, references to BX IM–9216 shall be read to refer to Exchange Rule 1614(b). Similarly, the introduction states that the procedures set forth in BX Rule 9216(b) and 9143(e)(3), which govern the handling of violations of rules subject to the MRVP (''MRVP violations'') and the issuance of MRVP violation letters, shall also apply to the Exchange's handling of other violations of Rules listed in Rule 1614(b) that are not subject to the MRVP (''minor rule violations'') and the issuance of minor rule violation letters, except that the Exchange shall promptly report any final disciplinary action to the Commission, in accordance with SEC Rule 19d–1(c)(1). These proposed references are necessary to account for Nasdaq ISE's proposed revisions to Chapter 16 of its rules, which will retain the Exchange's existing authority to impose fines of up to $2,500 for MRVP violations and up to $5,000 for minor rule violations, as well as the Exchange's existing fine schedule for

[32] *See* proposed Rule 100(a)(21A).

[33] *See* BX Options Rules Ch. V, Sec. 6(l).

[34] *See id.*

[35] *See* SR–ISE–2018–59.

such violations, which will be set forth in Rule 1614(b).

Conclusion

The changes proposed herein will allow the Exchange to harmonize its investigatory and disciplinary processes with the processes of BX, thus providing a uniform process for the investigation and discipline of Members and Associated Persons across all of the Nasdaq, Inc. exchanges, as administered by FINRA pursuant to Regulatory Services Agreements. Harmonizing the investigatory and disciplinary processes of all of the Nasdaq, Inc. exchanges will bring efficiency to FINRA's administration of its responsibilities under the RSAs because the process [sic] it must follow are nearly identical, and are all based on the process that FINRA follows. Harmonized processes will bring consistency to investigations and adjudication of rule violations, and will reduce the number of disciplinary processes and requirements with which Members and Associated Persons, as well as their counsel, must be familiar.

The Exchange believes that the new investigatory and disciplinary processes are substantially similar to the existing process, and where there are differences between the new and old processes, the Exchange believes that the new process does not disadvantage its Members or Associated Persons. To the contrary, the Exchange believes that the new process will benefit all parties as it provides greater detail and specificity than the retired Rules, and that it is consequently more transparent.

The Exchange intends to announce the operative date of the new Rules at least 30 days in advance via a regulatory alert.[36] To facilitate an orderly transition from the Existing Rules to the new Rules, the Exchange is proposing to apply the Existing Rules to all Letters of Consent[37] that the Chief Regulatory Officer of the Exchange has approved and which are pending approval of the BCC prior to the operative date. The Exchange also will apply the Existing Rules to any matter for which, prior to the operative date, the Exchange has provided notice to a subject of its determination to impose an MRVP violation fine or a minor rule violation fine whereby the subject may yet or has contested the determination pursuant to Existing Rule 1614(a). In terms of formal disciplinary matters, any matter that has been approved for the issuance of a statement of charges[38] by the CRO will continue under the Existing Rules. Moreover, any appeal of a matter that is pending before an OEP pursuant to Existing Rule 720, a Review Panel pursuant to Existing Rule 720A, or the BCC pursuant to Existing Rule 303 will continue under the Existing Rules. As a consequence of this transition process, the Exchange will retain the BCC, the OEP, the Review Panel, and the existing processes during the transition period until such time that there are no longer any matters proceeding under the Existing Rules. To facilitate this transition process, the Exchange will retain a transitional Rulebook that will contain the Exchange's Rules as they are at the time of [sic] that this proposal is filed with the Commission. This transitional Rulebook will apply only to matters initiated prior to the operational date of the changes proposed herein and it will be posted to the Exchange's public rules website. When the transition is complete and there are no longer any Members, Associated Persons, or other persons subject to the existing disciplinary processes, the Exchange will remove the transitional Rulebook from its public rules website.

The Exchange furthermore notes that it expects the transition from the BCC to the Exchange Review Council to be smooth given that it expects to nominate the existing (and shared) membership of the BX, Nasdaq, and Phlx Review Councils to also become members of the Exchange Review Council.[39] The Exchange does not expect that any existing members of the BCC will be nominated to become members of the Exchange Review Council; however, the Exchange will ensure that, in advance of the operative day, the members of the Exchange Review Council will familiarize themselves with the Rules and procedures of the Exchange so that they will be prepared to fulfill their responsibilities.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[40] in general, and furthers the objectives of Section 6(b)(5) of the Act,[41] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest, and are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange also believes that the proposal is consistent with Section 6(b)(6) of the Act,[42] which requires that the rules of an exchange provide that its members be appropriately disciplined for violations of the Act as well as the rules and regulations thereunder, or the rules of the Exchange, by expulsion, suspension, limitation of activities, functions, and operations, fine, censure, being suspended or barred from being associated with a member, or any other fitting sanction.

First, the Exchange's proposals are consistent with the Act to [sic] make miscellaneous changes to the Existing Rules to account for the adoption of the BX Rule 8000 and 9000 Series and the replacement of the BCC with the Exchange Review Council. For example, subject to Chapter 90, proposed changes to Rule 303 re-assign responsibility to the Exchange Review Council to review decisions of the Exchange's Membership Department to deny or condition applications for membership and association with Exchange Members and to deny or condition continuing membership or association. The proposal also establishes a new process by which the Exchange Review Council will adjudicate such reviews. The Exchange believes that these proposed changes to the Existing Rules are consistent with the Act because the new adjudicatory processes that the Exchange proposes to adopt in place of its existing processes are substantially similar to those that BX already utilizes. Moreover, the Exchange believes that the proposed processes will facilitate prompt, appropriate, and fair adjudications, consistent with the Act.

Second, the Exchange's proposals are consistent with the Act to [sic] make minor updates, corrections, and conforming amendments to the Exchange's Rules because they are necessary to ensure that the Exchange's

[36] The Exchange notes that the proposed changes will not become operative unless and until the Commission approves the Exchange's request, which it has filed pursuant to Section 36 of the Exchange Act and SEC Rule 0–12 thereunder, for an exemption from the rule filing requirements of Section 19(b) of the Exchange Act as to changes to Chapters 80 and 90 that are effected solely by virtue of a change to the BX Rule 8000 or 9000 Series.

[37] A ''Letter of Consent'' is a means by which the Exchange may consensually address a violation of its Rules without resort to the formal disciplinary process. *See* Existing Rule 1603.

[38] A ''statement of charges'' is formal disciplinary complaint. *See* Existing Rule 1604.

[39] The Exchange anticipates that the members of the Exchange Review Council will serve in a manner that is consistent with their tenures on the Nasdaq, BX, and Phlx review councils. That is, to the extent that the tenure of a member of these other review councils is due to expire on a particular date, then the same expiration date will apply to that member's tenure on the Exchange Review Council. All terms for members on the Exchange Review Council will comply with Article VI, Section 4 of the proposed By-Laws.

[40] 15 U.S.C. 78f(b).

[41] 15 U.S.C. 78f(b)(5).

[42] 15 U.S.C. 78f(b)(6).

cross-references and terminology remain current and accurate.

Third, the proposed rule change is necessary to ensure that the Exchange maintains a disciplinary process, in accordance with Section 6(b)(5) and (6) of the Act,[43] once Nasdaq ISE deletes its disciplinary rules from chapters 15–17 of the Nasdaq ISE rulebook, which the Exchange presently incorporates by reference. The proposed rule change will also ensure that going forward, the Exchange's disciplinary rules will continue to exist in harmony with those of Nasdaq ISE. As noted earlier, Nasdaq ISE is similarly proposing to incorporate by reference the BX Rule 8000 and 9000 Series into new chapters 80 and 90 of its rulebook as to well make similar conforming changes to its other rules.

The Exchange believes that harmonizing its investigative, disciplinary, and adjudicatory processes with those of BX will reduce the burden on Members and Associated Persons that are also members of BX, Nasdaq, Phlx, and/or FINRA. The Exchange notes that all of its Members are also members of BX, Nasdaq, Phlx, and/or FINRA. BX, Nasdaq, Phlx, and FINRA already have in place investigative, disciplinary, and adjudicatory processes that are the same or similar to those that the Exchange proposes to incorporate by reference.

As discussed above, the Exchange believes that the proposed Rules will benefit all parties involved in the Exchange's disciplinary and adjudicatory processes as they will include greater detail and specificity than do the Existing Rules. The proposal will render the Exchange's investigatory, disciplinary, and adjudicatory processes more transparent than the Existing Rules.

The Exchange also believes that adopting an Exchange Review Council is consistent with the Act because the Council's mandate is to, among other things, ensure consistent and fair application of the Exchange rules pertaining to discipline of Members and Associated Persons. The Exchange Review Council will be a body appointed by the Exchange Board of Directors and composed of representatives of the securities industry as well as persons from outside the securities industry. The broad membership of the new Exchange Review Council will ensure that the decisions and guidance it provides will be fair and balanced. The Exchange Review Council will be similar in structure and function to the BX exchange review council. In addition to reviewing appeals of disciplinary actions, the Exchange Review Council will also have jurisdiction to review membership decisions (proposed Rule 303), and appeals regarding limitations placed on Members or their employees that are subject to a statutory disqualification (BX Rule 9524). Additionally, the Exchange Review Council may consider and make recommendations to the Board on policy and rule changes relating to business and sales practices of Exchange Members and Associated Persons, and enforcement policies, including policies with respect to fines and other sanctions. Thus, the Exchange Review Council will provide the Exchange and market participants with a fair and impartial body overseeing disciplinary matters, as well as the rules and policies concerning the disciplinary process. For these reasons, the Exchange believes that adoption of the Exchange Review Council is consistent with the Act.

The Exchange believes that eliminating the BCC, the OEP (as provided for under Existing Rule 720), and the Review Panel (as provided for under Existing Rule 720A) is consistent with Sections 6(b)(5) and 6(b)(6) of the Act,[44] because the Exchange Review Council and the New Hearing Panels will assume the responsibilities of the BCC and the Panels. In particular, the functions of the current Hearing Panels of the BCC (''Current Hearing Panels'')—which include adjudicating disciplinary actions—will be handled by new Hearing Panels, which FINRA's Office of Hearing Officers (''OHO'') shall convene (''New Hearing Panels'').[45] Going forward, the BCC's (and the CRO's) responsibility for approving settlements will be assumed by the Exchange Review Council and, in certain instances, FINRA's Office of Disciplinary Affairs (the ''ODA'').[46] The BCC's responsibilities for hearing appeals of Exchange decisions on membership or association with a Member will be assumed by the Exchange Review Council. The responsibilities of the OEP and the Review Panel to hear appeals of Exchange determinations to nullify or adjust transactions that involve obvious errors or that result from system disruptions and malfunctions also will be assumed by the Exchange Review Council. The Exchange believes that the proposal will provide for the Exchange Review Council, the New Hearing Panels, and the ODA to execute the responsibilities of the BCC and the Panels in a manner that the Commission, within the context of the BX Rules, has already deemed to be consistent with the Act.[47] For example, the Exchange proposes to replace its existing process for handling appeals of membership decisions, as set forth in Existing Rule 303 and Chapter 17, with a process that BX already employs in BX Rules 1015 and 1016. Moreover, Exchange Members and Associated Persons will already be familiar with the proposed responsibilities and procedures of the Exchange Review Council, the New Hearing Panels, and the ODA from their experiences as members of BX and other SROs whose rules provide for similar assignments of responsibilities and processes.

The Exchange believes that its proposal furthers the objectives of Section 6(b)(7) of the Act[48] in that it is designed to provide a fair procedure for the disciplining of Members and Associated Persons, the denial of membership to any person seeking membership therein, the barring of any person from becoming associated with a Member thereof, and the prohibition or limitation by the Exchange of any person with respect to access to services offered by the Exchange or a Member thereof. Specifically, the Exchange believes that the proposed investigatory, disciplinary, and adjudicatory processes are consistent with Section 6(b)(7) of the Act[49] because they are based on the existing processes used by BX. The BX processes are well-established as consistent with the Act.[50]

Last, the Exchange believes that its proposal to phase-in the implementation of the new investigatory, disciplinary, and adjudicatory processes is consistent with Section 6(b)(7)[51] of the Act because both the current and proposed processes are consistent with the Act, providing fair procedures for investigating, disciplining, and adjudicating the rights of Members and Associated Persons. The Exchange is proposing to provide advanced notice of the implementation date of the new processes, and will apply the new

[43] 15 U.S.C. 78f(b)(5)–(6).

[44] *Id.*

[45] The OHO is an office within FINRA that is independent of the FINRA enforcement function and not involved in investigating or litigating cases.

[46] Pursuant to BX Rule 9270, proposed settlements must be submitted to and accepted by the Exchange Review Council, except that proposed settlements involving an affiliate of the Exchange must be reviewed by the ODA. Like the OHO, the ODA is an office within FINRA that is independent of the FINRA enforcement function and not involved in investigating or litigating cases.

[47] *See* Securities Exchange Act Release No. 34–59154 (Dec. 23, 2008), 73 FR 80468 (Dec. 31, 2008) (SR–BSE–2008–048).

[48] 15 U.S.C. 78f(b)(7).

[49] *Id.*

[50] *See* n.46, *supra.*

[51] 15 U.S.C. 78f(b)(7).

processes to new matters that are initiated on or after that implementation date. Any matters initiated prior to the implementation date will be completed using the current processes. As a consequence, the Exchange will delete the applicable portions of Chapters 15–17 from the Exchange's Rulebook, but it will maintain a transitional Rulebook on the Exchange's public rules website (*http://nasdaqmrx.cchwallstreet.com/*), which will contain the Exchange Rules as they are at the time of filing this rule change.[52] These transitional Rules will apply exclusively to the matters initiated prior to the implementation date. Upon conclusion of the last matter to which the transitional rules apply, the Exchange will remove the defunct transitional rules from its public rules website. Thus, the transition will be conducted in a fair, orderly, and transparent manner.

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, as amended [sic]. The proposed rule change is not intended to address competitive issues, but it should reduce burdens on Members, [sic] and Associated Persons. Specifically and as described in detail above, the Exchange believes that this change will bring efficiency and consistency in application of the investigative, disciplinary, and adjudicatory processes, thereby reducing the burden on Members and Associated Persons who are also members of BX and the other Nasdaq, Inc. Exchanges.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[53] and subparagraph (f)(6) of Rule 19b–4 thereunder.[54]

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: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–MRX–2018–23 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–MRX–2018–23. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 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–MRX–2018–23 and should be submitted on or before August 21, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[55]

Eduardo A. Aleman,

Assistant Secretary.

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[52] The posting of the transitional rules on the public rules website will make it clear what disciplinary proceedings are governed by the transitional rules (*i.e.,* matters initiated prior to the implementation date).

[53] 15 U.S.C. 78s(b)(3)(A)(iii).

[54] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[55] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–83709; File No. SR–NYSENAT–2018–15]

Self-Regulatory Organizations; NYSE National, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Schedule of Fees and Rebates

July 25, 2018.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on July 13, 2018, NYSE National, Inc. (''Exchange'' or ''NYSE National'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its Schedule of Fees and Rebates (the ''Price List'') related to colocation to provide Users with access to the

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

systems, and connectivity to the data feeds, of various additional third parties. In addition, the Exchange proposes to amend its Price List to update the names of certain third parties to reflect their current names. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the co-location [4] services offered by the Exchange to provide Users [5] with access to the systems, and connectivity to the data feeds, of various additional third parties. In addition, the Exchange proposes to amend its Price List to update the names of certain third parties to reflect their current names. The Exchange proposes to make the corresponding amendments to the Exchange's Price List related to these co-location services to reflect these proposed changes.

As set forth in the Price List, the Exchange charges fees for connectivity to the execution systems of third party markets and other content service providers (''Third Party Systems''), and data feeds from third party markets and other content service providers (''Third Party Data Feeds'').[6] The lists of Third Party Systems and Third Party Data Feeds are set forth in the Price List.

The Exchange proposes to provide access to BM&F Bovespa, Canadian Securities Exchange (''CSE''), ITG TriAct MatchNow, NASDAQ Canada, Neo Aequitas, Omega, and OTC Markets Group as additional Third Party Systems (''Proposed Third Party Systems''). In addition, it proposes to provide connectivity to the same third parties' data feeds, with the exception of the OTC Markets Group [7] (''Proposed Third Party Data Feeds'').

BM&F Bovespa is a Brazilian national securities exchange. CSE and Neo Aequitas are Canadian national securities exchanges. NASDAQ Canada, also Canadian national securities exchange, operates three trading books for trading in Canadian securities: CXC, CXD, and CX2. ITG TriAct MatchNow and Omega are Canadian alternative markets that match customer orders in Canadian securities. OTC Markets Group operates trading platforms for over-the-counter securities.

The Exchange would provide access to the Proposed Third Party Systems (''Access''), and connectivity to the Proposed Third Party Data Feeds (''Connectivity''), as conveniences to Users. Use of Access or Connectivity would be completely voluntary. The Exchange is not aware of any impediment to third parties offering Access or Connectivity.

The Exchange does not have visibility into whether third parties currently offer, or intend to offer, Users access to the Proposed Third Party Systems and connectivity to the Proposed Third Party Data Feeds, as such third parties are not required to make that information public. However, if one or more third parties presently offer, or in the future opt to offer, such Access and Connectivity to Users, a User may utilize the Secure Financial Transaction Infrastructure (''SFTI'') network, a third party telecommunication network, third party wireless network, a cross connect, or a combination thereof to access such services and products through a connection to an access center outside the data center (which could be a SFTI access center, a third-party access center, or both), another User, or a third party vendor.

Access to the Proposed Third Party Systems

The Exchange proposes to revise the Price List to provide that Users may obtain connectivity to the Proposed Third Party Systems for a fee. As with the current Third Party Systems, Users would connect to the Proposed Third Party Systems over the internet protocol (''IP'') network, a local area network available in the data center.[8]

As with the current Third Party Systems, in order to obtain access to a Proposed Third Party System, the User would enter into an agreement with the relevant Proposed Third Party, pursuant to which the third party content service provider would charge the User for access to the Proposed Third Party System. The Exchange would then establish a unicast connection between the User and the Proposed Third Party System over the IP network.[9] The Exchange would charge the User for the connectivity to the Proposed Third Party System. A User would only receive, and only be charged for, access to the Proposed Third Party System for which it enters into agreements with the third party content service provider.

The Exchange has no ownership interest in any of the Proposed Third Party Systems. Establishing a User's access to a Proposed Third Party System would not give the Exchange any right to use the Proposed Third Party System. Connectivity to a Proposed Third Party System would not provide access or order entry to the Exchange's execution system, and a User's connection to the Proposed Third Party System would not be through the Exchange's execution system.

As with the existing connections to Third Party Systems, the Exchange proposes to charge a monthly recurring fee for connectivity to the Proposed Third Party Systems. Specifically, when a User requests access to a Proposed Third Party System, it would identify the applicable content service provider and what bandwidth connection it required.

The Exchange proposes to modify its Price List to add the Proposed Third Party Systems to its existing list of Third Party Systems. The Exchange does not

[4] The Exchange initially filed rule changes relating to its co-location services with the Commission on May 18, 2018. *See* Securities Exchange Act Release No. 83351 (May 31, 2018), 83 FR 26314 (June 6, 2018) (SR–NYSENAT–2018–07). The Exchange operates a data center in Mahwah, New Jersey (the ''data center'') from which it provides co-location services to Users.

[5] For purposes of the Exchange's co-location services, a ''User'' means any market participant that requests to receive co-location services directly from the Exchange. *See id.* at note 9. As specified in the Price List, a User that incurs co-location fees for a particular co-location service pursuant thereto would not be subject to co-location fees for the same co-location service charged by the Exchange's affiliates NYSE American LLC (''NYSE American''), New York Stock Exchange LLC (''NYSE''), and NYSE Arca, Inc. (''NYSE Arca'' and, together with NYSE American and NYSE, the ''Affiliate SROs''). *See id.* at note 11.

[6] *See supra* note 4.

[7] The Exchange currently provides connectivity to the OTC Markets Group data feed as a Third Party Data Feed.

[8] *See supra* note 4.

[9] Information flows over existing network connections in two formats: ''unicast'' format, which is a format that allows one-to-one communication, similar to a phone line, in which information is sent to and from the Exchange; and ''multicast'' format, which is a format in which information is sent one-way from the Exchange to multiple recipients at once, like a radio broadcast.

propose to change the monthly recurring fee the Exchange charges Users for unicast connectivity to each Third Party System, including the Proposed Third Party Systems.

Connectivity to the Proposed Third Party Data Feeds

The Exchange proposes to revise the Price List to provide that Users may obtain connectivity to the Proposed Third Party Data Feeds for a fee. The Exchange would receive a Proposed Third Party Data Feed from the content service provider at the Exchange's data center. The Exchange would then provide connectivity to that data to Users for a fee. Users would connect to the Proposed Third Party Data Feeds over the IP network.[10] The Proposed Third Party Data Feeds would include trading information concerning the securities that are traded on the relevant Proposed Third Party Systems.

In order to connect to a Proposed Third Party Data Feed, a User would enter into a contract with the content service provider, pursuant to which the content service provider would charge the User for the data feed. The Exchange would receive the Proposed Third Party Data Feed over its fiber optic network and, after the content service provider and User entered into the contract and the Exchange received authorization from the content service provider, the Exchange would re-transmit the data to the User over the User's port. The Exchange would charge the User for the connectivity to the Proposed Third Party Data Feed. A User would only receive, and would only be charged for, connectivity to a Proposed Third Party Data Feed for which it entered into a contract.

The Exchange has no affiliation with the sellers of the Proposed Third Party Data Feeds. It would have no right to use the Proposed Third Party Data Feeds other than as a redistributor of the data. The Proposed Third Party Data Feeds would not provide access or order entry to the Exchange's execution system. The Proposed Third Party Data Feeds would not provide access or order entry to the execution systems of the third parties generating the feeds. The Exchange would receive the Proposed Third Party Data Feeds via arms-length agreements and it would have no inherent advantage over any other distributor of such data.

As it does with the existing Third Party Data Feeds, the Exchange proposes to charge a monthly recurring fee for connectivity to the Proposed Third Party Data Feeds. Depending on its needs and bandwidth, a User may opt to receive all or some of the feeds or services included in the Proposed Third Parties' Data Feeds.

The Exchange proposes to add the following fees for connectivity to the Proposed Third Party Data Feeds to its existing list in the Price List: (i) A $3,000 per month fee for BM&F Bovespa; (ii) a $1,500 per month fee for NASDAQ Canada; (iii) a $1,200 fee for Neo Aequitas; and (iv) a $1,000 per month fee for each of the CSE, ITG TriAct MatchNow and Omega.

Name Changes

The Exchange proposes to update references to the International Securities Exchange, LLC (''ISE'') to reflect its acquisition by NASDAQ, Inc. (''NASDAQ'').[11] The Exchange also proposes to update references to Bats and Chicago Board Options Exchange (''Cboe'') to reflect their business combination and name changes.[12] In the sections entitled, ''Connectivity to Third Party Systems'' and ''Connectivity to Third Party Data Feeds'', the Exchange proposes to replace references to ''International Securities Exchange (ISE)'' with ''NASDAQ ISE''. The Exchange also proposes to delete a reference to ''BATS'' and replace it with ''Cboe BYX Exchange (CboeBYX), Cboe BZX Exchange (CboeBZX), Cboe EDGA Exchange (CboeEDGA), and Cboe EDGX Exchange (CboeEDGX)'' and to replace references to ''Chicago Board Options Exchange (CBOE)'' with ''Cboe Exchange (Cboe) and Cboe C2 Exchange (C2)''. In each case, the names would be updated to their current names, clearly delineating the third parties to which the Exchange provides connectivity and access.

In a non-substantive change, the Exchange proposes to reorganize the table of Third Party Systems to ensure it remains alphabetical in light of the proposed name changes. The Exchange does not propose to amend any fee related to connectivity to ISE or Cboe systems or access to ISE or Cboe data.

General

As is the case with all Exchange co-location arrangements, (i) neither a User nor any of the User's customers would be permitted to submit orders directly to the Exchange unless such User or customer is a member organization, a Sponsored Participant or an agent thereof (*e.g.,* a service bureau providing order entry services); (ii) use of the co-location services proposed herein would be completely voluntary and available to all Users on a non-discriminatory basis; [13] and (iii) a User would only incur one charge for the particular co-location service described herein, regardless of whether the User connects only to the Exchange or to the Exchange and one or more of the Affiliate SROs.[14]

The proposed change is not otherwise intended to address any other issues relating to co-location services and/or related fees, and the Exchange is not aware of any problems that Users would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed fee change is consistent with Section 6(b) of the Act,[15] in general, and furthers the objectives of Sections 6(b)(5) of the Act,[16] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to, and perfect the mechanisms of, a free and open market and a national market system and, in general, to protect investors and the public interest and because it is not designed to permit

[10] *See supra* note 4, at 26315, 26316.

[11] *See* Securities Exchange Act Release No. 78119 (June 27, 2016), 81 FR 41611 (SR–ISE2016–11; SR–ISE Gemini–2016–05; SR–ISE Mercury–2016–10) (Order Granting Accelerated Approval of Proposed Rule Changes, Each as Modified by Amendment No. 1 Thereto, Relating to a Corporate Transaction in Which Nasdaq, Inc. Will Become the Indirect Parent of ISE, ISE Gemini, and ISE Mercury). *See also* Securities Exchange Act Release No. 80325 (March 29, 2017), 82 FR 16445 (April 4, 2017) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Rename the Exchange as Nasdaq ISE, LLC).

[12] *See, e.g.,* Securities Exchange Act Release No. 81981 (October 30, 2017), 82 FR 51309 (November 3, 2017) (SR–CBOE–2017–066); and 81962 (October 26, 2017), 82 FR 50711 (November 1, 2017) (SR–BatsBZX–2017–70).

[13] As is currently the case, Users that receive co-location services from the Exchange will not receive any means of access to the Exchange's trading and execution systems that is separate from, or superior to, that of other Users. In this regard, all orders sent to the Exchange enter the Exchange's trading and execution systems through the same order gateway, regardless of whether the sender is co-located in the data center or not. In addition, co-located Users do not receive any market data or data service product that is not available to all Users, although Users that receive co-location services normally would expect reduced latencies in sending orders to, and receiving market data from, the Exchange.

[14] *See* SR–NYSENAT–2018–07, *supra* note 4 at 26314. The Affiliate SROs have also submitted substantially the same proposed rule change to propose the changes described herein. *See* SR–NYSEArca–2018–52, SR–NYSEAmerican–2018–35, and SR–NYSE–2018–32.

[15] 15 U.S.C. 78f(b).

[16] 15 U.S.C. 78f(b)(5).

unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed changes would remove impediments to, and perfect the mechanisms of, a free and open market and a national market system and, in general, protect investors and the public interest because, by offering additional services, the Exchange would give each User additional options for addressing its access and connectivity needs, responding to User demand for access and connectivity options. Providing additional services would help each User tailor its data center operations to the requirements of its business operations by allowing it to select the form and latency of access and connectivity that best suits its needs.

The Exchange would provide Access and Connectivity as conveniences to Users. Use of Access or Connectivity would be completely voluntary. The Exchange is not aware of any impediment to third parties offering Access or Connectivity. The Exchange does not have visibility into whether third parties currently offer, or intend to offer, Users access to the Proposed Third Party Systems and connectivity to the Proposed Third Party Data Feeds. However, if one or more third parties presently offer, or in the future opt to offer, such access and connectivity to Users, a User may utilize the SFTI network, a third party telecommunication network, third party wireless network, a cross connect, or a combination thereof to access such services and products through a connection to an access center outside the data center (which could be a SFTI access center, a third-party access center, or both), another User, or a third party vendor.

The Exchange believes that the proposed changes would remove impediments to, and perfect the mechanisms of, a free and open market and a national market system and, in general, protect investors and the public interest because, by offering Access and Connectivity to Users when available, the Exchange would give Users additional options for connectivity and access to new services as soon as they are available, responding to User demand for access and connectivity options.

The Exchange also believes that the proposed fee change is consistent with Section 6(b)(4) of the Act,[17] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Exchange believes that the proposed fee changes are consistent with Section 6(b)(4) of the Act for multiple reasons. The Exchange operates in a highly competitive market in which exchanges offer co-location services as a means to facilitate the trading and other market activities of those market participants who believe that co-location enhances the efficiency of their operations. Accordingly, fees charged for co-location services are constrained by the active competition for the order flow of, and other business from, such market participants. If a particular exchange charges excessive fees for co-location services, affected market participants will opt to terminate their co-location arrangements with that exchange, and adopt a possible range of alternative strategies, including placing their servers in a physically proximate location outside the exchange's data center (which could be a competing exchange), or pursuing strategies less dependent upon the lower exchange-to-participant latency associated with co-location. Accordingly, the exchange charging excessive fees would stand to lose not only co-location revenues but also the liquidity of the formerly co-located trading firms, which could have additional follow-on effects on the market share and revenue of the affected exchange.

The Exchange believes that the additional services and fees proposed herein would be equitably allocated and not unfairly discriminatory because, in addition to the services being completely voluntary, they would be available to all Users on an equal basis (*i.e.,* the same products and services would be available to all Users). All Users that voluntarily selected to receive Access or Connectivity would be charged the same amount for the same services. Users that opted to use Access or Connectivity would not receive access or connectivity that is not available to all Users, as all market participants that contracted with the relevant market or content provider would receive access or connectivity.

The Exchange believes that the proposed charges would be reasonable, equitably allocated and not unfairly discriminatory because the Exchange would offer the Access and Connectivity as conveniences to Users, but in order to do so must provide, maintain and operate the data center facility hardware and technology infrastructure. The Exchange must handle the installation, administration, monitoring, support and maintenance of such services, including by responding to any production issues. Since the inception of co-location, the Exchange has made numerous improvements to the network hardware and technology infrastructure and has established additional administrative controls. The Exchange has expanded the network infrastructure to keep pace with the increased number of services available to Users, including resilient and redundant feeds. In addition, in order to provide Access and Connectivity, the Exchange would maintain multiple connections to each Proposed Third Party Data Feed and Proposed Third Party System, allowing the Exchange to provide resilient and redundant connections; adapt to any changes made by the relevant third party; and cover any applicable fees charged by the relevant third party, such as port fees. In addition, Users would not be required to use any of their bandwidth for Access and Connectivity unless they wish to do so.

The Exchange believes the proposed fees for Access and Connectivity would be reasonable because they would allow the Exchange to defray or cover the costs associated with offering Users Access and Connectivity while providing Users the convenience of receiving such Access and Connectivity within co-location, helping them tailor their data center operations to the requirements of their business operations.

For the reasons above, the proposed changes would not unfairly discriminate between or among market participants that are otherwise capable of satisfying any applicable co-location fees, requirements, terms and conditions established from time to time by the Exchange.

The Exchange also believes that the proposal to update the names of ISE, Bats and Cboe removes impediments to, and perfects the mechanisms of, a free and open market and a national market system. The Exchange does not propose to amend any fee related to connectivity to ISE or Cboe systems or access to ISE or Cboe data. The Exchange simply proposes to update its Price List to accurately reflect NASDAQ's acquisition of ISE and the business combination and name change of Bats and Cboe. Therefore, the Exchange believes the proposed rule change would avoid any potential investor confusion regarding the third parties to which the Exchange provides access and connectivity.

The Exchange believes that the non-substantive change to ensure the names in the table of Third Party Systems are in alphabetical order would remove impediments to, and perfect the

[17] 15 U.S.C. 78f(b)(4).

mechanisms of, a free and open market and a national market system and, in general, protect investors and the public interest because the amendment would clarify Exchange rules and make it easier for market participants to find Third Party Systems in the table. The Exchange believes that this proposed non-substantive change is reasonable because the change would have no impact on pricing or services offered. Rather, the change would alleviate possible market participant confusion by making it easier to find NASDAQ, ISE and Cboe in the table.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[18] the Exchange believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act because all of the proposed services are completely voluntary.

The Exchange believes that providing Users with additional options for connectivity and access to new services would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act because such proposed Access and Connectivity would satisfy User demand for access and connectivity options. The Exchange would provide Access and Connectivity as conveniences equally to all Users. The Exchange does not have visibility into whether third parties currently offer, or intend to offer, Users access to the Proposed Third Party Systems and connectivity to the Proposed Third Party Data Feeds, as third parties are not required to make that information public. However, if one or more third parties presently offer, or in the future opt to offer, such access and connectivity to Users, a User may utilize the SFTI network, a third party telecommunication network, third party wireless network, a cross connect, or a combination thereof to access such services and products through a connection to an access center outside the data center (which could be a SFTI access center, a third-party access center, or both), another User, or a third party vendor. Users that opt to use the proposed Access or Connectivity would not receive access or connectivity that is not available to all Users, as all market participants that contract with the content provider may receive access or connectivity. In this way, the proposed changes would enhance competition by helping Users tailor their Access and Connectivity to the needs of their business operations by allowing them to select the form and latency of access and connectivity that best suits their needs.

The Exchange operates in a highly competitive market in which exchanges offer co-location services as a means to facilitate the trading and other market activities of those market participants who believe that co-location enhances the efficiency of their operations. Accordingly, fees charged for co-location services are constrained by the active competition for the order flow of, and other business from, such market participants. If a particular exchange charges excessive fees for co-location services, affected market participants will opt to terminate their co-location arrangements with that exchange, and adopt a possible range of alternative strategies, including placing their servers in a physically proximate location outside the exchange's data center (which could be a competing exchange), or pursuing strategies less dependent upon the lower exchange-to-participant latency associated with co-location. Accordingly, the exchange charging excessive fees would stand to lose not only co-location revenues but also the liquidity of the formerly co-located trading firms, which could have additional follow-on effects on the market share and revenue of the affected exchange. For the reasons described above, the Exchange believes that the proposed rule change reflects this competitive environment.

The Exchange believes that the proposal to update the name of ISE to reflect its acquisition by NASDAQ and Bats and Cboe to reflect their business combination and name change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposal is ministerial in nature and is not designed to have any competitive impact. It simply seeks to update the Price List to accurately reference these markets in light of their recent name changes.

The Exchange believes that the proposed non-substantive change to ensure the names in the table of Third Party Systems are in alphabetical order would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act because the change would have no impact on pricing or the services offered. Rather, the change would alleviate possible market participant confusion by making it easier to find Third Party Systems in the table.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[19] and Rule 19b–4(f)(6) thereunder.[20] 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 prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.[21]

A proposed rule change filed under Rule 19b–4(f)(6)[22] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[23] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange requests that the Commission waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange represents that the proposed rule changes present no new or novel issues. According to the Exchange, waiver of the operative delay would allow Users to access the Proposed Third Party Systems and the Proposed Third Party Data Feeds without delay, which would assist Users in tailoring their data center operations to the requirements of their business operations. The Exchange also represents that the proposed changes to the Price List would provide Users with more complete information regarding

[18] 15 U.S.C. 78f(b)(8).

[19] 15 U.S.C. 78s(b)(3)(A)(iii).

[20] 17 CFR 240.19b–4(f)(6).

[21] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[22] 17 CFR 240.19b–4(f)(6).

[23] 17 CFR 240.19b–4(f)(6)(iii).

their Access and Connectivity options. The Exchange further asserts that waiver of the operative delay would help avoid potential investor confusion by allowing the Exchange to immediately update the names of the exchanges noted above to reflect recent business combinations and name changes. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission waives the 30-day operative delay and designates the proposed rule change operative upon filing.[24]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[25] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSENAT–2018–15 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSENAT–2018–15. 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–NYSENAT–2018–15 and should be submitted on or before August 21, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[26]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–16277 Filed 7–30–18; 8:45 am]

BILLING CODE 8011–01–P

[24] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[25] 15 U.S.C. 78s(b)(2)(B).

[26] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–83706; File No. SR–NYSE–2018–32]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Price List Related to Colocation

July 25, 2018.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on July 13, 2018, New York Stock Exchange LLC (''NYSE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its Price List related to colocation to provide Users with access to the systems, and connectivity to the data feeds, of various additional third parties. In addition, the Exchange proposes to amend its Price List to update the names of certain third parties to reflect their current names. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the co-location[4] services offered by the Exchange to provide Users[5] with access to the systems, and connectivity to the

[4] The Exchange initially filed rule changes relating to its co-location services with the Commission in 2010. *See* Securities Exchange Act Release No. 62960 (September 21, 2010), 75 FR 59310 (September 27, 2010) (SR–NYSE–2010–56). The Exchange operates a data center in Mahwah, New Jersey (the ''data center'') from which it provides co-location services to Users.

[5] For purposes of the Exchange's co-location services, a ''User'' means any market participant that requests to receive co-location services directly from the Exchange. *See* Securities Exchange Act Release No. 76008 (September 29, 2015), 80 FR 60190 (October 5, 2015) (SR–NYSE–2015–40). As specified in the Price List, a User that incurs co-location fees for a particular co-location service pursuant thereto would not be subject to co-location fees for the same co-location service charged by the Exchange's affiliates NYSE American LLC (''NYSE American''), NYSE National, Inc. (''National''), and NYSE Arca, Inc. (''NYSE Arca'' and, together with NYSE American and NYSE National, the ''Affiliate SROs''). *See* Securities Exchange Act Release No. 70206 (August 15, 2013), 78 FR 51765 (August 21, 2013) (SR–NYSE–2013–59).

data feeds, of various additional third parties. In addition, the Exchange proposes to amend its Price List to update the names of certain third parties to reflect their current names. The Exchange proposes to make the corresponding amendments to the Exchange's Price List related to these co-location services to reflect these proposed changes.

As set forth in the Price List, the Exchange charges fees for connectivity to the execution systems of third party markets and other content service providers (''Third Party Systems''), and data feeds from third party markets and other content service providers (''Third Party Data Feeds'').[6] The lists of Third Party Systems and Third Party Data Feeds are set forth in the Price List.

The Exchange proposes to provide access to BM&F Bovespa, Canadian Securities Exchange (''CSE''), ITG TriAct MatchNow, NASDAQ Canada, Neo Aequitas, Omega, and OTC Markets Group as additional Third Party Systems (''Proposed Third Party Systems''). In addition, it proposes to provide connectivity to the same third parties' data feeds, with the exception of the OTC Markets Group[7] (''Proposed Third Party Data Feeds'').

BM&F Bovespa is a Brazilian national securities exchange. CSE and Neo Aequitas are Canadian national securities exchanges. NASDAQ Canada, also Canadian national securities exchange, operates three trading books for trading in Canadian securities: CXC, CXD, and CX2. ITG TriAct MatchNow and Omega are Canadian alternative markets that match customer orders in Canadian securities. OTC Markets Group operates trading platforms for over-the-counter securities.

The Exchange would provide access to the Proposed Third Party Systems (''Access''), and connectivity to the Proposed Third Party Data Feeds (''Connectivity''), as conveniences to Users. Use of Access or Connectivity would be completely voluntary. The Exchange is not aware of any impediment to third parties offering Access or Connectivity.

The Exchange does not have visibility into whether third parties currently offer, or intend to offer, Users access to the Proposed Third Party Systems and connectivity to the Proposed Third Party Data Feeds, as such third parties are not required to make that information public. However, if one or more third parties presently offer, or in the future opt to offer, such Access and Connectivity to Users, a User may utilize the Secure Financial Transaction Infrastructure (''SFTI'') network, a third party telecommunication network, third party wireless network, a cross connect, or a combination thereof to access such services and products through a connection to an access center outside the data center (which could be a SFTI access center, a third-party access center, or both), another User, or a third party vendor.

Access to the Proposed Third Party Systems

The Exchange proposes to revise the Price List to provide that Users may obtain connectivity to the Proposed Third Party Systems for a fee. As with the current Third Party Systems, Users would connect to the Proposed Third Party Systems over the internet protocol (''IP'') network, a local area network available in the data center.[8]

As with the current Third Party Systems, in order to obtain access to a Proposed Third Party System, the User would enter into an agreement with the relevant Proposed Third Party, pursuant to which the third party content service provider would charge the User for access to the Proposed Third Party System. The Exchange would then establish a unicast connection between the User and the Proposed Third Party System over the IP network.[9] The Exchange would charge the User for the connectivity to the Proposed Third Party System. A User would only receive, and only be charged for, access to the Proposed Third Party System for which it enters into agreements with the third party content service provider.

The Exchange has no ownership interest in any of the Proposed Third Party Systems. Establishing a User's access to a Proposed Third Party System would not give the Exchange any right to use the Proposed Third Party System. Connectivity to a Proposed Third Party System would not provide access or order entry to the Exchange's execution system, and a User's connection to the Proposed Third Party System would not be through the Exchange's execution system.

As with the existing connections to Third Party Systems, the Exchange proposes to charge a monthly recurring fee for connectivity to the Proposed Third Party Systems. Specifically, when a User requests access to a Proposed Third Party System, it would identify the applicable content service provider and what bandwidth connection it required.

The Exchange proposes to modify its Price List to add the Proposed Third Party Systems to its existing list of Third Party Systems. The Exchange does not propose to change the monthly recurring fee the Exchange charges Users for unicast connectivity to each Third Party System, including the Proposed Third Party Systems.

Connectivity to the Proposed Third Party Data Feeds

The Exchange proposes to revise the Price List to provide that Users may obtain connectivity to the Proposed Third Party Data Feeds for a fee. The Exchange would receive a Proposed Third Party Data Feed from the content service provider at the Exchange's data center. The Exchange would then provide connectivity to that data to Users for a fee. Users would connect to the Proposed Third Party Data Feeds over the IP network.[10] The Proposed Third Party Data Feeds would include trading information concerning the securities that are traded on the relevant Proposed Third Party Systems.

In order to connect to a Proposed Third Party Data Feed, a User would enter into a contract with the content service provider, pursuant to which the content service provider would charge the User for the data feed. The Exchange would receive the Proposed Third Party Data Feed over its fiber optic network and, after the content service provider and User entered into the contract and the Exchange received authorization from the content service provider, the Exchange would re-transmit the data to the User over the User's port. The Exchange would charge the User for the connectivity to the Proposed Third Party Data Feed. A User would only receive, and would only be charged for, connectivity to a Proposed Third Party Data Feed for which it entered into a contract.

The Exchange has no affiliation with the sellers of the Proposed Third Party Data Feeds. It would have no right to use the Proposed Third Party Data Feeds

[6] *See* Securities Exchange Act Release No. 80311 (March 24, 2017), 82 FR 15741 (March 30, 2017) (SR–NYSE–2016–45).

[7] The Exchange currently provides connectivity to the OTC Markets Group data feed as a Third Party Data Feed.

[8] *See* Securities Exchange Act Release No. 74222 (February 6, 2015), 80 FR 7888 (February 12, 2015) (SR–NYSE–2015–05) (notice of filing and immediate effectiveness of proposed rule change to include IP network connections).

[9] Information flows over existing network connections in two formats: ''unicast'' format, which is a format that allows one-to-one communication, similar to a phone line, in which information is sent to and from the Exchange; and ''multicast'' format, which is a format in which information is sent one-way from the Exchange to multiple recipients at once, like a radio broadcast.

[10] *See supra* note 8, at 7888 (''The IP network also provides Users with access to away market data products'').

other than as a redistributor of the data. The Proposed Third Party Data Feeds would not provide access or order entry to the Exchange's execution system. The Proposed Third Party Data Feeds would not provide access or order entry to the execution systems of the third parties generating the feeds. The Exchange would receive the Proposed Third Party Data Feeds via arms-length agreements and it would have no inherent advantage over any other distributor of such data.

As it does with the existing Third Party Data Feeds, the Exchange proposes to charge a monthly recurring fee for connectivity to the Proposed Third Party Data Feeds. Depending on its needs and bandwidth, a User may opt to receive all or some of the feeds or services included in the Proposed Third Parties' Data Feeds.

The Exchange proposes to add the following fees for connectivity to the Proposed Third Party Data Feeds to its existing list in the Price List: (i) A $3,000 per month fee for BM&F Bovespa; (ii) a $1,500 per month fee for NASDAQ Canada; (iii) a $1,200 fee for Neo Aequitas; and (iv) a $1,000 per month fee for each of the CSE, ITG TriAct MatchNow and Omega.

Name Changes

The Exchange proposes to update references to the International Securities Exchange, LLC (''ISE'') to reflect its acquisition by NASDAQ, Inc. (''NASDAQ'').[11] The Exchange also proposes to update references to Bats and Chicago Board Options Exchange (''Cboe'') to reflect their business combination and name changes.[12] In the sections entitled, ''Connectivity to Third Party Systems'' and ''Connectivity to Third Party Data Feeds'', the Exchange proposes to replace references to ''International Securities Exchange (ISE)'' with ''NASDAQ ISE''. The Exchange also proposes to delete a reference to ''BATS'' and replace it with ''Cboe BYX Exchange (CboeBYX), Cboe BZX Exchange (CboeBZX), Cboe EDGA Exchange (CboeEDGA), and Cboe EDGX Exchange (CboeEDGX)'' and to replace references to ''Chicago Board Options Exchange (CBOE)'' with ''Cboe Exchange (Cboe) and Cboe C2 Exchange (C2)''. In each case, the names would be updated to their current names, clearly delineating the third parties to which the Exchange provides connectivity and access.

In a non-substantive change, the Exchange proposes to reorganize the table of Third Party Systems to ensure it remains alphabetical in light of the proposed name changes. The Exchange does not propose to amend any fee related to connectivity to ISE or Cboe systems or access to ISE or Cboe data.

General

As is the case with all Exchange co-location arrangements, (i) neither a User nor any of the User's customers would be permitted to submit orders directly to the Exchange unless such User or customer is a member organization, a Sponsored Participant or an agent thereof (*e.g.,* a service bureau providing order entry services); (ii) use of the co-location services proposed herein would be completely voluntary and available to all Users on a non-discriminatory basis; [13] and (iii) a User would only incur one charge for the particular co-location service described herein, regardless of whether the User connects only to the Exchange or to the Exchange and one or more of the Affiliate SROs.[14]

The proposed change is not otherwise intended to address any other issues relating to co-location services and/or related fees, and the Exchange is not aware of any problems that Users would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed fee change is consistent with Section 6(b) of the Act,[15] in general, and furthers the objectives of Sections 6(b)(5) of the Act,[16] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to, and perfect the mechanisms of, a free and open market and a national market system and, in general, to protect investors and the public interest and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed changes would remove impediments to, and perfect the mechanisms of, a free and open market and a national market system and, in general, protect investors and the public interest because, by offering additional services, the Exchange would give each User additional options for addressing its access and connectivity needs, responding to User demand for access and connectivity options. Providing additional services would help each User tailor its data center operations to the requirements of its business operations by allowing it to select the form and latency of access and connectivity that best suits its needs.

The Exchange would provide Access and Connectivity as conveniences to Users. Use of Access or Connectivity would be completely voluntary. The Exchange is not aware of any impediment to third parties offering Access or Connectivity. The Exchange does not have visibility into whether third parties currently offer, or intend to offer, Users access to the Proposed Third Party Systems and connectivity to the Proposed Third Party Data Feeds. However, if one or more third parties presently offer, or in the future opt to offer, such access and connectivity to Users, a User may utilize the SFTI network, a third party telecommunication network, third party wireless network, a cross connect, or a combination thereof to access such services and products through a connection to an access center outside the data center (which could be a SFTI access center, a third-party access center, or both), another User, or a third party vendor.

The Exchange believes that the proposed changes would remove impediments to, and perfect the mechanisms of, a free and open market and a national market system and, in general, protect investors and the public

[11] *See* Securities Exchange Act Release No. 78119 (June 27, 2016), 81 FR 41611 (SR–ISE2016–11; SR–ISE Gemini–2016–05; SR–ISE Mercury–2016–10) (Order Granting Accelerated Approval of Proposed Rule Changes, Each as Modified by Amendment No. 1 Thereto, Relating to a Corporate Transaction in Which Nasdaq, Inc. Will Become the Indirect Parent of ISE, ISE Gemini, and ISE Mercury). *See also* Securities Exchange Act Release No. 80325 (March 29, 2017), 82 FR 16445 (April 4, 2017) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Rename the Exchange as Nasdaq ISE, LLC).

[12] *See, e.g.,* Securities Exchange Act Release No. 81981 (October 30, 2017), 82 FR 51309 (November 3, 2017) (SR–CBOE–2017–066); and 81962 (October 26, 2017), 82 FR 50711 (November 1, 2017) (SR-BatsBZX–2017–70).

[13] As is currently the case, Users that receive co-location services from the Exchange will not receive any means of access to the Exchange's trading and execution systems that is separate from, or superior to, that of other Users. In this regard, all orders sent to the Exchange enter the Exchange's trading and execution systems through the same order gateway, regardless of whether the sender is co-located in the data center or not. In addition, co-located Users do not receive any market data or data service product that is not available to all Users, although Users that receive co-location services normally would expect reduced latencies in sending orders to, and receiving market data from, the Exchange.

[14] *See* SR–NYSE–2013–59, *supra* note 6 at 51766. The Affiliate SROs have also submitted substantially the same proposed rule change to propose the changes described herein. *See* SR–NYSEArca–2018–52, SR–NYSEAmerican–2018–35, and SR–NYSENat–2018–15.

[15] 15 U.S.C. 78f(b).

[16] 15 U.S.C. 78f(b)(5).

interest because, by offering Access and Connectivity to Users when available, the Exchange would give Users additional options for connectivity and access to new services as soon as they are available, responding to User demand for access and connectivity options.

The Exchange also believes that the proposed fee change is consistent with Section 6(b)(4) of the Act,[17] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Exchange believes that the proposed fee changes are consistent with Section 6(b)(4) of the Act for multiple reasons. The Exchange operates in a highly competitive market in which exchanges offer co-location services as a means to facilitate the trading and other market activities of those market participants who believe that co-location enhances the efficiency of their operations. Accordingly, fees charged for co-location services are constrained by the active competition for the order flow of, and other business from, such market participants. If a particular exchange charges excessive fees for co-location services, affected market participants will opt to terminate their co-location arrangements with that exchange, and adopt a possible range of alternative strategies, including placing their servers in a physically proximate location outside the exchange's data center (which could be a competing exchange), or pursuing strategies less dependent upon the lower exchange-to-participant latency associated with co-location. Accordingly, the exchange charging excessive fees would stand to lose not only co-location revenues but also the liquidity of the formerly co-located trading firms, which could have additional follow-on effects on the market share and revenue of the affected exchange.

The Exchange believes that the additional services and fees proposed herein would be equitably allocated and not unfairly discriminatory because, in addition to the services being completely voluntary, they would be available to all Users on an equal basis (*i.e.,* the same products and services would be available to all Users). All Users that voluntarily selected to receive Access or Connectivity would be charged the same amount for the same services. Users that opted to use Access or Connectivity would not receive access or connectivity that is not available to all Users, as all market participants that contracted with the relevant market or content provider would receive access or connectivity.

The Exchange believes that the proposed charges would be reasonable, equitably allocated and not unfairly discriminatory because the Exchange would offer the Access and Connectivity as conveniences to Users, but in order to do so must provide, maintain and operate the data center facility hardware and technology infrastructure. The Exchange must handle the installation, administration, monitoring, support and maintenance of such services, including by responding to any production issues. Since the inception of co-location, the Exchange has made numerous improvements to the network hardware and technology infrastructure and has established additional administrative controls. The Exchange has expanded the network infrastructure to keep pace with the increased number of services available to Users, including resilient and redundant feeds. In addition, in order to provide Access and Connectivity, the Exchange would maintain multiple connections to each Proposed Third Party Data Feed and Proposed Third Party System, allowing the Exchange to provide resilient and redundant connections; adapt to any changes made by the relevant third party; and cover any applicable fees charged by the relevant third party, such as port fees. In addition, Users would not be required to use any of their bandwidth for Access and Connectivity unless they wish to do so.

The Exchange believes the proposed fees for Access and Connectivity would be reasonable because they would allow the Exchange to defray or cover the costs associated with offering Users Access and Connectivity while providing Users the convenience of receiving such Access and Connectivity within co-location, helping them tailor their data center operations to the requirements of their business operations.

For the reasons above, the proposed changes would not unfairly discriminate between or among market participants that are otherwise capable of satisfying any applicable co-location fees, requirements, terms and conditions established from time to time by the Exchange.

The Exchange also believes that the proposal to update the names of ISE, Bats and Cboe removes impediments to, and perfects the mechanisms of, a free and open market and a national market system. The Exchange does not propose to amend any fee related to connectivity to ISE or Cboe systems or access to ISE or Cboe data. The Exchange simply proposes to update its Price List to accurately reflect NASDAQ's acquisition of ISE and the business combination and name change of Bats and Cboe. Therefore, the Exchange believes the proposed rule change would avoid any potential investor confusion regarding the third parties to which the Exchange provides access and connectivity.

The Exchange believes that the non-substantive change to ensure the names in the table of Third Party Systems are in alphabetical order would remove impediments to, and perfect the mechanisms of, a free and open market and a national market system and, in general, protect investors and the public interest because the amendment would clarify Exchange rules and make it easier for market participants to find Third Party Systems in the table. The Exchange believes that this proposed non-substantive change is reasonable because the change would have no impact on pricing or services offered. Rather, the change would alleviate possible market participant confusion by making it easier to find NASDAQ, ISE and Cboe in the table.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[18] the Exchange believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act because all of the proposed services are completely voluntary.

The Exchange believes that providing Users with additional options for connectivity and access to new services would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act because such proposed Access and Connectivity would satisfy User demand for access and connectivity options. The Exchange would provide Access and Connectivity as conveniences equally to all Users. The Exchange does not have visibility into whether third parties currently offer, or intend to offer, Users access to the Proposed Third Party Systems and connectivity to the Proposed Third Party Data Feeds, as third parties are not required to make that information public. However, if one or more third parties presently offer, or in the future

[17] 15 U.S.C. 78f(b)(4).

[18] 15 U.S.C. 78f(b)(8).

opt to offer, such access and connectivity to Users, a User may utilize the SFTI network, a third party telecommunication network, third party wireless network, a cross connect, or a combination thereof to access such services and products through a connection to an access center outside the data center (which could be a SFTI access center, a third-party access center, or both), another User, or a third party vendor. Users that opt to use the proposed Access or Connectivity would not receive access or connectivity that is not available to all Users, as all market participants that contract with the content provider may receive access or connectivity. In this way, the proposed changes would enhance competition by helping Users tailor their Access and Connectivity to the needs of their business operations by allowing them to select the form and latency of access and connectivity that best suits their needs.

The Exchange operates in a highly competitive market in which exchanges offer co-location services as a means to facilitate the trading and other market activities of those market participants who believe that co-location enhances the efficiency of their operations. Accordingly, fees charged for co-location services are constrained by the active competition for the order flow of, and other business from, such market participants. If a particular exchange charges excessive fees for co-location services, affected market participants will opt to terminate their co-location arrangements with that exchange, and adopt a possible range of alternative strategies, including placing their servers in a physically proximate location outside the exchange's data center (which could be a competing exchange), or pursuing strategies less dependent upon the lower exchange-to-participant latency associated with co-location. Accordingly, the exchange charging excessive fees would stand to lose not only co-location revenues but also the liquidity of the formerly co-located trading firms, which could have additional follow-on effects on the market share and revenue of the affected exchange. For the reasons described above, the Exchange believes that the proposed rule change reflects this competitive environment.

The Exchange believes that the proposal to update the name of ISE to reflect its acquisition by NASDAQ and Bats and Cboe to reflect their business combination and name change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposal is ministerial in nature and is not designed to have any competitive impact. It simply seeks to update the Price List to accurately reference these markets in light of their recent name changes.

The Exchange believes that the proposed non-substantive change to ensure the names in the table of Third Party Systems are in alphabetical order would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act because the change would have no impact on pricing or the services offered. Rather, the change would alleviate possible market participant confusion by making it easier to find Third Party Systems in the table.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [19] and Rule 19b–4(f)(6) thereunder.[20] 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 prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder. [21]

A proposed rule change filed under Rule 19b–4(f)(6) [22] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[23] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange requests that the Commission waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange represents that the proposed rule changes present no new or novel issues. According to the Exchange, waiver of the operative delay would allow Users to access the Proposed Third Party Systems and the Proposed Third Party Data Feeds without delay, which would assist Users in tailoring their data center operations to the requirements of their business operations. The Exchange also represents that the proposed changes to the Price List would provide Users with more complete information regarding their Access and Connectivity options. The Exchange further asserts that waiver of the operative delay would help avoid potential investor confusion by allowing the Exchange to immediately update the names of the exchanges noted above to reflect recent business combinations and name changes. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission waives the 30-day operative delay and designates the proposed rule change operative upon filing.[24]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [25] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSE–2018–32 on the subject line.

[19] 15 U.S.C. 78s(b)(3)(A)(iii).

[20] 17 CFR 240.19b–4(f)(6).

[21] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[22] 17 CFR 240.19b–4(f)(6).

[23] 17 CFR 240.19b–4(f)(6)(iii).

[24] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[25] 15 U.S.C. 78s(b)(2)(B).

Paper Comments

• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2018–32. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2018–32 and should be submitted on or before August 21, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[26]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–16274 Filed 7–30–18; 8:45 am]

BILLING CODE 8011–01–P

[26] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #15600 and #15601; MASSACHUSETTS Disaster Number MA–00074]

Presidential Declaration of a Major Disaster for Public Assistance Only for the State of Massachusetts

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of Massachusetts (FEMA–4379–DR), dated 07/19/2018.

Incident: Severe Winter Storm and Snowstorm.

Incident Period: 03/13/2018 through 03/14/2018.

DATES: Issued on 07/19/2018.

Physical Loan Application Deadline Date: 09/17/2018.

Economic Injury (EIDL) Loan Application Deadline Date: 04/19/2019.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 07/19/2018, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties:

Essex, Middlesex, Norfolk, Suffolk, Worcester.

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations With Credit Available Elsewhere	2.500
Non-Profit Organizations Without Credit Available Elsewhere	2.500
For Economic Injury:	
Non-Profit Organizations Without Credit Available Elsewhere	2.500

The number assigned to this disaster for physical damage is 15600B and for economic injury is 156010.

(Catalog of Federal Domestic Assistance Number 59008)

Jerome Edwards,

Acting Associate Administrator for Disaster Assistance.

[FR Doc. 2018–16358 Filed 7–30–18; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #15584 and #15585; Texas Disaster Number TX–00500]

Presidential Declaration Amendment of a Major Disaster for the State of Texas

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the State of Texas (FEMA–4377–DR), dated 07/06/2018.

Incident: Severe Storms and Flooding.

Incident Period: 06/19/2018 through 07/13/2018.

DATES: Issued on 07/19/2018.

Physical Loan Application Deadline Date: 09/04/2018.

Economic Injury (EIDL) Loan Application Deadline Date: 04/08/2019.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for the State of Texas, dated 07/06/2018, is hereby amended to establish the incident period for this disaster as beginning 06/19/2018 and continuing through 07/13/2018.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2018–16354 Filed 7–30–18; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #15598 and #15599; Maryland Disaster Number MD–00038]

Presidential Declaration of a Major Disaster for Public Assistance Only for the State of Maryland

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of Maryland (FEMA–4376–DR), dated 07/02/2018.

Incident: Severe Storms and Flooding.

Incident Period: 05/27/2018 through 05/28/2018.

DATES: Issued on 07/02/2018.

Physical Loan Application Deadline Date: 08/31/2018.

Economic Injury (EIDL) Loan Application Deadline Date: 04/02/2019.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 07/02/2018, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Baltimore, Howard.

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations With Credit Available Elsewhere	2.500
Non-Profit Organizations Without Credit Available Elsewhere	2.500
For Economic Injury:	
Non-Profit Organizations Without Credit Available Elsewhere	2.500

The number assigned to this disaster for physical damage is 155986 and for economic injury is 155990.

(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2018–16353 Filed 7–30–18; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent To Rule on Request To Release Airport Property at Perry-Houston County Airport, Perry, GA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comment.

SUMMARY: The FAA proposes to rule and invites public comment on the release of land at Perry-Houston County Airport, Perry, GA.

DATES: Comments must be received on or before August 30, 2018.

ADDRESSES: Comments on this application may be mailed or delivered to the FAA at the following address: Aimee McCormick, Federal Aviation Administration, Atlanta Airports District Office, 1701 Columbia Ave., Ste. 220, College Park, GA 30337.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to: William R. Jerles, Jr., Chairman, Perry-Houston County Airport Authority, P.O. Box 1572, Perry, GA 31069.

FOR FURTHER INFORMATION CONTACT: Aimee McCormick, Federal Aviation Administration, Atlanta Airports District Office, 1701 Columbia Ave., Ste. 220, College Park, GA 30337, *aimee.mccormick@faa.gov.* The request to release property may be reviewed, by appointment, in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA invites public comment on the request to release 38.26 acres of airport property at Perry-Houston County Airport (PXE) under the provisions of 49 U.S.C. 47107(h)(2).

On March 16, 2018, the Georgia Department of Transportation Aviation Program Manager, on behalf of the Perry-Houston County Airport Authority, requested the FAA release 38.26 acres of airport property for an equal 38.26 acres of adjacent land at same fair market value (FMV) cost. The land to be released by the airport authority will be used as farmland while the land to be acquired by the airport authority will be used for future airport development as needed. FAA has determined that the proposed property release at Perry-Houston County Airport (PXE), as submitted by Perry-Houston County Airport Authority, meets the procedural requirements of the Federal Aviation Administration and release of the property does not and will not impact future aviation needs at the airport. The FAA may approve the request, in whole or in part, no sooner than thirty days after the publication of this notice.

The following is a brief overview of the request:

Perry-Houston County Airport (PXE) is proposing the release of 38.26 acres of airport property to be used for farmland and equal to the acquisition of contiguous, adjacent 38.26 acres of land for future aviation development as needed. The release of land is necessary to comply with Federal Aviation Administration Grant Assurances that do not allow federally acquired airport property to be used for non-aviation purposes. Release of the airport owned land will result in the land at Perry-Houston County Airport (PXE) being changed from aeronautical to non-aeronautical use and release the lands from the conditions of the Airport Improvement Program Grant Agreement Grant Assurances. In accordance with 49 U.S.C. § 47107(c)(2)(B)(i) and (iii), the airport will transfer the equal fair market value properties between owners the parties.

Any person may inspect, by appointment, the request in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT**. In addition, any person may, upon appointment and request, inspect the application, notice and other documents determined by the FAA to be related to the application in person at Perry-Houston County Airport.

Issued in Atlanta, GA, on July 24, 2018.

Larry F. Clark,

Manager, Atlanta Airports District Office.

[FR Doc. 2018–16252 Filed 7–30–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: Pilot Certification and Qualification Requirements for Air Carrier Operations

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The collection involves FAA review of Airline Transport Pilot (ATP) Certification Training Program (CTP) submittals to determine that the program complies with the applicable requirements. It also involves FAA review of an institution of higher education's application for the authority to certify its graduates meet the minimum regulatory requirements.

DATES: Written comments should be submitted by October 1, 2018.

ADDRESSES: Send comments to the FAA at the following address: Barbara Hall, Federal Aviation Administration, ASP–110, 10101 Hillwood Parkway, Fort Worth, TX 76177.

FOR FURTHER INFORMATION CONTACT: Barbara Hall by email at: *Barbara.L.Hall@faa.gov;* phone: 940–594–5913.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 2120–0755.

Title: Pilot Certification and Qualification Requirements for Air Carrier Operations.

Form Numbers: 8700–1.

Type of Review: This is a renewal of an information collection.

Background: FAA aviation safety inspectors review the Airline Transport Pilot (ATP) Certification Training Program (CTP) submittals to determine that the program complies with the applicable requirements of 14 CFR 61.156. The programs that comply with the minimum requirements receive approval to begin offering the course to applicants for an ATP certificate with a multiengine class rating or an ATP certificate obtained concurrently with an airplane type rating. FAA aviation inspectors also review an institution of higher education's application for the authority to certify its graduates meet the minimum requirements of 14 CFR 61.160. The institutions of higher education that receive a letter of authorization for their degree program(s) are authorized to place a certifying statement on a graduates' transcript indicating he or she is eligible for a restricted privileges ATP certificate.

Respondents: 41.

Frequency: On occasion.

Estimated Average Burden per Response: 3.1 hours.

Estimated Total Annual Burden: 980 hours.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Issued in Washington, DC, on July 24, 2018.

Robin Darden,

Management Support Specialist, Performance, Policy, and Records Management Branch, ASP–110.

[FR Doc. 2018–16368 Filed 7–30–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent To Rule on Request To Release Airport Property at Myrtle Beach International Airport, Myrtle Beach, SC

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comment.

SUMMARY: The FAA proposes to rule and invites public comment on the release of land at Myrtle Beach International Airport, Myrtle Beach, SC.

DATES: Comments must be received on or before August 30, 2018.

ADDRESSES: Comments on this application may be mailed or delivered to the FAA at the following address: Aimee McCormick, Federal Aviation Administration, Atlanta Airports District Office, 1701 Columbia Ave., Ste. 220, College Park, GA 30337.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to: Kirk Lovell, Director of Air Service and Business Development, Horry County Department of Airports, 1100 Jetport Rd., Myrtle Beach, SC 29577.

FOR FURTHER INFORMATION CONTACT: Aimee McCormick, Federal Aviation Administration, Atlanta Airports District Office, 1701 Columbia Ave., Ste. 220, College Park, GA 30337, *aimee.mccormick@faa.gov.* The request to release property may be reviewed, by appointment, in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA invites public comment on the request to release 2 acres of airport property at Myrtle Beach International Airport (MYR) under the provisions of 49 U.S.C. 47107(h)(2).

On May 23, 2018 the Horry County Department of Airports requested the FAA release of 2 acres of property for sale and development of an outpatient medical clinic. FAA has determined that the proposed property release at Myrtle Beach International Airport (MYR), as submitted by Horry County Department of Airports, meets the procedural requirements of the Federal Aviation Administration and release of the property does not and will not impact future aviation needs at the airport. The FAA may approve the request, in whole or in part, no sooner than thirty days after the publication of this notice.

The following is a brief overview of the request:

Myrtle Beach International Airport (MYR) is proposing the release of airport property totaling 2 acres to be developed and used for an outpatient medical clinic. The release of land is necessary to comply with Federal Aviation Administration Grant Assurances that do not allow federally acquired airport property to be used for non-aviation purposes. The sale of the subject property will result in the land at Myrtle Beach International Airport (MYR) being changed from aeronautical to non-aeronautical use and release the lands from the conditions of the Airport Improvement Program Grant Agreement Grant Assurances. In accordance with 49 U.S.C. 47107(c)(2)(B)(i) and (iii), the airport will receive fair market value for the property, which will be subsequently reinvested in another eligible airport improvement project for aviation facilities at Myrtle Beach International Airport.

Any person may inspect, by appointment, the request in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT**. In addition, any person may, upon appointment and request, inspect the application, notice and other documents determined by the FAA to be related to the application in person at Myrtle Beach International Airport.

Issued in Atlanta, GA, on July 23, 2018.

Larry F. Clark,

Manager, Atlanta Airports District Office.

[FR Doc. 2018–16251 Filed 7–30–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: Airport Noise Compatibility Planning

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB)

approval to renew an information collection. The collection involves information on voluntary airport noise compatibility programs. The respondents are airport operators that voluntarily submit noise exposure maps and noise compatibility programs to the FAA for review and approval. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on May 25, 2018. The information to be collected is necessary because noise compatibility program measures are eligible for Federal grants-in-aid if they are provided to FAA for review in approval in advance.

DATES: Written comments should be submitted by August 30, 2018.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the attention of the Desk Officer, Department of Transportation/FAA, and sent via electronic mail to *oira_submission@omb.eop.gov,* or faxed to (202) 395–6974, or mailed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW, Washington, DC 20503.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

FOR FURTHER INFORMATION CONTACT: Barbara Hall by email at: *Barbara.L.Hall@faa.gov;* phone: 940–594–5913.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 2120–0517.

Title: Airport Nosie Compatibility Planning.

Form Numbers: There are no FAA forms associated with this collection.

Type of Review: Renewal of an information collection.

Background: The voluntarily submitted information from the current CFR part 150 collection, *e.g.,* airport noise exposure maps and airport noise compatibility programs, or their revisions, is used by the FAA to conduct reviews of the submissions to determine if an airport sponsor's noise compatibility program is eligible for Federal grant funds. If airport operators did not voluntarily submit noise exposure maps and noise compatibility programs for FAA review and approval, the airport operator would not be eligible for the set aside of discretionary grant funds.

Respondents: Approximately 15 airport operators.

Frequency: Information is collected on occasion.

Estimated Average Burden per Response: 3,950 hours.

Estimated Total Annual Burden: 59,250 hours.

Issued in Washington, DC, on July 24, 2018.

Robin Darden,

Management Support Specialist, Performance, Policy, and Records Management Branch, ASP–110.

[FR Doc. 2018–16366 Filed 7–30–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: Flight and Duty Limitations and Rest Requirements—Flightcrew Members

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The collection involves reporting exceeded flight duty periods and flight times, including scheduled maximum and actual flight duty periods and flight times, basic flight information (*e.g.,* city pairs, departure times, flight number), and reason for exceedance. Reporting and recordkeeping are required any time a certificated air carrier has exceeded a maximum daily flight time limit or a maximum daily Flight Duty Period (FDP) limit. It is also required for the voluntary development of a Fatigue Risk Management System (FRMS), and for fatigue training. The information is necessary to monitor trends in exceedance and possible underlying systemic causes requiring operator action, and to determine whether operator is scheduling realistically.

DATES: Written comments should be submitted by October 1, 2018.

ADDRESSES: Send comments to the FAA at the following address: Barbara Hall, Federal Aviation Administration, ASP–110, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

FOR FURTHER INFORMATION CONTACT: Barbara Hall by email at: *Barbara.L.Hall@faa.gov;* phone: 940–594–5913

SUPPLEMENTARY INFORMATION:

OMB Control Number: 2120–0751.

Title: Flight and Duty Limitations and Rest Requirements—Flightcrew Members.

Form Numbers: There are no forms associated with this collection.

Type of Review: This is a renewal of an information collection.

Background: The FAA collects reports from air carriers conducting passenger operations certificated under 14 CFR part 121 as prescribed in 14 CFR part 117 Flightcrew Member Duty and Rest Requirements, §§ 117.11 and 117.19. Air carriers are required to submit a report of exceeded flight duty periods and flight times, including scheduled maximum and actual flight duty periods and flight times, basic flight information (*e.g.,* city pairs, departure times, flight number), and reason for exceedance. The purpose for the reports is to notify the FAA that the certificate holder has extended a flight time and/or FDP limitation. This information enables FAA to monitor trends in exceedance and possible underlying systemic causes requiring operator action as well as determine whether operators are scheduling realistically. Additionally, if air carriers choose to develop a Fatigue Risk Management System (FRMS) they are required to collect data specific to the need of the operation for which they will seek an FRMS authorization. It results in an annual recordkeeping and reporting burden when carriers adopt the system because they need to report the related activities to the FAA. Each

air carrier is also required to develop specific elements and incorporate these elements into their training program. Once the elements have been incorporated, the air carrier must submit the revised training program for approval.

Respondents: 67 certificated air carriers.

Frequency: On occasion.

Estimated Average Burden per Response: 20 hours.

Estimated Total Annual Burden: 3,178 hours.

Issued in Washington, DC, on July 24, 2018.

Robin Darden,

Management Support Specialist, Performance, Policy, and Records Management Branch, ASP–110.

[FR Doc. 2018–16364 Filed 7–30–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: Certification of Airports

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. 14 CFR part 139 establishes certification requirements for airports serving scheduled air carrier operations in aircraft with 10–30 seats.

The collection involves FAA Form 5280–1, Application for Airport Operating Certificate. Every airport that wants to become a certificated Part 139 airport must complete this form, as well as provide a draft Airport Certification Manual (ACM). In addition, currently certificated Part 139 airports must maintain their ACM, as well as keep and maintain records related to training, self-inspection, and other requirements of Part 139.

These records allow the FAA to verify compliance with Part 139 safety and operational requirements to ensure that the airports meet the minimum safety requirements of Part 139, which in turn enhances the safety of the flying public.

DATES: Written comments should be submitted by October 1, 2018.

ADDRESSES: Send comments to the FAA at the following address: Barbara Hall, Federal Aviation Administration, ASP–110, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

FOR FURTHER INFORMATION CONTACT: Barbara Hall by email at: *Barbara.L.Hall@faa.gov;* phone: 940–594–5913.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 2120–0675.

Title: Certification of Airports, 14 CFR part 139.

Form Numbers: FAA Form 5280–1.

Type of Review: Renewal of an information collection.

Background: The statutory authority to issue airport operating certificates to airports serving certain air carriers and to establish minimum safety standards for the operation of those airports is currently found in Title 49, United States Code (U.S.C.) § 44706, Airport operation certificates. The FAA uses this authority to issue requirements for the certification and operation of certain airports that service commercial air carriers. These requirements are contained in Title 14, Code of Federal Regulation part 139 (14 CFR part 139), Certification and Operations: Land Airports Serving Certain Air Carriers, as amended. Information collection requirements are used by the FAA to determine an airport operator's compliance with part 139 safety and operational requirements, and to assist airport personnel to perform duties required under the regulation.

Operators of certificated airports are required to complete FAA Form 5280–1 and develop, and comply with, a written document, an Airport Certification Manual (ACM), that details how an airport will comply with the requirements of part 139. The ACM shows the means and procedures whereby the airport will be operated in compliance with part 139, plus other instructions and procedures to help personnel concerned with operation of the airport to perform their duties and responsibilities.

When an airport satisfactorily complies with such requirements, the FAA issues to that facility an airport operating certificate (AOC) that permits an airport to serve air carriers. The FAA periodically inspects these airports to ensure continued compliance with part 139 safety requirements, including the maintenance of specified records. Both the application for an AOC and annual compliance inspections require operators of certificated airports to collect and report certain operational information. The AOC remains in effect as long as the need exists and the operator complies with the terms of the AOC and the ACM.

The likely respondents to new information requests are those civilian U.S. airport certificate holders who operate airports that serve scheduled and unscheduled operations of air carrier aircraft with more than 30 passenger seats (approximately 530 airports). These airport operators already hold an AOC and comply with all current information collection requirements.

Operators of certificated airports are permitted to choose the methodology to report information and can design their own recordkeeping system. As airports vary in size, operations and complexities, the FAA has determined this method of information collection allows airport operators greater flexibility and convenience to comply with reporting and recordkeeping requirements. 100% of the information may be submitted electronically.

The FAA has an automated system, the Certification and Compliance Management Information System (CCMIS), which allows FAA airport safety and certification inspectors to enter into a national database airport inspection information. This information is monitored to detect trends and developing safety issues, to allocate inspection resources, and generally, to be more responsive to the needs of regulated airports.

Respondents: Approximately 530 airports.

Frequency: Information collected on occasion.

Estimated Average Burden per Response: 22 hours.

Estimated Total Annual Burden: 95,191 hours.

Issued in Washington, DC, on July 24, 2018.

Robin Darden,

Management Support Specialist, Performance, Policy, and Records Management Branch, ASP–110.

[FR Doc. 2018–16367 Filed 7–30–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Membership in the National Parks Overflights Advisory Group

AGENCY: Federal Aviation Administration, Transportation

ACTION: Notice.

SUMMARY: By **Federal Register** notice on April 20, 2018 the National Park Service (NPS) and the Federal Aviation Administration (FAA) invited interested persons to apply to fill two openings on the National Parks Overflights Advisory Group (NPOAG) to represent air tour operator concerns and Native American interests. This notice informs the public of the selection made for the vacancy representing air tour operators and invites persons interested in serving on the NPOAG to apply for current and future openings representing Native American concerns, and future openings representing general aviation, and air tour operator interests.

DATES: Persons interested in applying for the NPOAG openings representing air tour operator and Native American interests need to apply by September 14, 2018.

FOR FURTHER INFORMATION CONTACT: Keith Lusk, Special Programs Staff, Federal Aviation Administration, Western-Pacific Region Headquarters, 727 S Aviation Boulevard, Suite #150, El Segundo, CA 90245, telephone: (424) 405–7017, email: *Keith.Lusk@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The National Parks Air Tour Management Act of 2000 (the Act) was enacted on April 5, 2000, as Public Law 106–181, and subsequently amended in the FAA Modernization and Reform Act of 2012. The Act required the establishment of the advisory group within one year after its enactment. The NPOAG was established in March 2001. The advisory group is comprised of a balanced group of representatives of general aviation, commercial air tour operations, environmental concerns, and Native American tribes. The Administrator of the FAA and the Director of NPS (or their designees) serve as ex officio members of the group. Representatives of the Administrator and Director serve alternating one-year terms as chairman of the advisory group.

In accordance with the Act, the advisory group provides ''advice, information, and recommendations to the Administrator and the Director—

(1) On the implementation of this title [the Act] and the amendments made by this title;

(2) On commonly accepted quiet aircraft technology for use in commercial air tour operations over a national park or tribal lands, which will receive preferential treatment in a given air tour management plan;

(3) On other measures that might be taken to accommodate the interests of visitors to national parks; and

(4) At the request of the Administrator and the Director, safety, environmental, and other issues related to commercial air tour operations over a national park or tribal lands.''

Membership

The current NPOAG is made up of one member representing general aviation, three members representing the commercial air tour industry, four members representing environmental concerns, and two members representing Native American interests. Members serve 3-year terms. Current members of the NPOAG are as follows:

Melissa Rudinger representing general aviation; Alan Stephen and Matt Zuccaro representing commercial air tour operators with one open seat; Les Blomberg, Rob Smith, John Eastman, and Dick Hingson representing environmental interests; and Martin Begaye representing Native American tribes with one open seat.

Selection

Eric Lincoln has been selected to represent commercial air tour operators. No selection was made for the opening to represent Native American interests. In addition, three more seats are expiring in October/November 2018. The upcoming openings are one each to represent Native American concerns, general aviation, and air tour operator interests.

The FAA and NPS invite persons interested in applying for the four openings on the NPOAG to contact Mr. Keith Lusk (contact information is written above in **FOR FURTHER INFORMATION CONTACT**). Requests to serve on the NPOAG must be made to Mr. Lusk in writing and postmarked or emailed on or before September 14, 2018. The request should indicate whether or not you are a member of an association or group related to air tour operator, general aviation, or Native American concerns or have another affiliation with issues relating to aircraft flights over national parks. The request should also state what expertise you would bring to the NPOAG as related to issues and concerns with aircraft flights over national parks. The term of service for NPOAG members is 3 years. Current members may re-apply for another term.

On August 13, 2014, the Office of Management and Budget issued revised guidance regarding the prohibition against appointing or not reappointing federally registered lobbyists to serve on advisory committees (79 FR 47482).

Therefore, before appointing an applicant to serve on the NPOAG, the FAA and NPS will require the prospective candidate to certify that they are not a federally registered lobbyist.

Issued in Hawthorne, CA, on July 23, 2018.

Keith Lusk,

Program Manager, Special Programs Staff, Western-Pacific Region.

[FR Doc. 2018–16253 Filed 7–30–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

United States Mint

Request for Applications for Appointment to the Citizens Coinage Advisory Committee

AGENCY: United States Mint, Department of the Treasury.

ACTION: Request for applications for appointment to the Citizens Coinage Advisory Committee.

SUMMARY: Pursuant to United States Code, the United States Mint is accepting applications for appointment to the Citizens Coinage Advisory Committee (CCAC) as a member specially qualified by virtue of his or her experience in American history.

FOR FURTHER INFORMATION CONTACT: Betty Birdsong, Acting United States Mint Liaison to the CCAC, 801 9th Street NW, Washington, DC 20220, or call 202–354–7770.

SUPPLEMENTARY INFORMATION: The CCAC was established to:

- Advise the Secretary of the Treasury on any theme or design proposals relating to circulating coinage, bullion coinage, Congressional Gold Medals, and national and other medals produced by the United States Mint.
- Advise the Secretary of the Treasury with regard to the events, persons, or places that the CCAC recommends to be commemorated by the issuance of commemorative coins in each of the five calendar years succeeding the year in which a commemorative coin designation is made.
- Make recommendations with respect to the mintage level for any commemorative coin recommended.

Total membership consists of eleven voting members appointed by the Secretary of the Treasury:

- One person specially qualified by virtue of his or her education, training, or experience as nationally or internationally recognized curator in the United States of a numismatic collection;
- One person specially qualified by virtue of his or her experience in the medallic arts or sculpture;
- One person specially qualified by virtue of his or her education, training, or experience in American history;
- One person specially qualified by virtue of his or her education, training, or experience in numismatics;
- Three persons who can represent the interests of the general public in the coinage of the United States; and
- Four persons appointed by the Secretary of the Treasury on the basis of the recommendations by the House and Senate leadership.

Members are appointed for a term of four years. No individual may be appointed to the CCAC while serving as an officer or employee of the Federal Government.

The CCAC is subject to the direction of the Secretary of the Treasury. Meetings of the CCAC are open to the public and are held approximately four to six times per year. The United States Mint is responsible for providing the necessary support, technical services, and advice to the CCAC. CCAC members are not paid for their time or services, but, consistent with Federal Travel Regulations, members are reimbursed for their travel and lodging expenses to attend meetings. Members are Special Government Employees and are subject to the Standards of Ethical Conduct for Employees of the Executive Branch (5 CFR part 2653).

The United States Mint will review all submissions and will forward its recommendations to the Secretary of the Treasury for appointment consideration. Candidates should include specific skills, abilities, talents, and credentials to support their applications. The United States Mint is interested in candidates who in addition to their experience in American history, have demonstrated interest and a commitment to actively participate in meetings and activities, and a demonstrated understanding of the role of the CCAC and the obligations of a Special Government Employee; possess demonstrated leadership skills in their fields of expertise or discipline; possess a demonstrated desire for public service and have a history of honorable professional and personal conduct, as well as successful standing in their communities; and who are free of professional, political, or financial interests that could negatively affect their ability to provide impartial advice.

Application Deadline: Friday, August 24, 2018.

Receipt of Applications: Any member of the public wishing to be considered for participation on the CCAC should submit a resume and cover letter describing his or her reasons for seeking and qualifications for membership, by email to *info@ccac.gov* or by mail to the United States Mint, 801 9th Street NW, Washington, DC 20220; Attn: Greg Weinman. Submissions must be postmarked no later than Friday, August 24, 2018.

Notice Concerning Delivery of First-Class and Priority Mail

First-class mail to the United States Mint is put through an irradiation process to protect against biological contamination. Support materials put through this process may suffer irreversible damage. We encourage you to consider using alternate delivery services, especially when sending time-sensitive material.

Dated: July 26, 2018.

David J. Ryder,

Director, United States Mint.

[FR Doc. 2018–16383 Filed 7–30–18; 8:45 am]

BILLING CODE P

DEPARTMENT OF VETERANS AFFAIRS

Veterans' Advisory Committee on Rehabilitation; Notice of Meeting Amended

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, that a meeting of the Veterans' Advisory Committee on Rehabilitation (VACOR) will be held on Tuesday and Wednesday, August 28–29, 2018, in Room 542, 1800 G Street NW, Washington, DC 20006. The meeting will begin at 8:30 a.m. EST and adjourn at 4:00 p.m. EST each day. The meeting is open to the public.

The purpose of the Committee is to provide advice to the Secretary on the rehabilitation needs of Veterans with disabilities and on the administration of VA's rehabilitation programs.

On August 28, 2018, Committee members will be provided with updated briefings on various VA programs designed to enhance the rehabilitative potential of disabled Veterans.

On August 29, 2018, the Committee will begin consideration of potential recommendations to be included in the Committee's next annual report.

Although no time will be allocated for receiving oral presentations from the public, members of the public may submit written statements for review by the Committee to Sabrina McNeil, Designated Federal Officer, Veterans Benefits Administration (28), 810 Vermont Avenue NW, Washington, DC 20420, or via email at *Sabrina.McNeil@va.gov.* In the communication, writers must identify themselves and state the organization, association or person(s) they represent. Because the meeting is being held in a government building, a photo I.D. must be presented at the Guard's Desk as part of the clearance process. Due to an increase in security protocols, and in order to prevent delays in clearance processing, you should allow an additional 30 minutes before the meeting begins. Any member of the public who wishes to attend the meeting should RSVP to Sabrina McNeil at (202) 461–9618 no later than close of business, August 20, 2018, at the phone number or email address noted above.

LaTonya L. Small,

Advisory Committee Management Officer.

[FR Doc. 2018–16343 Filed 7–30–18; 8:45 am]

BILLING CODE P

FEDERAL REGISTER

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Book 2 of 2 Books

Pages 37045–37420

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 416 and 419

Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 416 and 419

[CMS–1695–P]

RIN 0938–AT30

Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for CY 2019 to implement changes arising from our continuing experience with these systems. In this proposed rule, we describe the proposed 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. In addition, this proposed rule would update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program. The proposed rule also includes requests for information on promoting interoperability and electronic health care information exchange, improving beneficiary access to provider and supplier charge information, and leveraging the authority for the Competitive Acquisition Program (CAP) for Part B drugs and biologicals for a potential CMS Innnovation Center model. In addition, we are proposing to modify the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey measure under the Hospital Inpatient Quality Reporting (IQR) Program by removing the Communication about Pain questions.

DATES: To be assured consideration, comments on this proposed rule must be received at one of the addresses provided in the **ADDRESSES** section no later than 5 p.m. EST on September 24, 2018.

ADDRESSES: In commenting, please refer to file code CMS–1695–P when commenting on the issues in this proposed rule. 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–1695–P, 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–1695–P, 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.

If you intend to deliver your comments to the Baltimore address, please call the telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, we refer readers to the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: (We note that public comments must be submitted through one of the four channels outlined in the **ADDRESSES** section above. Comments may not be submitted via email.)

340B Drug Payment Policy to Nonexcepted Off-Campus Departments of a Hospital, contact Juan Cortes via email *Juan.Cortes@cms.hhs.gov* or at 410–786–4325.

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.

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 Vinitha Meyyur via email *Vinitha.Meyyur@cms.hhs.gov* or at 410–786–8819.

Blood and Blood Products, contact Joshua 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.

CPT Codes, contact Marjorie Baldo via email *Marjorie.Baldo@cms.hhs.gov* or at 410–786–4617.

Collecting Data on Services Furnished in Off-Campus Provider-Based Emergency Departments, contact Twi Jackson via email *Twi.Jackson@cms.hhs.gov* or at 410–786–1159.

Comment Solicitation to 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.

Expansion of Clinical Families of Services at Excepted Off-Campus Departments of a Provider, contact Juan Cortes via email *Juan.Cortes@cms.hhs.gov* or at 410–786–4325.

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 Twi Jackson via email

Twi.Jackson@cms.hhs.gov or at 410–786–1159.

Inpatient Only (IPO) Procedures List, contact Lela Strong-Holloway via email *Lela.Strong@cms.hhs.gov* or at 410–786–3213.

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 Twi Jackson via email *Twi.Jackson@cms.hhs.gov* or at 410–786–1159.

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.

OPPS Drugs, Radiopharmaceuticals, Biologicals, and Biosimilar Products, contact Josh McFeeters via email *Josh.McFeeters@cms.hhs.gov* or at 410–786–9732.

OPPS New Technology Procedures/Services, contact the New Technology APC email at *NewTechAPCapplications@cms.hhs.gov.*

OPPS Exceptions to the 2 Times Rule, contact Marjorie Baldo via email *Marjorie.Baldo@cms.hhs.gov* or at 410–786–4617.

OPPS Packaged Items/Services, contact Lela Strong-Holloway via email *Lela.Strong@cms.hhs.gov* or at 410–786–3213.

OPPS Pass-Through Devices, contact the Device Pass-Through email 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.

Partial Hospitalization Program (PHP) and Community Mental Health Center (CMHC) Issues, contact the PHP Payment Policy Mailbox at *PHPPaymentPolicy@cms.hhs.gov.*

Request for Information on Leveraging the Authority for the Competitive Acquisition Program (CAP) for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model, contact the CMS Innovation Center Team Mailbox via email at *CMMIPartBDrugCAP_RFI@cms.hhs.gov.*

Request for Information on Promoting Interoperability and Electronic Healthcare Information Exchange, contact Scott Cooper via email at *Scott.Cooper@cms.hhs.gov* or at 410–786–9465.

Request for Information on Requirements for Hospitals To Make Public a List of Their Standard Charges via the internet, contact Elise Barringer via email *Elise.Barringer@cms.hhs.gov* or at 410–786–9222.

Rural Hospital Payments, contact Joshua McFeeters via email *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.

All Other Issues Related to Hospital Outpatient and Ambulatory Surgical Center Payments Not Previously Identified, contact Marjorie Baldo via email *Marjorie.Baldo@cms.hhs.gov* or at 410–786–4617.

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.

Comments received timely will also be available for public inspection, generally beginning approximately 3 weeks after publication of the rule, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244, on Monday through Friday of each week from 8:30 a.m. to 4:00 p.m. EST. To schedule an appointment to view public comments, phone 1–800–743–3951.

Electronic Access

This **Federal Register** document is also available from the **Federal Register** online database through Federal Digital System (FDsys), a service of the U.S. Government Publishing Office. This database can be accessed via the internet at *https://www.gpo.gov/fdsys/.*

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.*

Table of Contents

I. Summary and Background

A. Executive Summary of This Document

1. Purpose

In this proposed rule, we are proposing to update 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, 2019. 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, relative payment weights, 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. We describe these and various other statutory authorities in the relevant sections of this proposed rule. In addition, this proposed rule would update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

In this proposed rule, we also are including three Requests for Information (RFIs) on: (1) Promoting interoperability and electronic health care information exchange through possible revisions to the CMS patient health and safety requirements for hospitals and other Medicare-participating and Medicaid-participating providers and suppliers; (2) improving beneficiary access to provider and supplier charge information; and (3) leveraging the authority for the Competitive Acqisition Program (CAP) for Part B drugs and biologicals for a potential CMS Innovation Center model. In addition, we are proposing to modify the HCAHPS Survey measure by removing the Communication about Pain questions from the HCAHPS Survey for the Hospital IQR Program, which are used to assess patients' experiences of care, effective with January 2022 discharges for the FY 2024 payment determination.

2. Improving Patient Outcomes and Reducing Burden Through Meaningful Measures

Regulatory reform and reducing regulatory burden are high priorities for CMS. To reduce the regulatory burden on the healthcare industry, lower health care costs, and enhance patient care, in October 2017, we launched the Meaningful Measures Initiative.[1] This initiative is one component of our agency-wide Patients Over Paperwork Initiative,[2] which is aimed at evaluating and streamlining regulations with a goal to reduce unnecessary cost and burden, increase efficiencies, and improve

[1] Meaningful Measures web page: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html.*

[2] Remarks by Administrator Seema Verma at the Health Care Payment Learning and Action Network (LAN) Fall Summit, as prepared for delivery on October 30, 2017. Available at: *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-10-30.html.*

beneficiary experience. The Meaningful Measures Initiative is aimed at identifying the highest priority areas for quality measurement and quality improvement in order to assess the core quality of care issues that are most vital to advancing our work to improve patient outcomes. The Meaningful Measures Initiative represents a new approach to quality measures that fosters operational efficiencies, and will reduce costs including, collection and reporting burden while producing quality measurement that is more focused on meaningful outcomes.

The Meaningful Measures framework has the following objectives:

- Address high-impact measure areas that safeguard public health;
- Patient-centered and meaningful to patients;
- Outcome-based where possible;
- Fulfill each program's statutory requirements;
- Minimize the level of burden for health care providers;
- Significant opportunity for improvement;
- Address measure needs for population based payment through alternative payment models; and
- Align across programs and/or with other payers.

In order to achieve these objectives, we have identified 19 Meaningful Measures areas and mapped them to six overarching quality priorities as shown in the table below.

Quality priority	Meaningful measure area
Making Care Safer by Reducing Harm Caused in the Delivery of Care	Healthcare-Associated Infections
	Preventable Healthcare Harm
Strengthen Person and Family Engagement as Partners in Their Care	Care is Personalized and Aligned with Patient's Goals
	End of Life Care According to Preferences
	Patient's Experience of Care
	Patient Reported Functional Outcomes
Promote Effective Communication and Coordination of Care	Medication Management
	Admissions and Readmissions to Hospitals
	Transfer of Health Information and Interoperability
Promote Effective Prevention and Treatment of Chronic Disease	Preventive Care
	Management of Chronic Conditions
	Prevention, Treatment, and Management of Mental Health
	Prevention and Treatment of Opioid and Substance Use Disorders
	Risk Adjusted Mortality
Work with Communities to Promote Best Practices of Healthy Living	Equity of Care
	Community Engagement
Make Care Affordable	Appropriate Use of Healthcare
	Patient-focused Episode of Care
	Risk Adjusted Total Cost of Care

By including Meaningful Measures in our programs, we believe that we can also address the following cross-cutting measure criteria:

- Eliminating disparities;
- Tracking measurable outcomes and impact;
- Safeguarding public health;
- Achieving cost savings;
- Improving access for rural communities; and
- Reducing burden.

We believe that the Meaningful Measures Initiative will improve outcomes for patients, their families, and health care providers while reducing burden and costs for clinicians and providers as well as promoting operational efficiencies.

3. Summary of the Major Provisions

- *OPPS Update:* For CY 2019, we are proposing to increase the payment rates under the OPPS by an outpatient department (OPD) fee schedule increase factor of 1.25 percent. This increase factor is based on the proposed hospital inpatient market basket percentage increase of 2.8 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS), minus the proposed multifactor productivity (MFP) adjustment of 0.8 percentage point, and minus a 0.75 percentage point adjustment required by the Affordable Care Act. Based on this proposed update, we estimate that total payments to OPPS providers (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix) for CY 2019 would be approximately $74.6 billion, an increase of approximately $4.9 billion compared to estimated CY 2018 OPPS payments.

We are proposing to continue 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 0.980 to the OPPS payments and copayments for all applicable services.

- *Comprehensive APCs:* For CY 2019, we are proposing to create three new comprehensive APCs (C–APCs). These proposed new C–APCs include ears, nose, and throat (ENT) and vascular procedures. This proposal would increase the total number of C–APCs to 65.

- *Proposed Changes to the Inpatient Only List:* For CY 2019, we are proposing to remove two procedures from the inpatient only list and add one procedure to the list.

- *Proposal and Comment Solicitation on Method to Control Unnecessary Increases in Volume of Outpatient Services:* To the extent that similar services can be safely provided in more than one setting, it is not prudent for the Medicare program to pay more for these services in one setting than another. We believe that capping the OPPS payment at the Physician Fee Schedule (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. In particular, we believe this method of capping payment will control unnecessary volume increases as manifested both in terms of numbers of covered outpatient department services furnished and costs of those services. Therefore, we are proposing to use our authority under section 1833(t)(2)(F) of the Act to apply 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) 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. In addition, we are soliciting public

comments on how to expand the Secretary's statutory authority under section 1833(t)(2)(F) of the Act to additional items and services paid under the OPPS that may represent unnecessary increases in hospital outpatient department utilization.

• *Expansion of Services at Off-Campus Provider-Based Departments (PBDs) Paid under the OPPS (Section 603):* For CY 2019, we are proposing that if an excepted off-campus PBD furnishes a service from a clinical family of services for which it did not previously furnish a service (and subsequently bill for that service) during a baseline period, services from this new clinical family of services would not be covered OPD services. Instead, services in the new clinical family of services would be paid under the PFS.

• *Proposal to Apply 340B Drug Payment Policy to Off-Campus Departments of a Hospital Paid under the Medicare Physician Fee Schedule:* For CY 2019, we are proposing to pay average sales price (ASP) minus 22.5 percent for 340B-acquired drugs furnished by nonexcepted, off-campus provider-based departments (PBDs). This is consistent with the payment methodology adopted in CY 2018 for 340B-acquired drugs furnished in hospital departments paid under the OPPS.

• *Payment Policy for Biosimilar Biological Products without Pass-Through Status That Are Acquired under the 340B Program:* For CY 2019, we are proposing to pay nonpass-through biosimilars acquired under the 340B program at ASP minus 22.5 percent of the biosimilar's own ASP rather than ASP minus 22.5 percent of the reference product's ASP.

• *Payment of Drugs, Biologicals, and Radiopharmaceuticals If Average Sales Price (ASP) Data Are Not Available:* For CY 2019, we are proposing to pay separately payable drugs and biological products that do not have pass-through payment status and are not acquired under the 340B Program at wholesale acquisition cost (WAC)+3 percent instead of WAC+6 percent. If WAC data are not available for a drug or biological product, we are proposing to continue our policy to pay separately payable drugs and biological products at 95 percent of the average wholesale price (AWP). 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.

• *Device-Intensive Procedure Criteria:* For CY 2019, we are proposing to modify the device-intensive criteria to allow procedures that involve single-use devices, regardless of whether or not they remain in the body after the conclusion of the procedure, to qualify as device-intensive procedures. We also are proposing to allow procedures with a device offset percentage of greater than 30 percent to qualify as device-intensive procedures. In addition, we are soliciting comments on whether any high-cost devices (other than capital equipment) should be left out of the definition of single-use devices or, alternatively, whether our proposed definition excludes devices that commenters believe should be subject to our device-intensive policy.

• *Device Pass-Through Payment Applications:* For CY 2019, we are evaluating seven applications for device pass-through payments and are seeking public comments in this CY 2019 proposed rule on whether these applications meet the criteria for device pass-through payment status.

• *New Technology APC Payment for Extremely Low-Volume Procedures:* For CY 2019, we are proposing to apply a ''smoothing methodology'' based on multiple years of claims data to establish a more stable rate for services assigned to New Technology APCs with fewer than 100 claims per year under the OPPS. Under the smoothing methodology, we would calculate the geometric mean costs, the median costs, and the arithmetic mean costs for these procedures to promote payment stability. This methodology allows the option to use of one of these methodologies to assign the most representative payment for the service. In addition, we are proposing to exclude low-volume services from bundling into C–APC procedures.

• *Cancer Hospital Payment Adjustment:* For CY 2019, we are proposing to continue to provide additional payments to cancer hospitals so that the 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 proposing that a target PCR of 0.88 would be used to determine the CY 2019 cancer hospital payment adjustment to be paid at cost report settlement. That is, the payment adjustments would be the additional payments needed to result in a PCR equal to 0.88 for each cancer hospital.

• *Rural Adjustment:* For 2019 and subsequent years, we are proposing to continue 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.

• *Ambulatory Surgical Center (ASC) Payment Update:* For CYs 2019 through 2023, we are proposing to update the ASC payment system using the hospital market basket update instead of the CPI–U. However, we are requesting public comments on ASCs' cost structure to assess whether the hospital market basket is an appropriate proxy for ASC costs. During this 5-year period, we intend to examine whether such adjustment leads to a migration of services from other settings to the ASC setting. Using the hospital market basket methodology, for CY 2019, we are proposing to increase payment rates under the ASC payment system by 2.0 percent for ASCs that meet the quality reporting requirements under the ASCQR Program. This proposed increase is based on a proposed hospital market basket percentage increase of 2.8 percent minus a proposed MFP adjustment required by the Affordable Care Act of 0.8 percentage point.

Based on this proposed update, we estimate that total payments to ASCs (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix) for CY 2019 would be approximately $4.89 billion, an increase of approximately $300 million compared to estimated CY 2018 Medicare payments to ASCs. We note that the CY 2019 ASC payment update, under our prior policy, would have been 1.3 percent, based on a projected CPI–U update of 2.1 percent minus a MFP adjustment required by the Affordable Care Act of 0.8 percentage point. In addition, we will 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.

• *Proposed Changes to the List of ASC Covered Surgical Procedures:* For CY 2019, we are proposing to revise our definition of ''surgery'' in the ASC payment system to account for certain ''surgery-like'' procedures that are assigned codes outside the Current Procedural Terminology (CPT) surgical range. In addition, we are proposing to add 12 cardiac catheterization procedures to the ASC covered procedures list. We also are soliciting public comments on our proposal to reassess, and soliciting further public comments on, procedures recently

added to the ASC covered procedures list.

• *Payment for Non-Opioid Pain Management Therapy:* For CY 2019, in response to the recommendation from the President's Commission on Combating Drug Addiction and the Opioid Crisis, we are proposing to change the packaging policy for certain drugs when administered in the ASC setting and provide 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 addition, we are soliciting public comments and peer-reviewed evidence to help determine whether we should pay separately for other non-opioid treatments for pain under the OPPS and the ASC payment system.

• *Hospital Outpatient Quality Reporting (OQR) Program:* For the Hospital OQR Program, we are proposing changes for the CY 2019, CY 2020, and CY 2021 payment determinations and subsequent years. Effective upon the final rule, we are proposing to: (1) Update measure removal Factor 7; (2) add a new removal Factor 8; and (3) codify our measure removal policies and factors. We also are providing clarification of our ''topped-out'' criteria. These proposals would align the Hospital OQR Program measure removal factors with those used in the ASCQR Program. In addition, beginning with CY 2019, we are proposing to update the frequency with which we would release a Hospital OQR Program Specifications Manual such that it would occur every 6 to 12 months. We also are proposing for the CY 2020 payment determination and subsequent years: (1) To update the participation status requirements by removing the Notice of Participation (NOP) form; and (2) to extend the reporting period for the OP–32: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure to 3 years.

Beginning with the CY 2020 payment determination and subsequent years, we also are proposing to remove the OP–27: Influenza Vaccination Coverage Among Healthcare Personnel measure.

Beginning with the CY 2021 payment determination and subsequent years, we are proposing to remove the following nine measures: (1) OP–5: Median Time to ECG; (2) OP–9: Mammography Follow-up Rates; (3) OP–11: Thorax CT Use of Contrast Material; (4) OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into Their Qualified/Certified EHR System as Discrete Searchable Data; (5) OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT; (6) OP–17: Tracking Clinical Results between Visits; (7) OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients; (8) OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use; and (9) OP–31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.

• *Ambulatory Surgical Center Quality Reporting (ASCQR) Program:* For the ASCQR Program, we are proposing changes in policies for the CY 2020 payment determination and CY 2021 payment determination and subsequent years. Effective upon the final rule, we are proposing to: (1) Remove one factor; (2) add two new measure removal factors; and (3) update the regulations to better reflect our measure removal policies. We also are making one clarification to measure removal Factor 1. These proposals would align the ASCQR Program measure removal factors with those used in the Hospital OQR Program.

Beginning with the CY 2020 payment determination and subsequent years, we are proposing to extend the reporting period for the ASC–12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure to 3 years. For the CY 2020 payment determination and subsequent years, we also are proposing to remove one measure from the ASCQR Program measure set, ASC–8: Influenza Vaccination Coverage Among Healthcare Personnel.

Beginning with the CY 2021 payment determination and subsequent years, we are proposing to remove seven measures: (1) ASC–1: Patient Burn; (2) ASC–2: Patient Fall; (3) ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; (4) ASC–4: All-Cause Hospital Transfer/Admission; (5) ASC–9: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients; (6) ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use; and (7) ASC–11: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.

• *Hospital Inpatient Quality Reporting (IQR) Program Update:* In this proposed rule, we are proposing to modify the HCAHPS Survey measure by removing the Communication about Pain questions from the HCAHPS Survey for the Hospital IQR Program, effective with January 2022 discharges for the FY 2024 payment determination and subsequent years.

4. Summary of Costs and Benefits

In sections XX. and XXI. of this proposed rule, we set forth a detailed analysis of the regulatory and Federalism impacts that the proposed changes would have on affected entities and beneficiaries. Key estimated impacts are described below.

a. Impacts of the Proposed OPPS Update

(1) Impacts of All Proposed OPPS Changes

Table 42 in section XX. of this proposed rule displays the distributional impact of all the proposed OPPS changes on various groups of hospitals and CMHCs for CY 2019 compared to all estimated OPPS payments in CY 2018. We estimate that policies in this proposed rule would result in a 0.1 percent overall decrease in OPPS payments to providers. We estimate that total OPPS payments for CY 2019, including beneficiary cost-sharing, to the approximate 3,800 facilities paid under the OPPS (including general acute care hospitals, children's hospitals, cancer hospitals, and CMHCs) would decrease by approximately $80 million compared to CY 2018 payments, excluding our estimated changes in enrollment, utilization, and case-mix.

We estimated the isolated impact of our proposed 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 17.9 percent decrease in CY 2019 payments to CMHCs relative to their CY 2018 payments.

(2) Impacts of the Proposed Updated Wage Indexes

We estimate that our proposed update of the wage indexes based on the FY 2019 IPPS proposed rule wage indexes would result in no estimated payment change for urban and rural hospitals under the OPPS. These proposed 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 proposed rule.

(3) Impacts of the Proposed Rural Adjustment and the Cancer Hospital Payment Adjustment

There are no significant impacts of our proposed CY 2019 payment policies for hospitals that are eligible for the rural adjustment or for the cancer hospital payment adjustment. We are not proposing to make any change in policies for determining the rural hospital payment adjustments. While we are implementing the required reduction to the cancer hospital payment adjustment in section 16002 of the 21st Century Cures Act for CY 2019, the proposed target payment-to-cost ratio (PCR) for CY 2019 remains the same as in CY 2018 and therefore does not impact the budget neutrality adjustments.

(4) Impacts of the Proposed OPD Fee Schedule Increase Factor

For the CY 2019 OPPS, we are proposing an OPD fee schedule increase factor of 1.25 percent to the conversion factor for CY 2019. As a result of the proposed OPD fee schedule increase factor and other budget neutrality adjustments, we estimate that rural and urban hospitals would experience increases of approximately 1.3 percent for urban hospitals and 1.5 percent for rural hospitals. Classifying hospitals by teaching status, we estimate nonteaching hospitals would experience increases of 1.4 percent, minor teaching hospitals would experience increases of 1.3 percent, and major teaching hospitals would experience a decrease of 1.1 percent. We also classified hospitals by type of ownership. We estimate that hospitals with voluntary ownership would experience increases of 1.3 percent, hospitals with proprietary ownership would experience increases of 1.4 percent, and hospitals with government ownership would experience decrease of 1.3 percent in payments.

(5) Impacts of the Proposal to Control for Unnecessary Increases in the Volume of Outpatient Services

In section X.B. of this proposed rule, we discuss our CY 2019 proposal to control for unnecessary increases in the volume of outpatient service by paying for clinic visits furnished at an off-campus provider-based department at a PFS-equivalent rate under the OPPS rather than at the standard OPPS rate. As a result of this proposal, we estimated decreases of 1.2 percent to urban hospitals, and estimated decreases of 1.3 percent to rural hospitals, with the estimated effect for individual groups of hospitals depending on the volume of clinic visits provided at off-campus provider-based departments.

b. Impacts of the Proposed 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 proposed CY 2019 payment rates, compared to estimated CY 2018 payment rates, generally ranges between an increase of 1 to 4 percent, depending on the service, with some exceptions. We estimate the impact of applying the hospital market basket update to proposed ASC payment rates would increase payments by $32 million under the ASC payment system in CY 2019 compared to if we applied an update based on CPI–U.

c. Impact of the Proposed Changes to the Hospital OQR Program

Across 3,300 hospitals participating in the Hospital OQR Program, we estimate that our proposed requirements would result in the following changes to costs and burdens related to information collection for the Hospital OQR Program compared to previously adopted requirements: (1) No change in the total collection of information burden or costs for the CY 2020 payment determination; (2) a total collection of information burden reduction of 1,468,614 hours and a total collection of information cost reduction of approximately $57.3 million for the CY 2021 payment determination due to the proposed removal of six specific measures: OP–5, OP–12, OP–17, OP–29, OP–30, and OP–31.

Further, we anticipate that the proposed removal of a total of 10 measures would result in a reduction in costs unrelated to information collection. For example, it may be costly for health care providers to track the confidential feedback, preview reports, and publicly reported information on a measure where we use the measure in more than one program. Also, when measures are in multiple programs, maintaining the specifications for those measures, as well as the tools we need to collect, validate, analyze, and publicly report the measure data may result in costs to CMS. In addition, beneficiaries may find it confusing to see public reporting on the same measure in different programs.

d. Impact of the Proposed Changes to the ASCQR Program

Across 3,937 ASCs participating in the ASCQR Program, we estimate that our proposed requirements would result in the following changes to costs and burdens related to information collection for the ASCQR Program compared to previously adopted requirements: (1) No change in the total collection of information burden or costs for the CY 2020 payment determination; (2) a total collection of information burden reduction of 140,585 hours and a total collection of information cost reduction of approximately $5.1 million for the CY 2021 payment determination due to the proposed removal of three specific measures: ASC–9, ASC–10, and ASC–11.

Further, we anticipate that the proposed removal of a total of eight measures would result in a reduction in costs unrelated to information collection. For example, it may be costly for health care providers to track the confidential feedback, preview reports, and publicly reported information on a measure where we use the measure in more than one program. Also, when measures are in multiple programs, maintaining the specifications for those measures as well as the tools we need to collect, analyze, and publicly report the measure data may result in costs to CMS. In addition, beneficiaries may find it confusing to see public reporting on the same measure in different programs.

B. Legislative and Regulatory Authority for the Hospital OPPS

When Title XVIII of the Social Security 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, and the 21st Century Cures Act (Pub. L. 114–255), enacted on December 13, 2016.

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 (section 1833(t)(2)(B) of the Act). In accordance with section 1833(t)(2) 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 generally 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 and in some cases, provides for a longer period under which transitional pass-through payments are made. 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 Physician Fee Schedule (PFS); 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 the Maryland All-Payer 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 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 21, 2016, for a 2-year period (81 FR 94378).

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 21, 2017. 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 2018 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 20–21, 2018'' (83 FR 19785).

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 21, 2017 meeting that the subcommittees continue. We accepted this recommendation.

Discussions of the other recommendations made by the Panel at the August 21, 2017 Panel meeting, namely endovascular procedure APCs, blood derived hematopoietic stem cell transplantation, OPPS payment for drugs acquired under the 340B program, and packaging of drug administration services, were discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59216) and the CY 2018 OPPS/ASC correction notice (82 FR 61184), or are included in the sections of this proposed rule that are specific to each recommendation. For discussions of earlier Panel meetings and recommendations, we refer readers to previously published OPPS/ASC proposed and final rules, the CMS website mentioned earlier in this section, and the FACA database at *http://facadatabase.gov.*

F. Public Comments Received on the CY 2018 OPPS/ASC Final Rule With Comment Period

We received approximately 127 timely pieces of correspondence on the

CY 2018 OPPS/ASC final rule with comment period that appeared in the **Federal Register** on December 14, 2017 (82 FR 59216), 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 will be set forth in the CY 2019 final rule with comment period under the appropriate subject matter headings.

II. Proposed Updates Affecting OPPS Payments

A. Proposed 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 this CY 2019 OPPS/ASC proposed rule, for CY 2019, we are proposing to recalibrate the APC relative payment weights for services furnished on or after January 1, 2019, and before January 1, 2020 (CY 2019), using the same basic methodology that we described in the CY 2018 OPPS/ASC final rule with comment period (82 FR 52367 through 52370), using updated CY 2017 claims data. That is, we are proposing to 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 proposed relative payment weights for CY 2019, we began with approximately 163 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, 2017, and before January 1, 2018, before applying our exclusionary criteria and other methodological adjustments. After the application of those data processing changes, we used approximately 86 million final action claims to develop the proposed CY 2019 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 this CY 2019 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 this proposed rule (which is available via the internet on the CMS website) includes the proposed list of bypass codes for CY 2019. The proposed list of bypass codes contains codes that were reported on claims for services in CY 2017 and, therefore, includes codes that were in effect in CY 2017 and used for billing, but were deleted for CY 2018. We retained these deleted bypass codes on the proposed CY 2019 bypass list because these codes existed in CY 2017 and were covered OPD services in that period, and CY 2017 claims data are used to calculate CY 2019 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 are identified by asterisks (*) in the third column of Addendum N to this proposed rule. HCPCS codes that we are proposing to add for CY 2019 are identified by asterisks (*) in the fourth column of Addendum N.

We are not proposing to remove any codes from the CY 2019 bypass list.

b. Proposed Calculation and Use of Cost-to-Charge Ratios (CCRs)

For CY 2019, in this CY 2019 OPPS/ASC proposed rule, we are proposing 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 proposed CY 2019 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 2017 claims data by comparing these claims data to the most recently available hospital cost reports, which, in most cases, are from CY 2016. For the proposed CY 2019 OPPS payment rates, we used the set of claims processed during CY 2017. 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 2017 (the year of claims data we used to calculate the proposed CY 2019 OPPS payment rates) and found that the National Uniform Billing Committee (NUBC) did not add any new revenue codes to the NUBC 2017 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 this proposed rule.

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 imagings (MRIs), computed tomography (CT) scans, and cardiac catheterization. However, in response to the CY 2014 OPPS/ASC proposed rule, commenters reported that some hospitals currently use an imprecise ''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), we finalized a policy to extend the transition policy for 1 additional year and 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.

As we discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59228), some stakeholders have raised concerns regarding using claims from all providers to calculate CT and MRI CCRs, regardless of the cost allocations statistic employed (78 FR 74840 through 74847). Stakeholders noted that providers continue to use the ''square feet'' cost allocation method and that including claims from such providers would cause significant reductions in the imaging APC payment rates.

Table 1 below demonstrates the relative effect on imaging APC payments after removing cost data for providers that report CT and MRI standard cost centers using ''square feet'' as the cost allocation method by extracting HCRIS data on Worksheet B–1. Table 2 below provides statistical values based on the CT and MRI standard cost center CCRs using the different cost allocation methods.

TABLE 1—PERCENTAGE CHANGE IN ESTIMATE 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	−3.6
5522	Level 2 Imaging without Contrast	5.5
5523	Level 3 Imaging without Contrast	4.3
5524	Level 4 Imaging without Contrast	4.7
5571	Level 1 Imaging with Contrast	7.7
5572	Level 2 Imaging with Contrast	8.4
5573	Level 3 Imaging with Contrast	2.8
8005	CT and CTA without Contrast Composite	13.9
8006	CT and CTA with Contrast Composite	11.4
8007	MRI and MRA without Contrast Composite	6.6
8008	MRI and MRA with Contrast Composite	7.4

TABLE 2—CCR STATISTICAL VALUES BASED ON USE OF DIFFERENT COST ALLOCATION METHODS

Cost allocation method	CT		MRI	
	Median CCR	Mean CCR	Median CCR	Mean CCR
All Providers	0.0377	0.0527	0.0780	0.1046
Square Feet Only	0.0309	0.0475	0.0701	0.0954
Direct Assign	0.0553	0.0645	0.1058	0.1227
Dollar Value	0.0446	0.0592	0.0866	0.1166
Direct Assign and Dollar Value	0.0447	0.0592	0.0867	0.1163

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 17.4 percent to 2,174 providers and the number of valid CT CCRs has increased by 14.8 percent to 2,244 providers. However, as shown in Table 1 above, nearly all imaging APCs would see an increase in payment rates for CY 2019 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 cost allocation method of ''square feet'' as shown in Table 2 above.

In response to provider concerns and to provide added flexibility for hospitals to improve their cost allocation methods, for the CY 2019 OPPS, we are proposing to extend our transition policy and remove claims from providers that use a cost allocation method of ''square feet'' to calculate CCRs used to estimate costs with the APCs for CT and MRI identified in Table 2 above. This proposed extension would mean that CMS would now be providing 6 years for providers to transition from a ''square feet'' cost allocation method to another cost allocation method. We do not believe another extension in CY 2020 will be warranted and expect to determine the imaging APC relative payment weights for CY 2020 using cost data from all providers, regardless of the cost allocation method employed.

2. Proposed Data Development Process and Calculation of Costs Used for Ratesetting

In this section of this proposed rule, we discuss the use of claims to calculate the proposed OPPS payment rates for CY 2019. The Hospital OPPS page on the CMS website on which this proposed rule 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 proposed 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 2017 claims that were used to calculate the proposed payment rates for the CY 2019 OPPS.

In the history of the OPPS, we have traditionally established the scaled relative weights on which payments are based using APC median costs, which is 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 2019, in this CY 2019 OPPS/ASC proposed rule, we are proposing to continue to use geometric mean costs to calculate the proposed relative weights on which the CY 2019 OPPS payment rates are based.

We used the methodology described in sections II.A.2.a. through II.A.2.c. of this proposed rule to calculate the costs we used to establish the proposed relative payment weights used in calculating the proposed OPPS payment rates for CY 2019 shown in Addenda A and B to this proposed rule (which are available via the internet on the CMS website). We refer readers to section II.A.4. of this proposed rule for a discussion of the conversion of APC costs to scaled payment weights.

We note that this will be the first year in which claims data containing lines with the modifier ''PN'' will be 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, we are proposing 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 details of the claims process used in this proposed rule, we refer readers to the claims accounting narrative under supporting documentation for this CY 2019 OPPS/ASC proposed rule on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

a. Proposed 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 this CY 2019 OPPS/ASC proposed rule, we are proposing 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 are proposing 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 are proposing 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 are proposing to calculate the costs upon which the proposed CY 2019 payment rates for blood and blood products are based using the actual blood-specific CCR for hospitals that reported costs and charges for a blood cost center and a hospital-specific, simulated blood-specific CCR for hospitals that did not report costs and charges for a blood cost center.

We continue to believe that the hospital-specific, simulated blood-specific, CCR methodology better responds to the absence of a blood-specific CCR for a hospital than alternative methodologies, such as defaulting to the overall hospital CCR or applying an average blood-specific CCR across hospitals. Because this methodology takes into account the unique charging and cost accounting structure of each hospital, we believe that it yields more accurate estimated costs for these products. We continue to believe that this methodology in CY 2019 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. of the CY 2018 OPPS/ASC final rule with comment period (82 FR 59234 through 59239), 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 this CY 2019 OPPS/ASC proposed rule, we are proposing 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 proposed payment rates of the C–APCs), we are proposing 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 refer readers to Addendum B to this proposed rule (which is available via the internet on the CMS website) for the proposed CY 2019 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).

(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 59232) 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 for HCPCS code P9072 (HCPCS code Q9988) 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 to the payment amount for services described by HCPCS P9037 for CY 2018 (82 FR 59232), as had been done previously, to determine the payment rate for services described by HCPCS code P9072. In this proposed rule, for CY 2019, we have 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. Accordingly, we believe that there are a sufficient number of claims to use to calculate a payment rate for HCPCS code P9073 for CY 2019. 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 for 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 only 59 claims reported for services described by HCPCS code Q9987, of which 3 were separately paid.

These findings imply 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 contain rapid bacterial testing of platelets claims, was $468.11, which is lower than the geometric mean cost for services described by HCPCS code Q9988 of $453.87, which would not have contained claims for rapid bacterial testing of platelets. Because the geometric mean for services described by HCPCS code Q9987 is 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 is higher than the geometric mean cost for services described by HCPCS code P9072.

Based on our analysis of claims data, we believe there are sufficient claims available to establish a payment rate for pathogen-reduced pheresis platelets without using a crosswalk. Therefore, we are proposing to calculate the payment rate for services described by HCPCS code P9073 in CY 2019 and in subsequent years using claims payment history, which is the standard methodology used by the OPPS for HCPCS and CPT codes with at least 2 years of claims history. We refer readers to Addendum B of this 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.

(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 this CY 2019 OPPS/ASC proposed rule, for CY 2019, we are proposing to use the costs derived from CY 2017 claims data to set the proposed CY 2019 payment rates for brachytherapy sources because CY 2017 is the same year of data we are proposing to use to set the proposed payment rates for most other items and services that would be paid under the CY 2019 OPPS. We are proposing to base the payment rates for brachytherapy sources on the geometric mean unit costs for each source, consistent with the methodology that we are proposing for other items and services paid under the OPPS, as discussed in section II.A.2. of this proposed rule. We also are proposing 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 are proposing 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 are proposing 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 2019 payment rates for brachytherapy sources are included in Addendum B to this proposed rule (which is available via the internet on the CMS website) and are identified with status indicator ''U''. For CY 2019, we are proposing to continue to assign status indicator ''U'' (Brachytherapy Sources, Paid under OPPS; separate APC payment) to HCPCS code C2645 (Brachytherapy planar source, palladium-103, per square millimeter) and to use external data (invoice prices) and other relevant information to establish the proposed APC payment rate for HCPCS code C2645. Specifically, we are proposing to set the payment rate at $4.69 per mm^2, the same rate that was in effect for CYs 2017 and 2018.

We note that, for CY 2019, we are proposing to assign status indicator ''E2'' (Items and Services for Which Pricing Information and Claims Data Are Not Available) to HCPCS code C2644 (Brachytherapy cesium-131 chloride) because this code was not reported on CY 2017 claims. Therefore, we are unable to calculate a proposed payment rate based on the general OPPS ratesetting methodology described earlier. Although HCPCS code C2644 became effective July 1, 2014, there are no CY 2017 claims reporting this code. Therefore, we are proposing to assign new proposed status indicator ''E2'' to HCPCS code C2644 in the CY 2019 OPPS.

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. Proposed Comprehensive APCs (C–APCs) for CY 2019

(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 one 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, we did not change the total number of C–APCs from 62.

Under this 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 proposed rule (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'' 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;
- Contains 8 or more units of services described by HCPCS code G0378 (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 referral 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. Therefore, the requirement for functional reporting under the regulations at 42 CFR 410.59(a)(4) and 42 CFR 410.60(a)(4) does not apply. 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 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 2019, in this CY 2019 OPPS/ASC proposed rule, we are proposing 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 list the complexity adjustments proposed for ''J1'' and add-on code combinations for CY 2019, along with all of the other proposed complexity adjustments, in Addendum J to this proposed rule (which is available via the internet on the CMS website).

Addendum J to this proposed rule includes the cost statistics for each code combination that would qualify for a complexity adjustment (including primary code and add-on code

combinations). Addendum J to this proposed rule also contains summary cost statistics for each of the paired code combinations that describe a complex code combination that would qualify for a complexity adjustment and are proposed to be reassigned to the next higher cost C–APC within the clinical family. The combined statistics for all proposed reassigned complex code combinations are represented by an alphanumeric code with the first 4 digits of the designated primary service followed by a letter. For example, the proposed geometric mean cost listed in Addendum J for the code combination described by complexity adjustment assignment 3320R, which is assigned to C–APC 5224 (Level 4 Pacemaker and Similar Procedures), includes all paired code combinations that are proposed to be reassigned to C–APC 5224 when CPT code 33208 is the primary code. Providing the information contained in Addendum J to this proposed rule allows stakeholders the opportunity to better assess the impact associated with the proposed reassignment of claims with each of the paired code combinations eligible for a complexity adjustment.

(2) Proposed Additional C–APCs for CY 2019

For CY 2019 and subsequent years, in this CY 2019 OPPS/ASC proposed rule, we are proposing to continue to apply the C–APC payment policy methodology made effective in CY 2015 and updated with the implementation of status indicator ''J2'' in CY 2016. We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79583) for a discussion of the C–APC payment policy methodology and revisions. Each year, in accordance with section 1833(t)(9)(A) of the Act, we review and revise the services within each APC group and the APC assignments under the OPPS. As a result of our annual review of the services and the APC assignments under the OPPS, we are proposing to add three C–APCs under the existing C–APC payment policy beginning in CY 2019: proposed C–APC 5163 (Level 3 ENT Procedures); proposed C–APC 5183 (Level 3 Vascular Procedures); and proposed C–APC 5184 (Level 4 Vascular 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 3 of this proposed rule lists the proposed C–APCs for CY 2019. All C–APCs are displayed in Addendum J to this proposed rule (which is available via the internet on the CMS website). Addendum J to this proposed rule also contains all of the data related to the C–APC payment policy methodology, including the list of proposed complexity adjustments and other information.

TABLE 3—PROPOSED CY 2019 C–APCS

C–APC	CY 2019 APC group title	Clinical family	Proposed 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 & Related Procedures	BREAS	
5094	Level 4 Breast/Lymphatic Surgery & 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	
5183	Level 3 Vascular Procedures	VASCX	*
5184	Level 4 Vascular Procedures	VASCX	*
5191	Level 1 Endovascular Procedures	EVASC	
5192	Level 2 Endovascular Procedures	EVASC	
5193	Level 3 Endovascular Procedures	EVASC	
5194	Level 4 Endovascular Procedures	EVASC	
5200	Implantation Wireless PA Pressure Monitor	WPMXX	
5211	Level 1 Electrophysiologic Procedures	EPHYS	
5212	Level 2 Electrophysiologic Procedures	EPHYS	
5213	Level 3 Electrophysiologic Procedures	EPHYS	
5222	Level 2 Pacemaker and Similar Procedures	AICDP	
5223	Level 3 Pacemaker and Similar Procedures	AICDP	
5224	Level 4 Pacemaker and Similar Procedures	AICDP	
5231	Level 1 ICD and Similar Procedures	AICDP	
5232	Level 2 ICD and Similar Procedures	AICDP	
5244	Level 4 Blood Product Exchange and Related Services	SCTXX	
5302	Level 2 Upper GI Procedures	GIXXX	
5303	Level 3 Upper GI Procedures	GIXXX	
5313	Level 3 Lower GI Procedures	GIXXX	
5331	Complex GI Procedures	GIXXX	
5341	Abdominal/Peritoneal/Biliary and Related Procedures	GIXXX	
5361	Level 1 Laparoscopy & Related Services	LAPXX	

TABLE 3—PROPOSED CY 2019 C–APCS—Continued

C–APC	CY 2019 APC group title	Clinical family	Proposed new C-APC
5362	Level 2 Laparoscopy & Related Services	LAPXX	
5373	Level 3 Urology & Related Services	UROXX	
5374	Level 4 Urology & Related Services	UROXX	
5375	Level 5 Urology & Related Services	UROXX	
5376	Level 6 Urology & Related Services	UROXX	
5377	Level 7 Urology & 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	
5462	Level 2 Neurostimulator & Related Procedures	NSTIM	
5463	Level 3 Neurostimulator & Related Procedures	NSTIM	
5464	Level 4 Neurostimulator & 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.

(3) Exclusion of Procedures Assigned to New Technology APCs From the Comprehensive APC (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. When a procedure assigned to a New Technology APC is included on the claim with a primary procedure, identified by OPPS status indicator ''J1'', payment for the new technology service is typically packaged into the payment for the primary procedure. Because the new technology service is not separately paid in this scenario, the overall number of single claims available to determine an appropriate clinical APC for the new service is reduced. This is 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, we are proposing to exclude 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. This issue is also addressed in section III.C.3.b. of this proposed rule.

c. Proposed 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.

In this CY 2019 OPPS/ASC proposed rule, for CY 2019 and subsequent years, we are proposing to continue our composite APC payment policies for mental health services and multiple imaging services, as discussed below. In addition, as discussed in section II.A.2.b.(3) and II.A.2.c. of the CY 2018 OPPS/ASC proposed rule and final rule with comment period (82 FR 33577 through 33578 and 59241 through 59242 and 59246, respectively), we are proposing to continue to assign CPT code 55875 (Transperineal placement of needs or catheters into prostate for interstitial radioelement application, with or without cystoscopy) to status indicator ''J1'' and to continue to assign the services described by CPT code 55875 to C–APC 5375 (Level 5 Urology and Related Services) for CY 2019.

(1) Mental Health Services Composite APC

In this CY 2019 OPPS/ASC proposed rule, we are proposing 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.

For CY 2019, we are proposing 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 2019. In addition, we are proposing to set the proposed payment rate for composite APC 8010 at the same payment rate that we are proposing 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.

(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 this CY 2019 OPPS/ASC proposed rule, we are proposing, for CY 2019 and subsequent years, to continue to pay for all multiple imaging procedures within an imaging family performed on the same date of service using the multiple imaging composite APC payment methodology. We continue to believe that this policy would reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session.

The proposed CY 2019 payment rates for the five multiple imaging composite APCs (APCs 8004, 8005, 8006, 8007, and 8008) are based on proposed geometric mean costs calculated from a partial year of CY 2017 claims available for this CY 2019 OPPS/ASC proposed rule that qualified for composite payment under the current policy (that is, those claims reporting more than one procedure within the same family on a single date of service). To calculate the proposed geometric mean costs, we used the same methodology that we have used to calculate the geometric mean costs for these composite APCs since CY 2014, as described in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74918). The imaging HCPCS codes referred to as ''overlap bypass codes'' that we removed from the bypass list for purposes of calculating the proposed multiple imaging composite APC geometric mean costs, in accordance with our established methodology as stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74918), are identified by asterisks in Addendum N to this CY 2019 OPPS/ASC proposed rule (which is available via the internet on the CMS website) and are discussed in more detail in section II.A.1.b. of this CY 2019 OPPS/ASC proposed rule.

For this CY 2019 OPPS/ASC proposed rule, we were able to identify approximately 638,902 ''single session'' claims out of an estimated 1.7 million potential claims for payment through composite APCs from our ratesetting claims data, which represents approximately37 percent of all eligible claims, to calculate the proposed CY 2019 geometric mean costs for the multiple imaging composite APCs. Table 4 of this CY 2019 OPPS/ASC proposed rule lists the proposed HCPCS codes that would be subject to the multiple imaging composite APC policy and their respective families and approximate composite APC proposed geometric mean costs for CY 2019.

TABLE 4—PROPOSED OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS

Proposed CY 2019 APC 8004 (ultrasound composite)	Proposed CY 2019 approximate APC geometric mean cost = $300
Family 1—Ultrasound	
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.
Proposed CY 2019 APC 8005 (CT and CTA without contrast composite) *	Proposed CY 2019 approximate APC geometric mean cost = $275
Family 2—CT and CTA with and without Contrast	
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.
Proposed CY 2019 APC 8006 (CT and CTA with contrast composite)	Proposed CY 2019 approximate APC geometric mean cost = $501
70487	Ct maxillofacial w/dye.
70460	Ct head/brain w/dye.

TABLE 4—PROPOSED OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS—Continued

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.

Proposed CY 2019 APC 8007 (MRI and MRA without contrast composite) *	Proposed CY 2019 approximate APC geometric mean cost = $556
Family 3—MRI and MRA with and without Contrast	
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.
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.
Proposed CY 2019 APC 8008 (MRI and MRA with contrast composite)	Proposed CY 2019 approximate APC geometric mean cost = $871
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.

3. Proposed 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 patient. 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 often occurs 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), and the

CY 2018 OPPS/ASC final rule with comment period (82 FR 59250). 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, 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 2019, 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 of 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 this CY 2019 OPPS/ASC proposed rule, for CY 2019, we are proposing 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 proposed changes to packaging policies beginning in CY 2019.

b. Proposed CY 2019 Packaging Policy for Non-Opioid Pain Management Treatments

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 expressed a variety of views on packaging under the OPPS. In the CY 2018 OPPS/ASC final rule with comment period, we summarized the comments received in response to our request (82 FR 59255). The 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. We 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, the President's Commission on Combating Drug Addiction and the Opioid Crisis (the Commission) recently recommended that CMS examine payment policies for certain drugs that function as a supply, specifically non-opioid pain management treatments. 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 opioid crisis was declared a national public health emergency under Federal law [7] and this determination was renewed on April 20, 2018.[8]

In response to stakeholder comments on the CY 2018 OPPS/ASC proposed rule and in light of the recommendations regarding payment policies for certain drugs, we recently 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. Currently, as noted above, drugs that function as a supply are packaged under the OPPS and the ASC payment system, regardless of the costs of the drugs. 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 specific drugs that function as a supply over a 5-year time period (CYs 2013 through 2017) to determine whether this packaging policy has 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. 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 a supply, including Exparel

[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.*

(HCPCS code C9290). 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 the FDA for administration into the postsurgical site to provide postsurgical analgesia.[9] 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. Exparel is currently the only non-opioid pain management drug that is packaged as a drug that functions as a supply when used in a surgical procedure under the OPPS and the ASC payment system.

From CYs 2013 through 2017, there was an overall increase in the OPPS Medicare utilization of Exparel of approximately 229 percent (from 2.3 million units to 7.7 million units) during this 5-year time period. The total number of claims reporting Exparel increased by 222 percent (from 10,609 claims to 34,183 claims) over this time period. This increase in utilization continued, even after the 3-year drug pass-through payment period ended for this product in 2014, with 18 percent overall growth in the total number of units used from CYs 2015 through 2017 (from 6.5 million units to 7.7 million units). The number of claims reporting Exparel increased by 21 percent during this time period (from 28,166 claims to 34,183 claims).

Thus, we have not found evidence to support the notion that the OPPS packaging policy has had an unintended consequence of discouraging the use of non-opioid treatment for postsurgical pain management in the hospital outpatient department. Therefore, based on this data analysis, we do not believe that changes are necessary under the OPPS for the packaged drug policy for drugs that function as a surgical supply when used in a surgical procedure in this setting at this time.

In terms of Exparel in particular, we have received several requests to pay separately for the drug rather than packaging payment for it as a surgical supply. In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66874 and 66875), in response to comments from stakeholders requesting separate payment for Exparel, we 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. We also stated that 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. In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59345), 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. In addition, we have reviewed recently available literature with respect to Exparel, including a briefing document[10] submitted for the 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 U.S.'' [11] On April 6, 2018, the FDA approved Exparel's new indication for use as an interscalene brachial plexus nerve block to produce postsurgical regional analgesia.[12] Based on our review of currently available OPPS Medicare claims data and public information from the manufacturer of the drug, we do not believe that the OPPS packaging policy has discouraged the use of Exparel for either of the drug's indications. Accordingly, we continue to believe it is appropriate to package payment for Exparel as we do with other postsurgical pain management drugs when it is furnished in a hospital outpatient department. However, we are seeking public comments on whether separate payment would nonetheless further incentivize appropriate use of Exparel in the hospital outpatient setting and peer-reviewed evidence that such increased utilization would lead to a decrease in opioid use and addiction among Medicare beneficiaries.

Although we found increases in utilization for Exparel when it is paid under the OPPS, we did notice different effects on Exparel utilization when examining the effects of our packaging policy under the ASC payment system. In particular, during the same 5-year period of CYs 2013 through 2017, the total number of units of Exparel used in the ASC setting decreased by 25 percent (from 98,160 total units to 73,595 total units) and the total number of claims reporting Exparel decreased by 16 percent (from 527 claims to 441 claims). In the ASC setting, after the pass-through payment period ended for Exparel at the end of CY 2014, the total number of units of Exparel used decreased by 70 percent (from 244,757 units to 73,595 units) between CYs 2015 and 2017. The total number of claims reporting Exparel also decreased during this time period by 62 percent (from 1,190 claims to 441 claims). However, there was an increase of 238 percent (from 98,160 total units to 331,348 total units) in the total number of units of Exparel used in the ASC setting during the time period of CYs 2013 and 2014 when the drug received pass-through payments, indicating that the payment rate of ASP +6 percent for Exparel may have an impact on its usage in the ASC setting. The total number of claims reporting Exparel also increased during this time period from 527 total claims to 1,540 total claims, an increase of 192 percent.

While several variables may contribute to this difference between utilization and claims reporting in 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 therefore, ASCs may be less likely to choose to furnish non-opioid postsurgical pain management treatments, which are typically more expensive than opioids, as a result. 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.

In light of the results of our evaluation of packaging policies under the OPPS and the ASC payment system, which showed decreased utilization for certain drugs that function as a supply in the ASC setting in comparison to the hospital outpatient department setting, as well as the Commission's recommendation to examine payment

[9] Available at: *https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/022496s000lbl.pdf.*

[10] 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.*

[11] Ibid, page 9.

[12] Available at: *https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/022496s009lbledt.pdf.*

policies for non-opioid pain management drugs that function as a supply, we believe a change in how we pay for non-opioid pain management drugs that function as surgical supplies may be warranted. In particular, we believe it may be 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, we are proposing in section XII.D.3. of this proposed rule 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 for CY 2019.

We have stated previously (82 FR 59250) that our packaging policies are designed to support our strategic goal of using larger payment bundles in the OPPS to maximize hospitals' incentives to provide 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 this proposal is a departure from our current ASC packaging policy for drugs (specifically, non-opioid pain management drugs) that function as a supply when used in a surgical procedure, we believe that this proposed change will 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, the proposal for payment of non-opioid pain management drugs in the ASC setting is presented in further detail in section XII.D.3. of this proposed rule. However, we also are interested in peer-reviewed evidence that demonstrates that non-opioid alternatives, such as Exparel, in the outpatient setting actually do lead to a decrease in prescription opioid use and addiction and are seeking public comments containing evidence that demonstrate whether and how such non-opioid alternatives affect prescription opioid use during or after an outpatient visit or procedure.

In addition, as noted in section XII.D.3. of this proposed rule, we are seeking comment on whether the proposed policy would 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) as well as whether there are other non-opioid pain management alternatives that would have similar effects and may warrant separate payment. For example, we are interested in identifying whether single post-surgical analgesic injections, such as Exparel, or other non-opioid drugs or devices that are used during an outpatient visit or procedure are associated with decreased opioid prescriptions and reduced cases of associated opioid addiction following such an outpatient visit or procedure. We also are requesting comments that provide evidence (such as published peer-reviewed literature) 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 separate payment under either or both the OPPS and the ASC payment system. The reduction or avoidance of prescription opioids would be the criteria we would seek to determine whether separate payment is warranted for CY 2019. Should evidence change over time, we would consider whether a reexamination of any policy adopted in the final rule would be necessary.

In addition, we are inviting the public to submit ideas on regulatory, subregulatory, policy, practice, and procedural changes to help prevent opioid use disorders and improve access to treatment under the Medicare program. We are interested in identifying barriers that may inhibit access to non-opioid alternatives for pain treatment and management or access to opioid use disorder treatment, including those barriers related to payment methodologies or coverage. In addition, consistent with our ''Patients Over Paperwork'' Initiative, we are interested in suggestions to improve existing requirements in order to more effectively address the opioid epidemic.

As noted above, we are interested in comments regarding other non-opioid treatments besides Exparel that might be affected by OPPS and ASC packaging policies, including alternative, non-opioid pain treatments, such as devices or therapy services that are not currently separable payable. We are specifically interested in comments regarding whether CMS should consider separate payment for such items and services for which payment is currently packaged under the OPPS and the ASC payment system that are effective non-opioid alternatives as well as evidence that demonstrates such items and services lead to a decrease in prescription opioid use during or after an outpatient visit or procedure in order to determine whether separate payment may be warranted. We intend to examine the evidence submitted to determine whether to adopt a final policy that incentivizes use of non-opioid alternative items and services that have evidence to demonstrate an associated decrease in prescription opioid use and addiction following an outpatient visit or procedure. Some examples of evidence that may be relevant could include an indication on the product's FDA label or studies published in peer-reviewed literature that such product aids in the management of acute or chronic pain and is an evidence-based non-opioid alternative for acute and/or chronic pain management. We would also be interested in evidence relating to products that have shown clinical improvement over other alternatives, such as a device that has been shown to provide a substantial clinical benefit over the standard of care for pain management. This could include, for example, spinal cord stimulators used to treat chronic pain such as the devices described by HCPCS codes C1822 (Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system), C1820 (Generator, neurostimulator (implantable), with rechargeable battery and charging system), and C1767 (Generator, neurostimulator (implantable), nonrechargeable) which are primarily assigned to APCs 5463 and 5464 (Levels 3 and 4 Neurostimulator and Related Procedures) with proposed CY 2019 payment rates of $18,718 and $27,662, respectively, that have received pass-through payment status as well as other similar devices.

Currently, all devices are packaged under the OPPS and the ASC payment system unless they have pass-through payment status. However, in light of the Commission's recommendation to review and modify ratesetting policies that discourage the use of non-opioid treatments for pain, we are interested in comments from stakeholders regarding whether, similar to the goals of the proposed payment policy for non-opioid pain management drugs that function as a supply when used in a surgical procedure, a policy of providing separate payment (rather than packaged payment) for these products, indefinitely or for a specified period of time, would also incentivize the use of alternative non-opioid pain

management treatments and improve access to care for non-opioid alternatives, particularly for innovative and low-volume items and services.

We also are interested in comments regarding whether we should provide separate payment for non-opioid pain management treatments or products using a mechanism such as an equitable payment adjustment under our 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. For example, we are considering whether an equitable payment adjustment in the form of an add-on payment for APCs that use a non-opioid pain management drug, device, or service would be appropriate. To the extent that commenters provide evidence to support this approach, we would consider adopting a final policy, which could include regulatory changes that would allow for an exception to the packaging of certain nonpass-through devices that represent non-opioid alternatives for acute or chronic pain that have evidence to demonstrate that their use leads to a decrease in opioid prescriptions or addictions, in the final rule for CY 2019 to effectuate such change.

Alternatively, we are interested in comments on whether a reorganization of the APC structure for procedures involving these products or establishing more granular APC groupings for specific procedure and device combinations to ensure that the payment rate for such services is aligned with the resources associated with procedures involving specific devices would better achieve our goal of incentivizing increased use of non-opioid alternatives, with the aim of reducing opioid use and subsequent addiction. For example, we would consider finalizing a policy to establish new APCs for procedures involving non-opioid pain management packaged items or services if such APCs would better recognize the resources involved in furnishing such items and services and decrease or eliminate the need for prescription opioids. In addition, given the general desire to encourage provider efficiency through creating larger bundles of care and packaging items and services that are integral, ancillary, supportive, dependent, or adjunctive to a primary service, we also are seeking comment on how such alternative payment structures would continue to balance the goals of incentivizing provider efficiencies with encouraging the use of non-opioid alternatives to pain management. Furthermore, because patients may receive opioid prescriptions following receipt of a non-opioid drug or implantation of a device, we are interested in identifying any cost implications for the patient and the Medicare program caused by this potential change in policy. The implications of incentivizing non-opioid pain management drugs available for postsurgical acute pain relief during or after an outpatient visit or procedure are also of interest, including for non-opioid drugs. The goal is to encourage appropriate use of such non-opioid alternatives. We note that this comment solicitation is also discussed in section XII.D.3. of this proposed rule.

4. Proposed 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 2018 OPPS/ASC final rule with comment period (82 FR 59255 through 59256), we applied this policy and calculated the relative payment weights for each APC for CY 2018 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 2019, as we did for CY 2018, we are proposing to continue to apply the policy established in CY 2013 and calculate relative payment weights for each APC for CY 2019 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 2019, as we did for CY 2018, we are proposing 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 2019, as we did for CY 2018, we are proposing to assign APC 5012 a relative payment weight of 1.00 and to divide the geometric mean cost of each APC by the geometric mean cost for APC 5012 to derive the unscaled relative payment weight for each APC. The choice of the APC on which to standardize the relative payment weights does not affect payments made under the OPPS because we scale the weights for budget neutrality.

We note that, in section X.B. of this proposed rule, we discuss our CY 2019 proposal to control for unnecessary increases in the volume of outpatient service by paying for clinic visits furnished at an off-campus provider-based department at a PFS-equivalent rate under the OPPS rather than at the standard OPPS rate. While the volume associated with these visits is included in the impact model, and thus used in calculating the weight scalar, the proposal has only a negligible effect on the scalar. Specifically, under the proposed policy, there would be 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 our proposal, the savings that would result from the change in payments for these clinic visits would not be budget neutral. Therefore, the impact of the proposed policy would generally not be reflected in the budget neutrality adjustments, whether the adjustment is to the OPPS relative weights or to the OPPS conversion factor.

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 2019 is neither greater than nor less than the estimated aggregate weight that would have been made without the changes. To comply with this requirement concerning the APC changes, we are proposing to compare

the estimated aggregate weight using the CY 2018 scaled relative payment weights to the estimated aggregate weight using the proposed CY 2019 unscaled relative payment weights.

For CY 2018, we multiplied the CY 2018 scaled APC relative payment weight applicable to a service paid under the OPPS by the volume of that service from CY 2017 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 2019, we are proposing to apply the same process using the estimated CY 2019 unscaled relative payment weights rather than scaled relative payment weights. We are proposing to calculate the weight scalar by dividing the CY 2018 estimated aggregate weight by the unscaled CY 2019 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: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.* Click on the CY 2019 OPPS proposed rule link and open the claims accounting document link at the bottom of the page.

We are proposing to compare the estimated unscaled relative payment weights in CY 2019 to the estimated total relative payment weights in CY 2018 using CY 2017 claims data, holding all other components of the payment system constant to isolate changes in total weight. Based on this comparison, we are proposing to adjust the calculated CY 2019 unscaled relative payment weights for purposes of budget neutrality. We are proposing to adjust the estimated CY 2019 unscaled relative payment weights by multiplying them by a proposed weight scalar of 1.4553 to ensure that the proposed CY 2019 relative payment weights are scaled to be budget neutral. The proposed CY 2019 relative payment weights listed in Addenda A and B to this 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 this 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 proposed rule) is included in the budget neutrality calculations for the CY 2019 OPPS.

B. Proposed 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 2019 IPPS/LTCH PPS proposed rule (83 FR 20381), consistent with current law, based on IHS Global, Inc.'s fourth quarter 2017 forecast of the FY 2019 market basket increase, the proposed FY 2019 IPPS market basket update is 2.8 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 2019.

Specifically, section 1833(t)(3)(F)(i) of the Act requires that, for 2012 and subsequent years, the OPD fee schedule increase factor under subparagraph (C)(iv) be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period) (the ''MFP adjustment''). In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51689 through 51692), we finalized our methodology for calculating and applying the MFP adjustment, and then revised this methodology as discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49509). In this proposed rule, the proposed MFP adjustment for FY 2019 is 0.8 percentage point.

We are proposing that if more recent data become subsequently available after the publication of this 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 2019 market basket update and the MFP adjustment, which are components in calculating the OPD fee schedule increase factor under sections 1833(t)(3)(C)(iv) and 1833(t)(3)(F) of the Act, in the CY 2019 OPPS/ASC final rule with comment period.

In addition, section 1833(t)(3)(F)(ii) of the Act requires that, for each of years 2010 through 2019, the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act be reduced by the adjustment described in section 1833(t)(3)(G) of the Act. For CY 2019, section 1833(t)(3)(G)(v) of the Act provides a 0.75 percentage point reduction to the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act. Therefore, in accordance with sections 1833(t)(3)(F)(ii) and 1833(t)(3)(G)(v) of the Act, we are proposing to apply a 0.75 percentage point reduction to the OPD fee schedule increase factor for CY 2019.

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 are proposing to apply an OPD fee schedule increase factor of 1.25 percent for the CY 2019 OPPS (which is 2.8 percent, the proposed estimate of the hospital inpatient market basket percentage increase, less the proposed 0.8 percentage point MFP adjustment, and less the 0.75 percentage point additional adjustment).

Hospitals that fail to meet the Hospital OQR Program reporting requirements are 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 XIII. of this proposed rule.

In this CY 2019 OPPS/ASC proposed rule, we are proposing to amend 42 CFR 419.32(b)(1)(iv)(B) by adding a new paragraph (*10*) to reflect the requirement in section 1833(t)(3)(F)(i) of the Act that, for CY 2019, we reduce the OPD fee schedule increase factor by the MFP adjustment as determined by CMS, and

to reflect the requirement in section 1833(t)(3)(G)(v) of the Act, as required by section 1833(t)(3)(F)(ii) of the Act, that we reduce the OPD fee schedule increase factor by an additional 0.75 percentage point for CY 2019.

To set the OPPS conversion factor for this CY 2019 OPPS/ASC proposed rule, we are proposing to increase the CY 2018 conversion factor of $78.636 by 1.25 percent. In accordance with section 1833(t)(9)(B) of the Act, we are proposing further to adjust the conversion factor for CY 2019 to ensure that any revisions made to the wage index and rural adjustment are made on a budget neutral basis. We are proposing to calculate an overall proposed budget neutrality factor of 1.0004 for wage index changes by comparing proposed total estimated payments from our simulation model using the proposed FY 2019 IPPS wage indexes to those payments using the FY 2018 IPPS wage indexes, as adopted on a calendar year basis for the OPPS.

For this CY 2019 OPPS/ASC proposed rule, we are proposing to maintain the current rural adjustment policy, as discussed in section II.E. of this proposed rule. Therefore, the proposed budget neutrality factor for the rural adjustment would be 1.0000.

For this CY 2019 OPPS/ASC proposed rule, we are proposing 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 this proposed rule. We are proposing to calculate a CY 2019 budget neutrality adjustment factor for the cancer hospital payment adjustment by comparing estimated proposed total CY 2019 payments under section 1833(t) of the Act, including the proposed CY 2019 cancer hospital payment adjustment, to estimated CY 2019 total payments using the CY 2018 final cancer hospital payment adjustment as required under section 1833(t)(18)(B) of the Act. The CY 2019 proposed estimated payments applying the proposed CY 2019 cancer hospital payment adjustment are the same as estimated payments applying the CY 2018 final cancer hospital payment adjustment. Therefore, we are proposing to apply a budget neutrality adjustment factor of 1.0000 to the conversion factor for the cancer hospital payment adjustment. In accordance with section 16002(b) of the 21st Century Cures Act, we are applying a budget neutrality factor calculated as if the proposed cancer hospital adjustment target payment-to-cost ratio was 0.89, not the 0.88 target payment-to-cost ratio we are proposing to apply as stated in section II.F. of this proposed rule.

For this CY 2019 OPPS/ASC proposed rule, we estimate that proposed pass-through spending for drugs, biologicals, and devices for CY 2019 would equal approximately $126.7 million, which represents 0.17 percent of total projected CY 2019 OPPS spending. Therefore, the proposed conversion factor would be adjusted by the difference between the 0.04 percent estimate of pass-through spending for CY 2018 and the 0.17 percent estimate of proposed pass-through spending for CY 2019, resulting in a proposed decrease for CY 2019 of 0.13 percent. Proposed estimated payments for outliers would remain at 1.0 percent of total OPPS payments for CY 2019. We estimate for this proposed rule that outlier payments would be 1.02 percent of total OPPS payments in CY 2018; the 1.00 percent for proposed outlier payments in CY 2019 would constitute a 0.02 percent increase in payment in CY 2019 relative to CY 2018.

For this CY 2019 OPPS/ASC proposed rule, we also are proposing 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 are proposing to make all other adjustments discussed above, but use a reduced OPD fee schedule update factor of −0.75 percent (that is, the proposed OPD fee schedule increase factor of 1.25 percent further reduced by 2.0 percentage points). This would result in a proposed reduced conversion factor for CY 2019 of $77.955 for hospitals that fail to meet the Hospital OQR Program requirements (a difference of −1.591 in the conversion factor relative to hospitals that met the requirements).

In summary, for CY 2019, we are proposing to amend § 419.32(b)(1)(iv)(B) by adding a new paragraph (*10*) to reflect the reductions to the OPD fee schedule increase factor that are required for CY 2019 to satisfy the statutory requirements of sections 1833(t)(3)(F) and (t)(3)(G)(v) of the Act. We are proposing to use a reduced conversion factor of $77.955 in the calculation of payments for hospitals that fail to meet the Hospital OQR Program requirements (a difference of −1.591 in the conversion factor relative to hospitals that met the requirements).

For CY 2019, we are proposing to use a conversion factor of $79.546 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 1.25 percent for CY 2019, the required proposed wage index budget neutrality adjustment of approximately1.0004, the proposed cancer hospital payment adjustment of 1.0000, and the proposed adjustment of 0.02 percentage point of projected OPPS spending for the difference in the pass-through spending and outlier payments that result in a proposed conversion factor for CY 2019 of $79.546.

C. Proposed 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 proposed rule.

The OPPS labor-related share is 60 percent of the national OPPS payment. This labor-related share is based on a regression analysis that determined that, for all hospitals, approximately 60 percent of the costs of services paid under the OPPS were attributable to wage costs. We confirmed that this labor-related share for outpatient services is appropriate during our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553). We are proposing to continue this policy for the CY 2019 OPPS. We refer readers to section II.H. of this proposed rule for a description and an example of how the wage index for a particular hospital is used to determine payment for the hospital.

As discussed in the claims accounting narrative included with the supporting documentation for this proposed rule (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 proposed FY 2019 pre-reclassified wage index that the IPPS uses 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 (c)(3) of our regulations. For the CY 2019 OPPS, we are proposing 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 (as discussed below, we are proposing not to extend the imputed floor under the OPPS for CY 2019 and subsequent years, consistent with our proposal in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20362 and 20363) not to extend the imputed floor under the IPPS for FY 2019 and subsequent fiscal years). Because the HOPD receives a wage index based on the geographic location of the specific inpatient hospital with which it is associated, the frontier State wage index adjustment applicable for the inpatient hospital also would apply for any associated HOPD. We refer readers to the FY 2011 through FY 2018 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; and for FY 2018, 82 FR 38142.

In addition to the changes required by the Affordable Care Act, we note that the proposed FY 2019 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). We refer readers to the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20353 through 20377) for a detailed discussion of all proposed changes to the FY 2019 IPPS wage indexes. We note that, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20362 through 20363), we proposed not to apply the imputed floor to the IPPS wage index computations for FY 2019 and subsequent fiscal years. Consistent with this, we are proposing not to extend the imputed floor policy under the OPPS beyond December 31, 2018 (the date the imputed floor policy is set to expire under the OPPS). We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38138 through 38142) for a detailed discussion of the application of the imputed floor under the IPPS for FY 2018.

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 2018 IPPS/LTCH PPS final rule (82 FR 38129 through 38130), 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. We 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.

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 OMB Bulletin No. 17–01, OMB announced that one Micropolitan Statistical Area now qualifies as a Metropolitan Statistical Area. The new urban CBSA is as follows:

- Twin Falls, Idaho (CBSA 46300). This CBSA is comprised of the principal city of Twin Falls, Idaho in Jerome County, Idaho and Twin Falls County, Idaho.

The OMB Bulletin No. 17–01 is available on the OMB website at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf.* In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20354), we noted that we did not have sufficient time to include this change in the computation of the proposed FY 2019 IPPS wage index, ratesetting, and Tables 2 and 3 associated with the FY 2019 IPPS/LTCH PPS proposed rule. We stated that this new CBSA may affect the IPPS budget neutrality factors and wage indexes, depending on whether the area is eligible for the rural floor and the impact of the overall payments of the hospital located in this new CBSA. As we did in the FY 2019 IPPS/LTCH

PPS proposed rule (83 FR 20354), we are providing below an estimate of this new area's wage index based on the average hourly wages for new CBSA 46300 and the national average hourly wages from the wage data for the proposed FY 2019 IPPS wage index (described in section III.B. of the preamble of the FY 2019 IPPS/LTCH PPS proposed rule). Currently, provider 130002 is the only hospital located in Twin Falls County, Idaho, and there are no hospitals located in Jerome County, Idaho. Thus, the proposed wage index for CBSA 46300 is calculated using the average hourly wage data for one provider (provider 130002).

Below we provide the proposed FY 2019 IPPS unadjusted and occupational mix adjusted national average hourly wages and the estimated CBSA average hourly wages. Taking the estimated average hourly wage of new CBSA 46300 and dividing by the proposed national average hourly wage results in the estimated wage indexes shown in the table below.

	Estimated unadjusted wage index for new CBSA 46300	Estimated occupational mix adjusted wage index for new CBSA 46300
Proposed National Average Hourly Wage	42.990625267	42.948428861
Estimated CBSA Average Hourly Wage	35.833564813	38.127590025
Estimated Wage Index	0.8335	0.8878

As we stated in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20354), for the proposed FY 2019 IPPS wage indexes, we would use the OMB delineations that were adopted beginning with FY 2015 to calculate the area wage indexes, with updates as reflected in OMB Bulletin Nos. 13–01, 15–01, and 17–01. We also stated that we would incorporate the revision from OMB Bulletin No. 17–01 in the final FY 2019 IPPS wage index, ratesetting, and tables. Similarly, for the proposed CY 2019 OPPS wage indexes, we are proposing to use the OMB delineations that were adopted beginning with CY 2015 to calculate the area wage indexes, with updates as reflected in OMB Bulletin Nos. 13–01, 15–01, and 17–01. We would incorporate the revision from OMB Bulletin No. 17–01 in the final CY 2019 OPPS wage index, ratesetting, and tables.

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. 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 the purposes of crosswalking counties to CBSAs for the OPPS wage index.

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.* In our transition to using only FIPS codes for counties for the IPPS wage index, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38130), we updated the FIPS codes used for crosswalking counties to CBSAs for the IPPS wage index effective October 1, 2017, to incorporate changes to the counties or county equivalent entities included in the Census Bureau's most recent list. We included these updates to calculate the area IPPS wage indexes in a manner that is generally consistent with the CBSA-based methodologies finalized in the FY 2005 IPPS final rule and the FY 2015 IPPS/LTCH PPS final rule. In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59261), we finalized our proposal to implement these FIPS code updates for the OPPS wage index effective January 1, 2018, beginning with the CY 2018 OPPS wage indexes.

For this CY 2019 OPPS/ASC proposed rule, we are proposing to use the FY 2019 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 2019. Therefore, any adjustments for the FY 2019 IPPS post-reclassified wage index would be reflected in the final CY 2019 OPPS wage index. (We refer readers to the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20353 through 20377) and the proposed FY 2019 hospital wage index files posted on the CMS website.) As explained above, 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.

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. We are proposing to continue this policy for CY 2019. The following is a brief summary of the major proposed FY 2019 IPPS wage index policies and adjustments that we are proposing to apply to these hospitals under the OPPS for CY 2019. We are inviting public comments on these proposals. We refer readers to the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20353 through 20377) for a detailed discussion of the proposed changes to the FY 2019 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 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 2019, we are proposing 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).

As stated earlier, in the FY 2015 IPPS/LTCH PPS final rule, we adopted the OMB labor market area delineations issued by OMB in OMB Bulletin No. 13–01 on February 28, 2013, based on standards published on June 28, 2010 (75 FR 37246 through 37252) and the 2010 Census data to delineate labor market areas for purposes of the IPPS wage index. For IPPS wage index purposes, for hospitals that were located in urban CBSAs in FY 2014 but were designated as rural under these revised OMB labor market area delineations, we generally assigned them the urban wage index value of the CBSA in which they were physically located for FY 2014 for a period of 3 fiscal years (79 FR 49957 through 49960). To be consistent, we applied the same policy to hospitals paid under the OPPS but not under the IPPS so that such hospitals maintained the wage index of the CBSA in which they were physically located for FY 2014 for 3 calendar years (until December 31, 2017). Because this 3-year transition ended at the end of CY 2017, it was not applied beginning in CY 2018.

In addition, under the IPPS, the imputed floor policy is set to expire effective October 1, 2018. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20362 through 20363), we proposed not to extend the imputed floor policy under the IPPS for FY 2019 and subsequent fiscal years. For purposes of the CY 2019 OPPS, the imputed floor policy is set to expire effective December 31, 2018. Consistent with the FY 2019 IPPS/LTCH PPS proposed rule, as discussed earlier, we are proposing not to extend the imputed floor policy under the OPPS beyond December 31, 2018.

For CMHCs, for CY 2019, we are proposing to continue to calculate the wage index by using the post-reclassification IPPS wage index based on the CBSA where the CMHC is located. As with OPPS hospitals and for the same reasons, for CMHCs previously located in urban CBSAs that were designated as rural under the revised OMB labor market area delineations in OMB Bulletin No. 13–01, we finalized a policy to maintain the urban wage index value of the CBSA in which they were physically located for CY 2014 for 3 calendar years (until December 31, 2017). Because this 3-year transition ended at the end of CY 2017, it was not applied beginning in CY 2018. The wage index that would apply to CMHCs for CY 2019 would include the rural floor adjustment, but would not include the imputed floor adjustment because, as discussed above, we are proposing to not extend the imputed floor policy beyond December 31, 2018. Also, the wage index that would apply to CMHCs would not include the out-migration adjustment because that adjustment only applies to hospitals.

Table 2 associated with the FY 2019 IPPS/LTCH PPS proposed 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 and IPPS hospitals that would receive the adjustment for FY 2019. We are including the out-migration adjustment information from Table 2 associated with the FY 2019 IPPS/LTCH PPS proposed rule as Addendum L to this proposed rule with the addition of non-IPPS hospitals that would receive the section 505 out-migration adjustment under the CY 2019 OPPS. 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 proposed FY 2019 IPPS wage index tables and Addendum L.

D. Proposed 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. MACs cannot calculate a CCR for some hospitals because there is no cost report available. For these hospitals, CMS uses the statewide average default CCRs to determine the payments mentioned earlier until a hospital's MAC is able to calculate the hospital's actual CCR from its most recently submitted Medicare cost report. These hospitals include, but are not limited to, 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 that appear to have a biased CCR (that is, the 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. L. 100–04), Chapter 4, Section 10.11).

In this CY 2019 OPPS/ASC proposed rule, we are proposing to update the default ratios for CY 2019 using the most recent cost report data. 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 detail on our process for calculating the statewide average CCRs, we refer readers to the CY 2019 OPPS proposed rule Claims Accounting Narrative that is posted on the CMS website. Table 5 below lists the proposed statewide average default CCRs for OPPS services furnished on or after January 1, 2019, based on proposed rule data.

TABLE 5—PROPOSED CY 2019 STATEWIDE AVERAGE CCRS

State	Urban/Rural	Proposed CY 2019 default CCR	Previous default CCR (CY 2018 OPPS Final Rule)
ALASKA	RURAL	0.655	0.659

TABLE 5—PROPOSED CY 2019 STATEWIDE AVERAGE CCRS—Continued

State	Urban/Rural	Proposed CY 2019 default CCR	Previous default CCR (CY 2018 OPPS Final Rule)
ALASKA	URBAN	0.224	0.218
ALABAMA	RURAL	0.190	0.190
ALABAMA	URBAN	0.154	0.155
ARKANSAS	RURAL	0.193	0.186
ARKANSAS	URBAN	0.195	0.200
ARIZONA	RURAL	0.241	0.232
ARIZONA	URBAN	0.157	0.160
CALIFORNIA	RURAL	0.181	0.181
CALIFORNIA	URBAN	0.188	0.193
COLORADO	RURAL	0.337	0.346
COLORADO	URBAN	0.201	0.204
CONNECTICUT	RURAL	0.322	0.324
CONNECTICUT	URBAN	0.251	0.249
DISTRICT OF COLUMBIA	URBAN	0.273	0.279
DELAWARE	URBAN	0.268	0.295
FLORIDA	RURAL	0.171	0.158
FLORIDA	URBAN	0.136	0.138
GEORGIA	RURAL	0.223	0.222
GEORGIA	URBAN	0.199	0.198
HAWAII	RURAL	0.355	0.332
HAWAII	URBAN	0.321	0.322
IOWA	RURAL	0.288	0.296
IOWA	URBAN	0.242	0.254
IDAHO	RURAL	0.339	0.339
IDAHO	URBAN	0.376	0.369
ILLINOIS	RURAL	0.209	0.214
ILLINOIS	URBAN	0.205	0.208
INDIANA	RURAL	0.256	0.299
INDIANA	URBAN	0.213	0.213
KANSAS	RURAL	0.266	0.264
KANSAS	URBAN	0.195	0.199
KENTUCKY	RURAL	0.179	0.184
KENTUCKY	URBAN	0.190	0.187
LOUISIANA	RURAL	0.211	0.212
LOUISIANA	URBAN	0.193	0.195
MASSACHUSETTS	RURAL	0.314	0.322
MASSACHUSETTS	URBAN	0.343	0.348
MAINE	RURAL	0.423	0.419
MAINE	URBAN	0.419	0.422
MARYLAND	RURAL	0.256	0.258
MARYLAND	URBAN	0.226	0.227
MICHIGAN	RURAL	0.296	0.302
MICHIGAN	URBAN	0.314	0.318
MINNESOTA	RURAL	0.376	0.379
MINNESOTA	URBAN	0.309	0.302
MISSOURI	RURAL	0.216	0.220
MISSOURI	URBAN	0.247	0.240
MISSISSIPPI	RURAL	0.219	0.213
MISSISSIPPI	URBAN	0.157	0.160
MONTANA	RURAL	0.478	0.486
MONTANA	URBAN	0.339	0.350
NORTH CAROLINA	RURAL	0.204	0.206
NORTH CAROLINA	URBAN	0.217	0.212
NORTH DAKOTA	RURAL	0.325	0.366
NORTH DAKOTA	URBAN	0.375	0.369
NEBRASKA	RURAL	0.304	0.313
NEBRASKA	URBAN	0.227	0.233
NEW HAMPSHIRE	RURAL	0.304	0.307
NEW HAMPSHIRE	URBAN	0.247	0.255
NEW JERSEY	URBAN	0.198	0.200
NEW MEXICO	RURAL	0.231	0.224
NEW MEXICO	URBAN	0.280	0.284
NEVADA	RURAL	0.163	0.175
NEVADA	URBAN	0.121	0.114
NEW YORK	RURAL	0.297	0.299
NEW YORK	URBAN	0.310	0.303
OHIO	RURAL	0.277	0.280
OHIO	URBAN	0.204	0.203

TABLE 5—PROPOSED CY 2019 STATEWIDE AVERAGE CCRS—Continued

State	Urban/Rural	Proposed CY 2019 default CCR	Previous default CCR (CY 2018 OPPS Final Rule)
OKLAHOMA	RURAL	0.215	0.215
OKLAHOMA	URBAN	0.166	0.169
OREGON	RURAL	0.277	0.290
OREGON	URBAN	0.327	0.336
PENNSYLVANIA	RURAL	0.264	0.267
PENNSYLVANIA	URBAN	0.177	0.173
PUERTO RICO	URBAN	0.547	0.577
RHODE ISLAND	URBAN	0.276	0.276
SOUTH CAROLINA	RURAL	0.166	0.170
SOUTH CAROLINA	URBAN	0.187	0.191
SOUTH DAKOTA	RURAL	0.338	0.391
SOUTH DAKOTA	URBAN	0.240	0.242
TENNESSEE	RURAL	0.173	0.173
TENNESSEE	URBAN	0.166	0.174
TEXAS	RURAL	0.218	0.205
TEXAS	URBAN	0.169	0.168
UTAH	RURAL	0.288	0.391
UTAH	URBAN	0.304	0.304
VIRGINIA	RURAL	0.177	0.177
VIRGINIA	URBAN	0.215	0.215
VERMONT	RURAL	0.392	0.393
VERMONT	URBAN	0.383	0.378
WASHINGTON	RURAL	0.260	0.256
WASHINGTON	URBAN	0.325	0.323
WISCONSIN	RURAL	0.342	0.348
WISCONSIN	URBAN	0.304	0.308
WEST VIRGINIA	RURAL	0.261	0.253
WEST VIRGINIA	URBAN	0.299	0.297
WYOMING	RURAL	0.397	0.407
WYOMING	URBAN	0.343	0.327

E. Proposed Adjustment for Rural Sole Community Hospitals (SCHs) and Essential Access Community Hospitals (EACHs) Under Section 1833(t)(13)(B) of the Act for CY 2019

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, 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 § 419.43(g) of the regulations to clarify that essential access community hospitals (EACHs) also are 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 2018. Further, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68590), we updated the regulations at § 419.43(g)(4) to specify, in general terms, that items paid at charges adjusted to costs by application of a hospital-specific CCR are excluded from the 7.1 percent payment adjustment.

For the CY 2019 OPPS, we are proposing 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. In addition, we are proposing to maintain this 7.1 percent payment adjustment for the years after CY 2019 until we identify data in the future that would support a change to this payment adjustment.

F. Proposed Payment Adjustment for Certain Cancer Hospitals for CY 2019

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 for purposes of the cancer hospital payment adjustment was 0.89. 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).

2. Proposed Policy for CY 2019

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 42 CFR 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. For CY 2019, we are proposing 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 are available at the time of the development of this proposed rule, reduced by 1.0 percentage point to comply with section 16002(b) of the 21st Century Cures Act. We are not proposing an additional reduction beyond the 1.0 percentage point reduction required by section 16002(b) for CY 2019. To calculate the proposed CY 2019 target PCR, we use the same extract of cost report data from HCRIS, as discussed in section II.A. of this proposed rule, used to estimate costs for the CY 2019 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 2017 claims data that we used to model the impact of the proposed CY 2019 APC relative payment weights (3,676 hospitals) because it is appropriate to use the same set of hospitals that we are using to calibrate the modeled CY 2019 OPPS. The cost report data for the hospitals in this dataset were from cost report

periods with fiscal year ends ranging from 2014 to 2017.

We then removed the cost report data of the 43 hospitals located in Puerto Rico from our dataset because we do not believe that their cost structure reflects 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 18 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 3,615 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 89 percent of reasonable cost (weighted average PCR of 0.89). Therefore, after applying the 1.0 percentage point reduction as required by section 16002(b) of the 21st Century Cures Act, we are proposing 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 0.88 for each cancer hospital.

Table 6 below indicates the proposed estimated percentage increase in OPPS payments to each cancer hospital for CY 2019 due to the proposed cancer hospital payment adjustment policy. The actual amount of the CY 2019 cancer hospital payment adjustment for each cancer hospital will be determined at cost report settlement and will depend on each hospital's CY 2019 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 6—PROPOSED ESTIMATED CY 2019 HOSPITAL-SPECIFIC PAYMENT ADJUSTMENT FOR CANCER HOSPITALS TO BE PROVIDED AT COST REPORT SETTLEMENT

Provider No.	Hospital name	Estimated percentage increase in OPPS payments for CY 2019 due to payment adjustment
050146	City of Hope Comprehensive Cancer Center	37.1
050660	USC Norris Cancer Hospital	13.4
100079	Sylvester Comprehensive Cancer Center	21.0
100271	H. Lee Moffitt Cancer Center & Research Institute	22.3
220162	Dana-Farber Cancer Institute	43.7
330154	Memorial Sloan-Kettering Cancer Center	46.9
330354	Roswell Park Cancer Institute	16.2
360242	James Cancer Hospital & Solove Research Institute	22.6
390196	Fox Chase Cancer Center	8.4
450076	M.D. Anderson Cancer Center	53.6
500138	Seattle Cancer Care Alliance	54.3

G. Proposed 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 2018, 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 $4,150 (the fixed-dollar amount threshold) (82 FR 59267 through 59268). 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 2017 OPPS payments, using CY 2017 claims available for this proposed rule, is approximately 1.0 percent of the total aggregated OPPS payments. Therefore, for CY 2017, we estimate that we paid the outlier target of 1.0 percent of total aggregated OPPS payments.

For this proposed rule, using CY 2017 claims data and CY 2018 payment rates, we estimate that the aggregate outlier payments for CY 2018 would be approximately 1.02 percent of the total CY 2018 OPPS payments. We are providing estimated CY 2019 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. Proposed Outlier Calculation for CY 2019

For CY 2019, we are proposing to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPPS. We are proposing 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 this proposed rule, we are proposing 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 this proposed rule.

To ensure that the estimated CY 2019 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPPS, we are proposing 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 $4,600.

We calculated this proposed fixed-dollar threshold of $4,600 using the standard methodology most recently used for CY 2018 (82 FR 59267 through 59268). For purposes of estimating outlier payments for this proposed rule, we used the hospital-specific overall ancillary CCRs available in the April 2018 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 2019 hospital outlier payments for this proposed rule, we inflated the charges on the CY 2017 claims using the same inflation factor of 1.085868 that we used to estimate the IPPS fixed-dollar outlier threshold for the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20581). We used an inflation factor of 1.04205 to estimate CY 2018 charges from the CY 2017 charges reported on CY 2017 claims. The methodology for determining this charge inflation factor is discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 20581). 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 are 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 are proposing to apply the same CCR inflation adjustment factor that we proposed to apply for the FY 2019 IPPS outlier calculation to the CCRs used to simulate the proposed CY 2019 OPPS outlier payments to determine the fixed-dollar threshold. Specifically, for CY 2019, we are proposing to apply an adjustment factor of 0.987842 to the CCRs that were in the April 2018 OPSF to trend them forward from CY 2018 to CY 2019. The methodology for calculating this proposed adjustment is discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20582).

To model hospital outlier payments for the proposed rule, we applied the overall CCRs from the April 2018 OPSF after adjustment (using the proposed CCR inflation adjustment factor of 0.987842 to approximate CY 2019 CCRs) to charges on CY 2017 claims that were adjusted (using the proposed charge inflation factor of 1.085868 to approximate CY 2019 charges). We simulated aggregated CY 2019 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 2019 OPPS payments. We estimated that a proposed fixed-dollar threshold of $4,600, 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 are proposing 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, we are proposing to continue 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 XIII. of this proposed rule.

H. Proposed 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 2019 OPPS/ASC proposed rule, the proposed 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 proposed rule and the proposed relative payment weight determined under section II.A. of this proposed rule. Therefore, the proposed national unadjusted payment rate for most APCs contained in Addendum A to this proposed rule (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 proposed rule (which is available via the internet on the CMS website) was calculated by multiplying the proposed CY 2019 scaled weight for the APC by the proposed CY 2019 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 XIII. of this proposed rule.

We demonstrate below the steps on how to determine the APC payments that would be made in a calendar year 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 this 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 note that, although blood and blood products with status indicator ''R'' and brachytherapy sources with status indicator ''U'' are not subject to wage adjustment, they are subject to reduced payments when a hospital fails to meet the Hospital OQR Program requirements.

Individual providers interested in calculating the payment amount that they would receive for a specific service from the proposed national unadjusted payment rates presented in Addenda A and B to this proposed rule (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 proposed 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 proposed 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 proposed reduced national unadjusted payment rate is calculated by multiplying the reporting ratio of 0.980 times the ''full'' national unadjusted payment rate. The proposed 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 in order to receive the proposed full CY 2019 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 * (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 proposed CY 2019 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 proposed rule. The proposed 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 2019 under the IPPS, reclassifications through the Metropolitan 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 proposed changes to the FY 2019 IPPS wage indexes, as applied to the CY 2019 OPPS, we refer readers to section II.C. of this proposed rule. We are proposing to continue 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 proposed rule (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 2019 IPPS, which are listed in Table 2 in the FY 2019 IPPS/LTCH PPS proposed rule 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 2019 IPPS Proposed Rule Home Page'' and select ''FY 2019 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 proposed full and reduced national unadjusted payment rates that would 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 used 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 proposed CY 2019 full national unadjusted payment rate for APC 5071 is approximately $581.99. The proposed reduced national unadjusted payment rate for APC 5071 for a hospital that fails to meet the Hospital OQR Program requirements is approximately $570.35. This proposed reduced rate is calculated by multiplying the proposed reporting ratio of 0.980 by the proposed full unadjusted payment rate for APC 5071.

The proposed FY 2019 wage index for a provider located in CBSA 35614 in New York is 1.2850. The labor-related portion of the proposed full national unadjusted payment is approximately $448.71 (.60 * $581.99 * 1.2850). The labor-related portion of the proposed reduced national unadjusted payment is approximately $439.74 (.60 * 570.35* 1.2850). The nonlabor-related portion of the proposed full national unadjusted payment is approximately $232.80 (.40 * $581.99). The nonlabor-related portion of the proposed reduced national unadjusted payment is approximately $228.14 (.40 * $570.35). The sum of the labor-related and nonlabor-related portions of the proposed full national adjusted payment is approximately $681.51 ($448.71 + $232.80). The sum of the portions of the proposed reduced national adjusted payment is approximately $667.88 ($439.74 + $228.14).

I. Proposed 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 calendar years 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. Proposed OPPS Copayment Policy

For CY 2019, we are proposing 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 are proposing 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, 2019 are included in Addenda A and B to this proposed rule (which are available via the internet on the CMS website).

As discussed in section XIII.E. of this proposed rule, for CY 2019, the proposed 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. Proposed 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, $116.40 is approximately 20 percent of the proposed full national unadjusted payment rate of $581.99. For APCs with only a minimum unadjusted copayment in Addenda A and B to this proposed rule (which are available via the internet on the CMS website), the beneficiary payment percentage is 20 percent.

The formula below is a mathematical representation of Step 1 and calculates the national copayment as a percentage of national payment for a given service.

B is the beneficiary payment percentage.

B = National unadjusted copayment for APC/national unadjusted payment rate for APC.

Step 2. Calculate the appropriate wage-adjusted payment rate for the APC for the provider in question, as indicated in Steps 2 through 4 under section II.H. of this proposed rule. Calculate the rural adjustment for eligible providers as indicated in Step 6 under section II.H. of this proposed rule.

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 proposed rule, 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 would be effective January 1, 2019, are shown in Addenda A and B to this proposed rule (which are available via the internet on the CMS website). We note that the proposed national unadjusted payment rates and copayment rates shown in Addenda A and B to this proposed rule reflect the proposed CY 2019 OPD fee schedule increase factor discussed in section II.B. of this proposed rule.

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. Proposed OPPS Ambulatory Payment Classification (APC) Group Policies

A. Proposed OPPS Treatment of New CPT and Level II HCPCS Codes

CPT and Level II HCPCS codes are used to report procedures, 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 and medical services;
- Category III CPT codes, which describe new and emerging technologies, services, and procedures; and
- Level II HCPCS codes, which are used primarily to identify products, supplies, temporary procedures, and services not described by CPT codes.

CPT codes are established by the American Medical Association (AMA) and the Level II HCPCS codes are established by the CMS HCPCS Workgroup. These codes are updated and changed throughout the year. CPT and HCPCS code changes that affect the OPPS are published both through the annual rulemaking cycle and through the OPPS quarterly update Change Requests (CRs). CMS releases new Level II HCPCS codes to the public or recognizes the release of new CPT codes by the AMA and makes these 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 CPT and Level II HCPCS 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 may more accurately describe items or services furnished and provides payment or more accurate payment for these items or services in a timelier manner than if we waited for the annual rulemaking process. We solicit public comments on these new codes and finalize our proposals related to these codes through our annual rulemaking process.

We note that, under the OPPS, the APC assignment determines the

payment rate for an item, procedure, or service. Those items, procedures, or services not paid separately under the hospital OPPS are assigned to appropriate status indicators. Certain payment status indicators provide separate payment, while other payment status indicators do not. Section XI. of this proposed rule discusses the various status indicators used under the OPPS.

In Table 7 below, we summarize our current process for updating codes through our OPPS quarterly update CRs, seeking public comments, and finalizing the treatment of these new codes under the OPPS.

TABLE 7—COMMENT TIMEFRAME FOR NEW OR REVISED HCPCS CODES

OPPS Quarterly update CR	Type of code	Effective date	Comments sought	When finalized
April 1, 2018	Level II HCPCS Codes	April 1, 2018	CY 2019 OPPS/ASC proposed rule.	CY 2019 OPPS/ASC final rule with comment period.
July 1, 2018	Level II HCPCS Codes	July 1, 2018	CY 2019 OPPS/ASC proposed rule.	CY 2019 OPPS/ASC final rule with comment period.
	Category I (certain vaccine codes) CPT Codes, Category III CPT codes.	July 1, 2018	CY 2019 OPPS/ASC proposed rule.	CY 2019 OPPS/ASC final rule with comment period.
October 1, 2018 ...	Level II HCPCS Codes	October 1, 2018 ..	CY 2019 OPPS/ASC final rule with comment period.	CY 2020 OPPS/ASC final rule with comment period.
January 1, 2019 ...	Category I and III CPT Codes ...	January 1, 2019 ..	CY 2019 OPPS/ASC proposed rule.	CY 2019 OPPS/ASC final rule with comment period.
	Level II HCPCS Codes	January 1, 2019 ..	CY 2019 OPPS/ASC final rule with comment period.	CY 2020 OPPS/ASC final rule with comment period.

1. Proposed Treatment of New HCPCS Codes That Were Effective April 1, 2018 for Which we Are Soliciting Public Comments in This CY 2019 OPPS/ASC Proposed Rule

Through the April 2018 OPPS quarterly update CR (Transmittal 4005, Change Request 10515, dated March 20, 2018), we made effective nine new Level II HCPCS codes for separate payment under the OPPS. In this CY 2019 OPPS/ASC proposed rule, we are soliciting public comments on the proposed APC and status indicator assignments for these Level II HCPCS codes, which are listed in Table 8 of this proposed rule. The proposed payment rates for these codes, where applicable, can be found in Addendum B to this proposed rule (which is available via the internet on the CMS website).

TABLE 8—NEW LEVEL II HCPCS CODES EFFECTIVE APRIL 1, 2018

CY 2018 HCPCS code	CY 2018 Long descriptor	Proposed CY 2019 SI	Proposed CY 2019 APC
C9462	Injection, delafloxacin, 1 mg	G	9462
C9463	Injection, aprepitant, 1 mg	G	9463
C9464	Injection, rolapitant, 0.5 mg	G	9464
C9465	Hyaluronan or derivative, Durolane, for intra-articular injection, per dose	G	9465
C9466	Injection, benralizumab, 1 mg	G	9466
C9467	Injection, rituximab and hyaluronidase, 10 mg	G	9467
C9468	Injection, factor ix (antihemophilic factor, recombinant), glycopegylated, Rebinyn, 1 i.u.	G	9468
C9469*	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg.	G	9469
C9749	Repair of nasal vestibular lateral wall stenosis with implant(s)	J1	5164

*HCPCS code C9469 (Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg), which was effective April 1, 2018, was deleted June 30, 2018 and replaced with HCPCS code Q9993 (Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg) effective July 1, 2018.

In addition, there were several new laboratory CPT Multianalyte Assays with Algorithmic Analyses (MAAA) codes (M codes) and Proprietary Laboratory Analyses (PLA) codes (U codes) that were effective April 1, 2018, but were too late to include in the April 2018 OPPS Update. Because these codes were released on the American Medical Association's (AMA) CPT website in February 2018, they were too late for us to include in the April 2018 OPPS Update CR and in the April 2018 Integrated Outpatient Code Editor (IOCE), and, consequently, were included in the July 2018 OPPS Update with an effective date of April 1, 2018. These CPT codes are listed below in Table 9. In this CY 2019 OPPS/ASC proposed rule, we are soliciting public comments on the proposed APC and status indicator assignments for these CPT codes, which are listed in Table 9 of this proposed rule. The proposed payment rates for these codes, where applicable, can be found in Addendum B to this proposed rule (which is available via the internet on the CMS website).

TABLE 9—NEW CPT MAAA AND PROPRIETARY LABORATORY ANALYSES (PLA) CODES EFFECTIVE APRIL 1, 2018

CY 2018 HCPCS code	CY 2018 Long descriptor	Proposed CY 2019 SI	Proposed CY 2019 APC
0012M	Oncology (urothelial), mRNA, gene expression profiling by real-time quantitative PCR of five genes (MDK, HOXA13, CDC2 [CDK1], IGFBP5, and XCR2), utilizing urine, algorithm reported as a risk score for having urothelial carcinoma.	A	N/A
0013M	Oncology (urothelial), mRNA, gene expression profiling by real-time quantitative PCR of five genes (MDK, HOXA13, CDC2 [CDK1], IGFBP5, and CXCR2), utilizing urine, algorithm reported as a risk score for having recurrent urothelial carcinoma.	A	N/A
0035U	Neurology (prion disease), cerebrospinal fluid, detection of prion protein by quaking-induced conformational conversion, qualitative.	Q4	N/A
0036U	Exome (*i.e.,* somatic mutations), paired formalin-fixed paraffin-embedded tumor tissue and normal specimen, sequence analyses.	A	N/A
0037U	Targeted genomic sequence analysis, solid organ neoplasm, DNA analysis of 324 genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden.	A	N/A
0038U	Vitamin D, 25 hydroxy D2 and D3, by LC–MS/MS, serum microsample, quantitative	Q4	N/A
0039U	Deoxyribonucleic acid (DNA) antibody, double stranded, high avidity	Q4	N/A
0040U	BCR/ABL1 (t(9;22)) (*e.g.,* chronic myelogenous leukemia) translocation analysis, major breakpoint, quantitative.	A	N/A
0041U	Borrelia burgdorferi, antibody detection of 5 recombinant protein groups, by immunoblot, IgM	Q4	N/A
0042U	Borrelia burgdorferi, antibody detection of 12 recombinant protein groups, by immunoblot, IgG	Q4	N/A
0043U	Tick-borne relapsing fever Borrelia group, antibody detection to 4 recombinant protein groups, by immunoblot, IgM.	Q4	N/A
0044U	Tick-borne relapsing fever Borrelia group, antibody detection to 4 recombinant protein groups, by immunoblot, IgG.	Q4	N/A

2. Proposed Treatment of New HCPCS Codes That Were Effective July 1, 2018 for Which we Are Soliciting Public Comments in This CY 2019 OPPS/ASC Proposed Rule

Through the July 2018 OPPS quarterly update CR (Transmittal 4075, Change Request 1078, dated June 15, 2018), we made 4 new Category III CPT codes and 10 Level II HCPCS codes effective July 1, 2018 (14 codes total), and assigned them to appropriate interim OPPS status indicators and APCs. As listed in Table 10 below, 13 of the 14 HCPCS codes are separately payable under the OPPS while 1 HCPCS code is not. Specifically, HCPCS code QQ994 is assigned to status indicator ''E1'' to indicate that the item is not payable by Medicare. In addition, we note that HCPCS code C9469 was deleted June 30, 2018, and replaced with HCPCS code Q9993 effective July 1, 2018. Because HCPCS code Q9993 describes the same drug as HCPCS code C9469, we are proposing to continue the drug's pass-through payment status and to assign HCPCS code Q9993 to the same APC and status indicators as its predecessor HCPCS code C9469, as shown in Table 10 below.

In this CY 2019 OPPS/ASC proposed rule, we are soliciting public comments on the proposed APC and status indicator assignments for CY 2019 for the CPT and Level II HCPCS codes implemented on July 1, 2018, all of which are listed in Table 10 below.

The proposed payment rates and status indicators for these codes, where applicable, can be found in Addendum B to this proposed rule (which is available via the internet on the CMS website).

TABLE 10—NEW HCPCS CODES EFFECTIVE JULY 1, 2018

CY 2018 HCPCS code	CY 2018 long descriptor	Proposed CY 2019 SI	Proposed CY 2019 APC
C9030	Injection, copanlisib, 1 mg	G	9030
C9031	Lutetium Lu 177, dotatate, therapeutic, 1 mCi	G	9067
C9032	Injection, voretigene neparvovec-rzyl, 1 billion vector genome	G	9070
Q5105	Injection, epoetin alfa, biosimilar, (Retacrit) (for esrd on dialysis), 100 units	K	9096
Q5106	Injection, epoetin alfa, biosimilar, (Retacrit) (for non-esrd use), 1000 units	K	9097
Q9991	Injection, buprenorphine extended-release (Sublocade), less than or equal to 100 mg	G	9073
Q9992	Injection, buprenorphine extended-release (Sublocade), greater than 100 mg	G	9239
Q9993 *	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg.	G	9469
Q9994	In-line cartridge containing digestive enzyme(s) for enteral feeding, each	E1	N/A
Q9995	Injection, emicizumab-kxwh, 0.5 mg	G	9257
0505T	Endovenous femoral-popliteal arterial revascularization, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed, with crossing of the occlusive lesion in an extraluminal fashion.	J1	5193
0506T	Macular pigment optical density measurement by heterochromatic flicker photometry, unilateral or bilateral, with interpretation and report.	Q1	5733
0507T	Near-infrared dual imaging (*i.e.,* simultaneous reflective and trans-illuminated light) of meibomian glands, unilateral or bilateral, with interpretation and report.	Q1	5733

TABLE 10—NEW HCPCS CODES EFFECTIVE JULY 1, 2018—Continued

CY 2018 HCPCS code	CY 2018 long descriptor	Proposed CY 2019 SI	Proposed CY 2019 APC
0508T	Pulse-echo ultrasound bone density measurement resulting in indicator of axial bone mineral density, tibia.	S	5522

*HCPCS code C9469 (Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg), which was effective April 1, 2018, was deleted June 30, 2018 and replaced with HCPCS code Q9993 (Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg) effective July 1, 2018.

In addition, there are several new PLA codes (U codes) that will be effective July 1, 2018, but were too late to include in the July 2018 OPPS Update. Consequently, these codes will instead be included in the October 2018 OPPS Update with an effective date of July 1, 2018. These CPT codes are listed below in Table 11 along with the proposed APC and status indicator assignment for these CPT codes. In this CY 2019 OPPS/ASC proposed rule, we are soliciting public comments on the proposed APC and status indicator assignments for these CPT codes. The proposed payment rates for these codes, where applicable, can be found in Addendum B to this proposed rule (which is available via the internet on the CMS website).

TABLE 11—NEW CPT PROPRIETARY LABORATORY ANALYSES (PLA) CODES EFFECTIVE JULY 1, 2018

CY 2018 HCPCS code	CY 2018 long descriptor	Proposed CY 2019 SI	Proposed CY 2019 APC
0045U	Oncology (breast ductal carcinoma in situ), mRNA, gene expression profiling by real-time RT–PCR of 12 genes (7 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence score.	A	N/A.
0046U	*FLT3* (fms-related tyrosine kinase 3) (*e.g.,* acute myeloid leukemia) internal tandem duplication (ITD) variants, quantitative.	A	N/A.
0047U	Oncology (prostate), mRNA, gene expression profiling by real-time RT–PCR of 17 genes (12 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a risk score.	A	N/A.
0048U	Oncology (solid organ neoplasia), DNA, targeted sequencing of protein-coding exons of 468 cancer-associated genes, including interrogation for somatic mutations and microsatellite instability, matched with normal specimens, utilizing formalin-fixed paraffin-embedded tumor tissue, report of clinically significant mutation(s).	A	N/A.
0049U	*NPM1* (nucleophosmin) (*e.g.,* acute myeloid leukemia) gene analysis, quantitative	A	N/A.
0050U	Targeted genomic sequence analysis panel, acute myelogenous leukemia, DNA analysis, 194 genes, interrogation for sequence variants, copy number variants or rearrangements.	A	N/A.
0051U	Prescription drug monitoring, evaluation of drugs present by LC–MS/MS, urine, 31 drug panel, reported as quantitative results, detected or not detected, per date of service.	Q4	N/A.
0052U	Lipoprotein, blood, high resolution fractionation and quantitation of lipoproteins, including all five major lipoprotein classes and subclasses of HDL, LDL, and VLDL by vertical auto profile ultracentrifugation.	Q4	N/A.
0053U	Oncology (prostate cancer), FISH analysis of 4 genes (*ASAP1, HDAC9, CHD1* and *PTEN*), needle biopsy specimen, algorithm reported as probability of higher tumor grade.	A	N/A.
0054U	Prescription drug monitoring, 14 or more classes of drugs and substances, definitive tandem mass spectrometry with chromatography, capillary blood, quantitative report with therapeutic and toxic ranges, including steady-state range for the prescribed dose when detected, per date of service.	Q4	N/A.
0055U	Cardiology (heart transplant), cell-free DNA, PCR assay of 96 DNA target sequences (94 single nucleotide polymorphism targets and two control targets), plasma.	A	N/A.
0056U	Hematology (acute myelogenous leukemia), DNA, whole genome next-generation sequencing to detect gene rearrangement(s), blood or bone marrow, report of specific gene rearrangement(s).	A	N/A.
0057U	Oncology (solid organ neoplasia), mRNA, gene expression profiling by massively parallel sequencing for analysis of 51 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a normalized percentile rank.	A	N/A.
0058U	Oncology (Merkel cell carcinoma), detection of antibodies to the Merkel cell polyoma virus oncoprotein (small T antigen), serum, quantitative.	Q4	N/A.
0059U	Oncology (Merkel cell carcinoma), detection of antibodies to the Merkel cell polyoma virus capsid protein (VP1), serum, reported as positive or negative.	Q4	N/A.
0060U	Twin zygosity, genomic targeted sequence analysis of chromosome 2, using circulating cell-free fetal DNA in maternal blood.	A	N/A.
0061U	Transcutaneous measurement of five biomarkers (tissue oxygenation [StO2], oxyhemoglobin [ctHbO2], deoxyhemoglobin [ctHbR], papillary and reticular dermal hemoglobin concentrations [ctHb1 and ctHb2]), using spatial frequency domain imaging (SFDI) and multi-spectral analysis.	Q4	N/A.

3. Proposed Process for New Level II HCPCS Codes That Will Be Effective October 1, 2018 and January 1, 2019 for Which We Will Be Soliciting Public Comments in the CY 2019 OPPS/ASC Final Rule With Comment Period

As has been our practice in the past, we will solicit comments on those new Level II HCPCS codes that are effective October 1, 2018 and January 1, 2019 in the CY 2019 OPPS/ASC final rule with comment period, thereby allowing us to finalize the status indicators, APCs, and payment rates for the codes in the CY 2020 OPPS/ASC final rule with comment period. These codes will be released to the public through the October and January OPPS quarterly update CRs and via the CMS HCPCS website (for Level II HCPCS codes).

For CY 2019, we are proposing to continue our established policy of assigning comment indicator ''NI'' in Addendum B to the OPPS/ASC final rule with comment period to those new Level II HCPCS codes that are effective October 1, 2018 and January 1, 2019 to indicate that we are assigning them an interim payment status, which is subject to public comment. We will be inviting public comments in the CY 2019 OPPS/ASC final rule with comment period on the status indicator, APC assignments, and payment rates for these codes, if applicable, which would then be finalized in the CY 2020 OPPS/ASC final rule with comment period.

4. Proposed Treatment of New and Revised CY 2019 Category I and III CPT Codes That Will Be Effective January 1, 2019 for Which We Are Soliciting Public Comments in This CY 2019 OPPS/ASC 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 2019 OPPS update, we received the CY 2019 CPT codes from AMA in time for inclusion in this CY 2019 OPPS/ASC proposed rule. The new, revised, and deleted CY 2019 Category I and III CPT codes can be found in Addendum B to this proposed rule (which is available via the internet on the CMS website). We note 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 assignment and status indicator.

Further, we remind 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 are including the 5-digit placeholder codes and their long descriptors for the new and revised CY 2019 CPT codes in Addendum O to this proposed rule (which is available via the internet on the CMS website) so that the public can adequately comment on our proposed APCs and status indicator assignments. The 5-digit placeholder codes can be found in Addendum O, specifically under the column labeled ''CY 2019 OPPS/ASC Proposed Rule 5-Digit AMA Placeholder Code,'' to this proposed rule. The final CPT code numbers will be included in the CY 2019 OPPS/ASC final rule with comment period. We note that not every code listed in Addendum O is subject to comment. For the new and revised Category I and III CPT codes, we are requesting comments on only those codes that are assigned to comment indicator ''NP''.

In summary, we are soliciting public comments on the proposed CY 2019 status indicators and APC assignments for the new and revised Category I and III CPT codes that will be effective January 1, 2019. The CPT codes are listed in Addendum B to this proposed rule with short descriptors only. We list them again in Addendum O to this proposed rule with long descriptors. We also are proposing to finalize the status indicator and APC assignments for these codes (with their final CPT code numbers) in the CY 2019 OPPS/ASC final rule with comment period. The proposed status indicator and APC assignment for these codes can be found in Addendum B to this proposed rule (which is available via the internet on the CMS website).

B. Proposed 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 and Level II HCPCS 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 proposed rule.

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. For CY 2019, we are proposing 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 2019 OPPS update will be discussed in the relevant specific sections throughout the CY 2019 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 this section of this proposed rule, for CY 2019, we are proposing 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.

For the CY 2019 OPPS update, we have identified the APCs with violations of the 2 times rule. Therefore, we are proposing changes to the procedure codes assigned to these APCs in Addendum B to this proposed rule. We note that Addendum B does not appear in the printed version of the **Federal Register** as part of this CY 2019 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 are proposing 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 2019 included in this proposed rule are related to changes in costs of services that were observed in the CY 2017 claims data newly available for CY 2019 ratesetting. Addendum B to this CY 2019 OPPS/ASC proposed rule identifies with a comment indicator ''CH'' those procedure codes for which we are proposing a change to the APC assignment or status indicator, or both, that were initially assigned in the July 1, 2018 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*).

3. Proposed APC Exceptions to the 2 Times Rule

Taking into account the APC changes that we are proposing to make for CY 2019, 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 2017 claims data available for this CY 2019 proposed rule, we found 16 APCs with violations of the 2 times rule. We applied the criteria as described above to identify the APCs for which we are proposing to make exceptions under the 2 times rule for CY 2019, and found that all of the 16 APCs we identified meet the criteria for an exception to the 2 times rule based on the CY 2017 claims data available for this 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 have 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 12 of this proposed rule lists the 16 APCs that we are proposing to make an exception for under the 2 times rule for CY 2019 based on the criteria cited above and claims data submitted between January 1, 2017, and December 31, 2017, and processed on or before December 31, 2017. For the final rule with comment period, we intend to use claims data for dates of service between January 1, 2017, and December 31, 2017, that were processed on or before June 30, 2018, and updated CCRs, if available. The proposed geometric mean costs for covered hospital outpatient services for these and all other APCs that were used in the development of this proposed rule can be found on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html.*

TABLE 12—PROPOSED APC EXCEPTIONS TO THE 2 TIMES RULE FOR CY 2019

Proposed CY 2019 APC	Proposed CY 2019 APC title
5071	Level 1 Excision/Biopsy/Incision and Drainage.
5113	Level 3 Musculoskeletal Procedures.
5521	Level 1 Imaging without Contrast.
5522	Level 2 Imaging without Contrast.
5523	Level 3 Imaging without Contrast.
5571	Level 1 Imaging with Contrast.
5612	Level 2 Therapeutic Radiation Treatment Preparation.
5691	Level 1 Drug Administration.
5692	Level 2 Drug Administration.
5721	Level 1 Diagnostic Tests and Related Services.
5724	Level 4 Diagnostic Tests and Related Services.
5731	Level 1 Minor Procedures.
5732	Level 2 Minor Procedures.
5735	Level 5 Minor Procedures.
5822	Level 2 Health and Behavior Services.
5823	Level 3 Health and Behavior Services.

C. Proposed New Technology APCs

1. Background

In the November 30, 2001 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 2018, 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. 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 techniques 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 2019, the proposed payment rates for New Technology APCs 1491 to 1599 and 1901 through 1908 can be found in Addendum A to this proposed rule (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. For these low-volume procedures, we are 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. 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 believe that it is appropriate to utilize our equitable adjustment authority at section 1833(t)(2)(E) of the Act to adjust how we determine the costs for low-volume services assigned to New Technology APCs. 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 believe that it is appropriate to adopt an adjustment for low-volume services assigned to New Technology APCs in order mitigate the wide payment fluctuations that can occur for new technology services with fewer than 100 claims and to provide more predictable payment for these services.

For purposes of this adjustment, 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 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. For these low-volume procedures, we are 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. 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 believe that using the median or arithmetic mean rather than the geometric mean (which ''trims'' the costs of certain claims out) may 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 believe that 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, we are proposing that, in each of our annual rulemakings, we will seek public comments on which statistical methodology should be used for each low-volume New Technology APC. In the preamble of each annual rulemaking (including this proposed rule), we will 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 would assign the service to the New Technology APC with the cost band that includes its payment rate.

Accordingly, for CY 2019, we are proposing to establish a different payment methodology for services assigned to New Technology APCs with fewer than 100 claims using our equitable adjustment authority under

section 1833(t)(2)(E) of the Act. Under this proposal, we are proposing to use up to 4 years of claims data to establish a payment rate for each applicable service both for purposes of assigning a service to a New Technology APC and for assigning a service to a regular APC at the conclusion of payment for the service through a New Technology APC. The goal of such a policy is to promote transparency and stability in the payment rates for these low-volume new technology procedures and to mitigate wide variation from year to year for such services. We also are proposing to use the geometric mean, the median, or the arithmetic mean to calculate the cost of furnishing the applicable service, present the result of each statistical methodology in our annual rulemaking, and solicit public comment on which methodology should be used to establish the payment rate. The geometric mean may not be representative of the actual cost of a service when fewer than 100 claims are present because the payment amounts for the claims may not be distributed normally. Under this proposal, we would have the option to use the median payment amount or the arithmetic mean to assign a more representative payment for the service. Once we identify the payment rate for a service, we would assign the service to the New Technology APC with the cost band that includes its payment rate.

3. Proposed Procedures Assigned to New Technology APC Groups for CY 2019

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 2019, in this CY 2019 OPPS/ASC proposed rule, we are proposing 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 1537, 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 are proposing to continue to assign to standard APCs, and one that we are proposing to reassign to a different New Technology APC for CY 2019. 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 13 of this proposed rule, and as listed in Addendum B to this CY 2019 OPPS/ASC proposed rule, we are proposing to continue to assign the procedures described by CPT codes 0071T and 0072T to APC 5414 (Level 4 Gynecologic Procedures), with a proposed payment rate of approximately $2,410 for CY 2019. We also are proposing to continue to assign the APC to status indicator ''J1'' (Hospital Part B services paid through a comprehensive APC) to indicate that payment for all covered Part B services reported on the claim are packaged with the payment for the primary ''J1'' service for the claim, except for services assigned to OPPS status indicator ''F'', ''G'', ''H'', ''L'', and ''U''; ambulance services; diagnostic and screening mammography; all preventive services; and certain Part B inpatient services. In addition, we are proposing 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), with a proposed payment rate of approximately $10,936 for CY 2019. We also are proposing to continue to assign HCPCS code C9734 to status indicator ''J1''.

For procedures described by CPT code 0398T, we have only identified one paid claim for a procedure in CY 2016 and two paid claims in CY 2017, for a total of three paid claims. We note that the procedures described by CPT code 0398T were first assigned to a New Technology APC in CY 2016. Accordingly, there are only 2 years of claims data available for the OPPS ratesetting purposes. The payment amounts for the claims vary widely, with a cost of $29,254 for the sole CY 2016 claim and a geometric mean cost of $4,647 for the two CY 2017 claims. We are concerned that the reported geometric mean cost for CY 2017, which we would normally use to determine the proposed payment rate for the procedures described by CPT code 0398T, is significantly lower than the reported cost of the claim received in CY 2016, as well as the payment rate for the procedures for CY 2016 ($9,750.50) and for CY 2017 ($17,500.50). 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 mentioned in section III.C.2. of this proposed rule, we are proposing 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 establish a payment rate that is more likely to be representative of the cost of the procedures described by CPT code 0398T, despite the low geometric mean costs for procedures described by CPT code 0398T available in the claims data used for this proposed rule. We continue to believe that this situation for the procedures described by CPT code 0398T is unique, given the very limited number of claims for the procedures and the high variability for the cost of the claims which makes it challenging to determine a reliable payment rate for the procedures.

Our analysis found that the arithmetic mean of the three claims is $12,849.11, the geometric mean of the three claims is $8,579.91 (compared to $4,646.56 for CY 2017), and the median of the claims is $4,676.77. Consistent with what we state in section III.C.2. of this proposed rule, we have presented the result of each statistical methodology in this preamble, and we are seeking public comments on which method should be used to establish payment for the

procedures described by CPT code 0398T. We believe that the arithmetic mean is the most appropriate representative cost of the procedures described by CPT code 0398T, which gives consideration to the payment rates established for the procedures in CY 2017 and CY 2018, without any trimming. The arithmetic mean also gives consideration to the range in cost for the three paid claims, which represent 2 years of claims data for the procedures. We are proposing to estimate the proposed payment rate for the procedures described by CPT code 0398T by calculating the arithmetic mean of the three paid claims for the procedures in CY 2016 and CY 2017, and assigning the procedures described by CPT code 0398T to the New Technology APC that includes the estimated cost. Accordingly, we are proposing to reassign the procedures described by CPT code 0398T from APC 1576 (New Technology—Level 39 ($15,001–$20,000)) to APC 1575 (New Technology—Level 38 ($10,001–$15,000)), with a proposed payment rate of $12,500.50. We refer readers to Addendum B to this 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 13—PROPOSED CY 2019 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 2018 OPPS SI	CY 2018 OPPS APC	CY 2018 OPPS payment rate	Proposed CY 2019 OPPS SI	Proposed CY 2019 OPPS APC	Proposed CY 2019 OPPS payment rate
0071T	Focused ultrasound ablation of uterine leiomyomata, including mr guidance; total leiomyomata volume less than 200 cc of tissue.	J1	5414	$2,272.77	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	2,272.77	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	1576	17,500.50	S	1575	Refer to OPPS Addendum B.
C9734	Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (mr) guidance.	J1	5115	5,606.42	J1	5115	Refer to OPPS Addendum B.

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 includes 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 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 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. 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 changes 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, 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 CY 2017 hospital outpatient claims data used for this CY 2019 OPPS/ASC proposed rule is approximately $152,021, which is $29,520 more than the payment rate for the procedure for CY 2018. We continue to note 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 did not exceed 10 claims for CY 2017. We continue to believe 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 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 want 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.

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 this proposed rule, we are proposing 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 establish a payment rate that is more representative of the likely cost of the service. We believe the likely cost of the Argus® II procedure is lower than the geometric mean cost calculated from the CY 2017 claims data used for this proposed rule and closer to the CY 2018 payment rate.

We analyzed claims data for the Argus® II procedure using the last 3 years of available data from CY 2015 through CY 2017. These data include claims from the last year (CY 2015) that the Argus® II received transitional device pass-through payments and the first 2 years since device pass-through payment status for the Argus® II expired. We found the geometric mean for the procedure to be $129,891 (compared to $152,021 in CY 2017 alone), the arithmetic mean to be $134,619, and the median to be $133,679. As indicated in our proposal in section III.C.2. of this proposed rule, we have presented the result of each statistical methodology in this preamble, and are requesting public comment on which methodology should be used to establish a payment rate. We are proposing to use the arithmetic mean, which generates the highest payment rate of the three statistical methodologies, to estimate the cost of the Argus® II procedure as a means to balance the fluctuations in the costs of the procedure that have occurred from CY 2015 through CY 2017, while acknowledging the higher payment rates for the procedure in CY 2015 and CY 2017. Therefore, for CY 2019, we are proposing to reassign the Argus® II procedure from APC 1904 (New Technology—Level 50 ($115,001–$130,000)) to APC 1906 (New Technology—Level 51 ($130,001–$145,000)), which would result in a proposed payment rate for the Argus® II procedure of $137,500.50.

As we do each year, we acquired 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 like the Argus® II procedure as they transition into mainstream medical practice (77 FR 68314). We note that this proposed payment rate includes both the surgical procedure (CPT code 0100T) and the use of the Argus® II device (HCPCS code C1841).

The most recent claims data available have shown another payment issue with regard to the Argus® II procedure. We have found that payment for the Argus® II procedure is sometimes bundled into the payment for another procedure. We have identified two possible instances in the CY 2017 claims data in which this may have occurred. The bundling of payment for the Argus® II procedure occurs when the procedure is reported with other eye procedures assigned to a comprehensive APC (C–APC). A C–APC bundles payment for all services related to the primary service into one payment rate. We are concerned that when payment for new technology services is bundled into the payment for comprehensive procedures, there is not complete claims information to estimate accurately the cost of these services to allow their assignment to clinical APCs. Therefore, we are proposing to exclude payment for all procedures assigned to New Technology APCs from being bundled into the payment for procedures assigned to a C–APC. This action would allow for separate payment for the Argus® II procedure even when it is performed with another comprehensive service, which would provide more cost information regarding the procedure. This proposal is also discussed in section II.A.2.c. of this proposed rule.

D. Proposed OPPS APC-Specific Policies

Section 1833(t)(9)(A) of the Act requires the Secretary to review, not less often than annually, and to revise the APC groups, the relative payment weights, and the wage and other adjustments to take into account changes in medical practices, changes in technology, the addition of new services, new cost data, and other relevant information and factors. 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. Although we do not discuss every APC change in the proposed and final rules, these changes are listed in the OPPS Addendum B of the proposed and final rules. Specifically, the procedure and service codes with revised APC and/or status indicator assignments are identified with comment indicator ''CH'' (Active HCPCS code in current year and next

calendar year, status indicator and/or APC assignment has changed) in the OPPS Addendum B payment file.

1. Endovascular Procedures (APCs 5191 Through 5194)

At the annual meeting for the HOP Panel held on August 21, 2017, the HOP Panel recommended that, for CY 2018, CMS examine the number of APCs for endovascular procedures. The HOP Panel also recommended that the appropriate Panel subcommittee review the APCs for endovascular procedures to determine whether more granularity (that is, more APCs) is warranted.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59293 through 59294), we stated that we believed that the current C–APC levels for the Endovascular Procedures C–APC family provide an appropriate distinction between the resource costs at each level and clinical homogeneity. We also stated that we would continue to review the C–APC structure for endovascular procedures to determine if any additional granularity is necessary for this C–APC family.

Using the most recent data available for this proposed rule, we have analyzed the four existing levels of the Endovascular Procedures C–APCs. We did not observe any violations of the 2 times rule within the current Endovascular Procedures C–APC structure. Some stakeholders have suggested that for certain procedures, such as angioplasty procedures involving the use of a drug-coated balloon in addition to a nondrug-coated balloon, resource costs are significantly higher than the geometric mean cost (and associated C–APC payment) for all of the angioplasty procedures combined. We recognize that the costs of a given procedure involving additional devices will be higher than the costs of the procedure when it does not involve such additional devices. However, the OPPS is a prospective payment system based on a system of averages in which the costs of some cases within an APC will be more costly than the APC payment rate, while the costs of other cases will be less costly. While we believe that there is sufficient granularity within the existing Endovascular Procedures C–APC structure and at least one stakeholder agrees, we have also received input from other stakeholders who have suggested alternative structures for this C–APC family that include a five-level structure and a six-level structure. An illustration of these proposed C–APC structure levels is displayed in Table 15 and Table 16, respectively. Because interested stakeholders have suggested a variety of options for the endovascular procedures C–APC structure, including keeping the existing C–APC structure, in this CY 2019 OPPS/ASC proposed rule, we are proposing to maintain the existing four-level structure for this C–APC family listed in Table 14 below. However, we are inviting public comments on our proposal, as well as the stakeholder-requested five-level and six-level structures displayed in the tables below. We note that the approximate geometric mean costs associated with the suggested five-level and six-level C–APC structures shown in Tables 15 and 16 are only estimates and, if either of the suggested structure levels are adopted, they would be subject to change, depending on the final rule with comment period data and the particular services that are assigned to each C–APC.

TABLE 14—PROPOSED CY 2019 C–APC STRUCTURE FOR ENDOVASCULAR PROCEDURES

C-APC	Proposed geometric mean cost
5191—Level 1 Endovascular Procedures	$2,882
5192—Level 2 Endovascular Procedures	4,843
5193—Level 3 Endovascular Procedures	9,945
5194—Level 4 Endovascular Procedures	15,789

TABLE 15—REQUESTED CY 2019 FIVE-LEVEL ENDOVASCULAR C–APC STRUCTURE

C-APC	Potential approximate geometric mean cost
5191—Level 1 Endovascular Procedures	$2,881
5192—Level 2 Endovascular Procedures	4,476
5193—Level 3 Endovascular Procedures	9,207
5194—Level 4 Endovascular Procedures	13,524
5195—New Level 5 Endovascular Procedures	16,926

TABLE 16—REQUESTED CY 2019 SIX-LEVEL ENDOVASCULAR C–APC STRUCTURE

C–APC	Potential approximate geometric mean cost
5191—Level 1 Endovascular Procedures	$2,880
5192—Level 2 Endovascular Procedures	4,722
5193—New Level 3 Endovascular Procedures	7,743
5194—Level 4 Endovascular Procedures	10,128
5195—New Level 5 Endovascular Procedures	12,216
5196—Level 6 Endovascular Procedures	16,140

2. Imaging Procedures and Services (APCs 5521 Through 5524 and 5571 Through 5573)

Section 1833(t)(2)(G) of the Act requires the Secretary to create additional groups of covered OPD services that classify separately those procedures that utilize contrast agents from those procedures that do not utilize contrast agents. In CY 2016, as a part of our comprehensive review of the structure of the APCs and procedure code assignments, we restructured the APCs that contain imaging services (80 FR 70392). The purpose of this restructuring was to more appropriately reflect the resource costs and clinical characteristics of the services classified within the Imaging APCs. The restructuring of the Imaging APCs resulted in broader groupings that removed the excessive granularity of grouping imaging services according to organ or physiologic system, which did not necessarily reflect either significant differences in resources or how these services are delivered in the hospital outpatient setting. In CY 2017, in response to public comments on the CY 2017 OPPS/ASC proposed rule, we further consolidated the Imaging APCs from 17 APCs in CY 2016 to 7 APCs in CY 2017 (81 FR 79633). These included four Imaging without Contrast APCs and three Imaging with Contrast APCs.

For CY 2018, we proposed to establish a new Level 5 Imaging without Contrast APC to more appropriately group certain imaging services with higher resource costs and stated that our latest claims data supported splitting the CY 2017 Level 4 Imaging without Contrast APC into two APCs such that the Level 4 Imaging without Contrast APC would include high frequency, low-cost services and the proposed Level 5 Imaging without Contrast APC would include low frequency high-cost services. Therefore, for CY 2018, we proposed to add a fifth level within the

Imaging without Contrast APCs (82 FR 33608). However, based on public comments, we did not finalize this proposal. In general, commenters disagreed with CMS' proposal to add a fifth level within the Imaging without Contrast APC series because they believed that the addition of a fifth level would reduce payment for several imaging services, including vascular ultrasound procedures (82 FR 59309 through 59311). Commenters also noted that the lower payment rates under the OPPS would also apply under the PFS.

For this CY 2019 proposed rule, we reviewed the services assigned to the seven imaging APCs listed below in Table 17. Specifically, we evaluated the resource costs and clinical coherence of the procedures associated with the four levels of Imaging without Contrast APCs and the three levels of Imaging with Contrast APCs, as well as identified for correction any 2 times rule violations, to the extent feasible. Based on the geometric mean cost for each APC, which is listed in Table 17, for CY 2019, we are proposing to maintain the seven Imaging APCs, which consist of four levels of Imaging without Contrast APCs and three levels of Imaging with Contrast APCs, and to make minor reassignments to the HCPCS codes within this series to resolve or mitigate any violations of the 2 times rule, or both.

TABLE 17—PROPOSED CY 2019 IMAGING APCS

CY 2019 APC	CY 2019 APC title	CY 2018 APC geometric mean cost	Proposed CY 2019 APC geometric mean cost
5521	Level 1 Imaging without Contrast	$62.08	$64.02
5522	Level 2 Imaging without Contrast	114.39	115.89
5523	Level 3 Imaging without Contrast	232.17	236.05
5524	Level 4 Imaging without Contrast	486.38	502.75
5571	Level 1 Imaging with Contrast	252.58	206.94
5572	Level 2 Imaging with Contrast	456.08	395.84
5573	Level 3 Imaging with Contrast	681.45	699.02

We are inviting public comments on our proposal to maintain the seven Imaging APCs and the current APC structure level of the imaging APCs. Moreover, we are specifically interested in receiving public comments and recommendations on the proposed HCPCS code reassignments associated with each of the seven Imaging APCs. We refer readers to Addendum B to this proposed rule (which is available via the internet on the CMS website) for the proposed list of specific codes that would be reassigned to each Imaging APC.

3. 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 to provide clinical homogeneity. However, we also indicated that we would continue to review the structure of these APCs to determine whether additional granularity would be necessary.

While we are not proposing any changes to the 2019 OPPS structure of the Musculoskeletal APC series in this proposed rule, we recognize that commenters have previously expressed concerns regarding the granularity of the current APC levels and requested establishment of additional levels. Therefore, we are soliciting comments on the creation of a new APC level between the current Level 5 and Level 6 within the Musculoskeletal APC series.

TABLE 18—PROPOSED CY 2019 MUSCULOSKELETAL PROCEDURES APCS

APC	Group title	HCPCS codes assigned to APC	Proposed APC geometric mean cost
5111	Level 1 Musculoskeletal Procedures	102	$229.40
5112	Level 2 Musculoskeletal Procedures	133	$1,345.93
5113	Level 3 Musculoskeletal Procedures	442	$2,673.08
5114	Level 4 Musculoskeletal Procedures	287	$5,816.78
5115	Level 5 Musculoskeletal Procedures	67	$10,935.83
5116	Level 6 Musculoskeletal Procedures	15	$15,785.37

4. Level 5 Intraocular Procedures (APC 5495)

In prior years, CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis) has been 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 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 policy is discussed in more detail in section III.C.2. of this proposed rule.

In reviewing the claims data available for this proposed rule for CY 2019 OPPS ratesetting, there are only two claims containing procedures described by CPT code 0308T. Based on those two claims, APC 5495 would have a proposed geometric mean of $5,438.99 and a proposed median of $8,237.56. Based on its estimated costs in the most recently available claims data, we believe that the procedure described by CPT code 0308T is more appropriately placed in the APC 5493, which has a geometric mean of $9,821.47, which is more comparable to that of CPT code 0308T. Therefore, for CY 2019, we are proposing to reassign the procedure described by CPT code 0308T from APC 5495 to APC 5493 (Level 3 Intraocular Procedures) and to delete APC 5495. We will continue to monitor the volume of claims reporting a procedure described by CPT code 0308T available to us for future ratesetting.

IV. Proposed OPPS Payment for Devices

A. Pass-Through Payments for Devices

1. Beginning Eligibility Date for Device Pass-Through Status and Quarterly Expiration of Device Pass-Through Payments

a. Background

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 have 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 changes to the device pass-through payment policy. We also have an established policy to package the costs of the devices that are no longer eligible for pass-through payments into the costs of the procedures with which the devices are reported in the claims data used to set the payment rates (67 FR 66763).

b. Expiration of Transitional Pass-Through Payments for Certain Devices

As stated earlier, section 1833(t)(6)(B)(iii) of the Act requires that, under the OPPS, a category of devices be eligible for transitional pass-through payments for at least 2 years, but not more than 3 years. There currently are no device categories eligible for pass-through payment.

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).

As specified in regulations at 42 CFR 419.66(b)(1) through (b)(3), to be eligible for transitional pass-through payment under the OPPS, a device must meet the following criteria: (1) 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 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; (2) 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 (3) 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 cryoblation, 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 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 2019

We received seven applications by the March 1, 2018 quarterly deadline, which is the last quarterly deadline for applications to be received in time to be included in this CY 2019 OPPS/ASC proposed rule. We received four of the applications in the second quarter of 2017, one of the applications in the third quarter of 2017, and two of the applications in the first quarter of 2018. None of the seven applications were approved for device pass-through payment during the quarterly review process.

Applications received for the later deadlines for the remaining 2018 quarters (June 1, September 1, and December 1), if any, will be presented in the CY 2020 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 seven applications received by the March 1, 2018 deadline is presented below.

(1) AquaBeam System

PROCEPT BioRobotics Corporation submitted an application for a new device category for transitional pass-through payment status for the AquaBeam System. 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.[13] 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 are inviting public comments on whether the AquaBeam System meets the 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 2000 interim final rule with comment period (65 FR 67804 through 67805), 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 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

[13] Chungtai B. Forde JC. Thomas DDM et al. Benign Prostatic Hyperplasia. Nature Reviews Disease Primers 2 (2016) article 16031.

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 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. We are inviting public comments on whether the AquaBeam System meets the eligibility criteria at § 419.66(b).

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. We have 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 are inviting public comments on this issue.

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 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) [14] and photoselective vaporization (PVP).[15]

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.[16] This was a multicenter study in four countries with 17 sites, 6 of which contributed 5 patients or fewer. Patients were randomized to receive 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.

Although there may be some evidence of the improved safety of the AquaBeam System over TURP, we believe 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 can be cited to show that AquaBeam System is a significant improvement over other available procedures.

Based on the evidence submitted with the application, we have insufficient evidence that the AquaBeam System provides a substantial clinical improvement over other similar products. We are inviting public comments on whether the AquaBeam System meets the substantial clinical improvement criterion.

[14] Montorsi, F. et al. (2004). 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.

[15] Bachmann A, et al. (2014). 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, 65(5):* 931–42.

[16] 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.

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, 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 68 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 test.

The second cost significance test, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $2,500 for the AquaBeam System exceeds the cost of the device-related portion of the APC payment amount for the related service of $0.00 by at least 25 percent. Therefore, we believe that the AquaBeam System meets the second cost significance test.

The third cost significance test, at § 419.66(d)(3), requires 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 test.

We are inviting public comments on whether the AquaBeam System meets the device pass-through payment criteria discussed in this section, including the cost criteria.

(2) BioBag® (Larval Debridement Therapy in a Contained Dressing)

BioMonde US, LLC resubmitted an application for a new device pass-through category for the BioBag® (larval debridement therapy in a contained dressing), hereinafter referred to as the BioBag®. The application submitted contained similar information to the previous application received in March 2016 that was evaluated in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79650). The only new information provided by the applicant were additional studies completed since the original application addressing the substantial clinical improvement criterion.

According to the applicant, BioBag® is a biosurgical wound treatment (''maggot therapy'') consisting of disinfected, living larvae (Lucilia sericata) in a polyester net bag; the larvae remove dead tissue from wounds. The BioBag® is indicated for debridement of nonhealing necrotic skin and soft tissue wounds, including pressure ulcers, venous stasis ulcers, neuropathic foot ulcers, and nonhealing traumatic or postsurgical wounds. Debridement, which is the action of removing devitalized tissue and bacteria from a wound, is required to treat or prevent infection and to allow the wound to progress through the healing process. This system contains disinfected, living larvae that remove the dead tissue from wounds and leave healthy tissue undisturbed. The larvae are provided in a sterile polyester net bag, available in different sizes. The only other similar product is free-range (that is, uncontained) larvae. Free-range larvae are not widely used in the United States because application is time consuming, there is a fear of larvae escaping from the wound, and there are concerns about proper and safe handling of the larvae. The total number of treatment cycles depends on the characteristics of the wound, the response of the wound, and the aim of the therapy. Most ulcers are completely debrided within 1 to 6 treatment cycles.

With respect to the newness criterion at § 419.66(b)(1), the applicant received FDA clearance for BioBag® through the premarket notification section 510(k) process on August 28, 2013, and the first U.S. sale of BioBag® occurred in April 2015. The June 1, 2017 application is more than 3 years after FDA clearance but less than 3 years after its first U.S. sale. We are inviting public comments on whether BioBag® meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), the applicant claimed that the BioBag® is an integral part of the wound debridement, is used for one patient only, comes in contact with human skin, and is applied in or on a wound. In addition, the applicant stated that the BioBag® meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, or item for which depreciation and financing expenses are recovered. We had also determined in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79650) that the BioBag® is not a material or supply furnished incident to a service. We are inviting public comments on whether BioBag® 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 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 BioBag®, the applicant suggested a category descriptor of ''Contained medicinal larvae for the debridement of necrotic non-healing skin and soft tissue wounds.'' We have not identified an existing pass-through payment category that describes the BioBag®.

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 the substantial clinical improvement criterion, the applicant provided substantial evidence that larval therapy may improve outcomes compared to other methods of wound debridement. However, given the existence of the Medical Maggots®, another form of larval therapy that has been on the market since 2004, the relevant comparison is between the BioBag® and the Medical Maggots®. There are many reasons to suspect that the BioBag® could improve outcomes and be preferable to the Medical Maggots®. In essence, with the latter, the maggots are directly placed on the wound, which may result in escape, leading to infection control issues as well as dosing variability. In addition, there are the issues with patient comfort. With the Biobag®, the maggots are in a sealed container so escape is not an issue. The applicant cited a study showing large decreases in maggot escape with the BioBag® as opposed to the Medical Maggots®. However, the applicant did not provide any data that clinical outcomes are improved using the BioBag® as opposed to the Medical Maggots®. Based on the studies presented, we believe there is insufficient data to determine whether the BioBag® offers a substantial clinical improvement over other treatments for wound care. We are inviting public comments on whether BioBag® meets the substantial clinical improvement criterion.

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. With respect to the cost criterion, the applicant stated that the BioBag® would be reported with CPT code 97602 (Removal of devitalized tissue from wound(s), non-selective debridement, without anesthesia (*e.g.,* wet-to-moist dressings, enzymatic, abrasion, larval therapy), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session). CPT code 97602 is assigned to APC 5051 (Level 1 Skin Procedures), with a proposed CY 2019 payment rate of $178.60, and the device offset is $0.02. The price of the BioBag® varies with the size of the bag ($375 to $435 per bag), and bag size selection is based on the size of the wound.

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 reasonable cost of $435 for the BioBag®

exceeds the applicable APC amount for the service related to the category of devices of $178.60 by 243.56 percent ($435/$178.60 × 100 = 243.56 percent). Thus, the BioBag® appears to meet the first cost significance test.

The second cost significance test, at § 419.66(d)(2), provides that the estimated average reasonable cost of devices in the category must exceed the cost of the device-related portion of the APC payment amount by at least 25 percent, which means the device cost needs to be at least 125 percent of the device offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $435 for the BioBag® exceeds the device-related portion of the APC amount for the related service of $0.02 by 2,175,000 percent ($435/$0.02 × 100 = 2,175,000 percent). Thus, the BioBag® appears to meet the second cost significance test.

Section 419.66(d)(3), the third cost significance test, requires that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount determined to be associated with the device exceeds 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $435 for the BioBag® and the portion of the APC payment for the device of $0.02 exceeds 10 percent at 243.55 percent (($435 − $0.02)/$178.60 × 100 = 243.55 percent). Thus, the BioBag® appears to meet the third cost significance test and satisfies the cost significance criterion. We are inviting public comments on whether the BioBag® Wound Matrix meets the device pass-through payment criteria discussed in this section, including the cost criteria.

(3) BlastX™ Antimicrobial Wound Gel

Next Science™ has submitted an application for a new device category for transitional pass-through payment status for BlastX™. According to the manufacturer, BlastX™ is a PEG-based aqueous hydrogel which contains citric acid, sodium citrate, and benzalkonium chloride, buffered to a pH of 4.0 at 2.33 osmolarity. BlastX™ received a 510(k) clearance from the FDA on March 6, 2017. BlastX™ is indicated for the management of wounds such as Stage I–IV pressure ulcers, partial and full thickness wounds, diabetic foot and leg ulcers, postsurgical wounds, first and second degree burns, and grafted and donor sites.

The manufacturer stated in its application for transitional pass-through payment status that BlastX™ works by disrupting the biofilm matrix in a wound and eliminating the bacteria absorbed within the gel. The manufacturer asserted that disrupting and eliminating the biofilm removes a major barrier to wound healing. The manufacturer also asserted that BlastX™ is not harmful to host tissue and stated that BlastX™ is applied to the wound every other day as a thin layer throughout the entire wound healing process.

When used as an adjunct to debridement, BlastX™ is applied immediately after debridement to eliminate any remaining biofilm and prevent the growth of new biofilm. Based on the evidence provided in the manufacturer's application, BlastX™ is not a skin substitute and cannot be considered for transitional pass-through payment status as a device. To be considered a device for purposes of the medical device pass-through payment process under the OPPS, a skin substitute needs to be applied in or on a wound or other skin lesion based on 42 CFR 419.66(b)(3). It should be a product that is primarily used in conjunction with the skin graft procedures described by CPT codes 15271 through 15278 or HCPCS codes C5271 through C5278 (78 FR 74937). The skin substitute should only be applied a few times during a typical treatment episode. BlastX™, according to the manufacturer, may be used in many other procedures other than skin graft procedures, including several debridement and active wound care management procedures. The manufacturer also stated that BlastX™ would be used in association with any currently available skin substitute product and that the product should be applied every other day, which is not how skin substitute products for skin graft procedures are used to heal wounds. BlastX™ is not a required component of the skin graft service, and is used as a supply that may assist with the wound healing process that occurs primarily because of the use of sheet skin substitute product in a skin graft procedure.

Therefore, with respect to the eligibility criterion at § 419.66(b)(3), we have determined that BlastX™ is not integral to the service provided (which is a skin graft procedure using a sheet skin substitute), is a material or supply furnished incidentally to a service, and is not surgically inserted into a patient. BlastX™ does not meet the basic criterion of being an eligible device for transitional pass-through payment. Therefore, it is not feasible to evaluate the product on the other criteria required for transitional pass-through payment for devices, including the newness criterion, the substantial clinical improvement criterion, and the cost criterion. We are inviting public comments on the eligibility of BlastX™ for transitional pass-through payment for devices.

(4) EpiCord®

MiMedx® submitted an application for a new OPPS device category for transitional pass-through payment status for EpiCord®, a skin substitute product. According to the applicant, EpiCord® is a minimally manipulated, dehydrated, devitalized cellular umbilical cord allograft for homologous use that provides a protective environment for the healing process. According to the applicant, EpiCord® is comprised of the protective elements of the umbilical cord with a thin amnion layer and a thicker Wharton's Jelly mucopolysaccharides component. The Wharton's Jelly contains collagen, hyaluronic acid, and chondroitin sulfate, which are the components principally responsible for its mechanical properties.

The applicant stated that EpiCord® is packaged as an individual unit in two sizes, 2 cm x 3 cm and 3 cm x 5 cm. The applicant asserted that EpiCord® is clinically superior to other skin substitutes because it is much thicker than dehydrated amnion/chorion allografts, which allows for application over exposed bone, tendon, nerves, muscle, joint capsule and hardware. According to the applicant, due to its unique thicker, stiffer structure, clinicians are able to apply or suture EpiCord® for deep, tunneling wounds where other products cannot fill the entire wound bed or dead spaces.

With respect to the newness criterion at § 419.66(b)(1), EpiCord® was added to the MiMedx® registration for human cells, tissues, and cellular and tissue-based products (HCT/Ps) on December 31, 2015. In adding EpiCord, MiMedx® asserted that EpiCord® conformed to the requirements for HCT/Ps regulated solely under section 361 of the Public Health Service Act and the regulations at 21 CFR part 1271. For these products, FDA requires that the manufacturer register and list its HCT/Ps with the FDA's Center for Biologics Evaluation and Research (CBER) within 5 days after beginning operations and update its registration annually, and MiMedx® provided documentation verifying that EpiCord® had been registered. However, no documentation regarding an FDA determination that EpiCord® is appropriate for regulation solely under section 361 of the Public Health Service Act had been submitted. According to

the applicant, December 31, 2015 was the first date of sale within the United States for EpiCord®. Therefore, it appears that market availability of EpiCord® is within 3 years of this application.

We note that a product that is regulated solely under section 361 of the Public Health Service Act and the regulations in 21 CFR part 1271 is not regulated as a device. The regulations at 21 CFR 1271.20 state that ''If you are an establishment that manufactures an HCT/P that does not meet the criteria set out in § 1271.10(a), and you do not qualify for any of the exceptions in § 1271.15, your HCT/P will be regulated as a drug, device, and/or biological product . . . .''). The Federal Food, Drug, and Cosmetic Act requires that manufacturers of devices that are not exempt obtain marketing approval or clearance for their products from FDA before they may offer them for sale in the United States. We did not receive documentation from the applicant that EpiCord® is regulated as a device by FDA in accordance with Medicare regulations at 42 CFR 419.66(b)(1). We are inviting public comments on whether EpiCord® meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, EpiCord® is a skin substitute product that is integral to the service provided, is used for one patient only, comes in contact with human tissue, and is surgically inserted into the patient. The applicant also claimed EpiCord® meets the device eligibility requirements of § 419.66(b)(4) because EpiCord® is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material. We are inviting public comments on whether EpiCord® meets these eligibility criteria.

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 category that describes EpiCord®. There are no present or previously established device categories for pass-through status that describe minimally manipulated, lyophilized, non-viable cellular umbilical membrane allografts. MiMedx® proposed a new device category descriptor of ''Dehydrated Human Umbilical Cord Allografts'' for EpiCord®.

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 regard to the substantial clinical improvement criterion, the applicant asserted that EpiCord® reduces the mortality rate with use of the device; reduces the rate of device-related complications; decreases the rate of subsequent diagnostic or therapeutic interventions; decreases the number of future hospitalizations or physician visits; provides more rapid beneficial resolution of the disease process treated because of the use of the device; decreases pain, bleeding, or other quantifiable symptom; and reduces recovery time.

To determine if the product meets the substantial improvement criterion, we compared EpiCord® to other skin substitute products. Compared to NEOX CORD 1K Wound Allograft, EpiCord® has half the levels of Vascular Endothelial Growth Factor (VEGF) and insulin-like growth factor binding protein-4 (IGFBP–4) and lower levels of Glial Cell Line Derived Neurotrophic Factor (GDNF) and Epidermal Growth Factor (EGF). Despite EpiCord® having higher levels of other growth factors, the cumulative effect of these differences has not been sufficiently demonstrated in the application. Moreover, most professional opinions do not compare EpiCord® to specific alternative skin substitutes; the few that do are, for the most part, of limited specificity (in terms of foci of superiority to other skin substitutes). Studies demonstrated 41 percent higher relative rates (4.1 percent higher absolute rates) of severe complications for EpiCord® compared to standard of care. Additionally, the control group was moist dressings and offloading (instead of another umbilical or biologic product). Furthermore, 38 percent of EpiCord® patients in the study were smokers versus 58 percent of control patients (smoking impairs wound healing; thus, this important dissimilarity between intervention and study populations casts doubt on attributing observed benefit to the intervention).

Based on the evidence submitted with the application, we have insufficient evidence that EpiCord® provides a substantial clinical improvement over other treatments for wound care. We are inviting public comments on whether EpiCord® meets the substantial clinical improvement criterion.

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. EpiCord® would be reported with CPT code 15271 or 15275. CPT code 15271 describes the 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. CPT code 15275 describes the application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area. Both codes are assigned to APC 5054 (Level 4 Skin Procedures). CPT codes 15271 through 15278 are assigned to either APC 5054 (Level 4 Skin Procedures), with a proposed CY 2019 payment rate of $1,593.38 and a device offset of $4.62, or APC 5055 (Level 5 Skin Procedures), with a proposed CY 2019 payment rate of $2,811.13 and a device offset of $37.11. The price of EpiCord® is $1,595 for the 2 cm x 3 cm and $3,695 for the 3 cm x 5 cm product size. To meet the cost criterion for device pass-through payment, a device must pass all three tests of the cost criterion for at least one APC. 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 $3,695 for the 3 cm x 5 cm product exceeds the applicable APC amount for the service related to the category of devices of $1,593.38 by 231.90 percent ($3,695/$1,593.38 $\times$ 100 percent = 231.90 percent). Therefore, it appears that EpiCord® meets the first cost significance test.

The second cost significance test, 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 $3,695 for the 3 cm x 5 cm product exceeds the device-related portion of the APC payment amount for the related service of $4.62 by 79,978.35 percent ($3,695/$4.62 × 100 percent = 79,978.35 percent). Therefore, it appears that EpiCord® meets the second cost significance test.

Section 419.66(d)(3), the third cost significance test, requires 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 $3,695 for the 3 cm x 5 cm product and the portion of the APC payment amount for the device of $4.62 exceeds 10 percent at 231.61 percent (($3,695 − $4.62)/$1,593.38) × 100 percent = 231.61 percent). Therefore, it appears that EpiCord® meets the third cost significance test. Based on the costs submitted by the applicant and the calculations noted earlier, it appears that EpiCord® meets the cost criterion at § 419.66(c)(3) for new device categories. We are inviting public comments on whether EpiCord® meets the cost criterion for device pass-through payment.

(5) remedē® System Transvenous Neurostimulator

Respicardia, Inc. submitted an application for a new device category for transitional pass-through payment status for the remedē® System Transvenous Neurostimulator. According to the applicant, the remedē® System is an implantable phrenic nerve stimulator indicated for the treatment of moderate to severe central sleep apnea (CSA) in adult patients. The applicant stated that the remedē® System is the first and only implantable neurostimulator to use transvenous sensing and stimulation technology. The applicant also stated that the remedē® System consists of an implantable pulse generator, a transvenous lead to stimulate the phrenic nerve and a transvenous sensing lead to sense respiration via transthoracic impedance. Lastly, the applicant stated that the device stimulates a nerve located in the chest (phrenic nerve) that is responsible for sending signals to the diaphragm to stimulate breathing to restore normal sleep and respiration in patients with moderate to severe central sleep apnea (CSA).

With respect to the newness criterion at § 419.66(b)(1), the applicant received a Category B Investigational Device Exemption (IDE) from FDA on April 18, 2013. Subsequently, the applicant received approval of its premarket approval (PMA) application from FDA on October 6, 2017. The application for a new device category for transitional pass-through payment status for the remedē® System was received on May 31, 2017, which is within 3 years of the date of the initial FDA approval or clearance. We are inviting public comments on whether the remedē® System meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the remedē® 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 remedē® 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.

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 remedē® System. The applicant proposed a category descriptor for the remedē® System of ''generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation.'' We are inviting public comments on this issue.

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 journal articles that discussed the health effects of central sleep apnea (CSA) which include fatigue, decreased mental acuity, myocardial ischemia, and dysrhythmias. The applicant stated that patients with CSA may suffer from poor clinical outcomes, including myocardial infarction and congestive heart failure.[17]

The applicant claims that the remedē® System has been found to significantly improve apnea-hypopnea index (AHI), which is an index used to indicate the severity of sleep apnea. AHI is represented by the number of apnea and hypopnea events per hour of sleep and was used as the primary effectiveness endpoint in the remedē® System pivotal trial. The applicant noted that the remedē® System was shown to improve AHI in small, self-controlled studies as well as in larger trials.

The applicant reported that in the pivotal study, a large, multicenter, randomized controlled trial of CSA patients, intention-to-treat analysis found that 51 percent (35/68) of CSA patients using the remedē® System had greater than 50 percent reduction of apnea-hypopnea index (AHI) from baseline at 6 months compared to 11 percent (8/73) of the control group ($p < 0.0001$). Per-protocol analysis found that 60 percent (35/58) of remedē® System patients had a greater than 50 percent reduction of AHI and in 74 percent (26/35) of these patients AHI dropped to <20.[18]

According to the applicant, an exploratory post-hoc analysis of patients with CSA and congestive heart failure (CHF) in the Pivotal trial found that, at 6 months, the remedē® System group had a greater percentage of patients with >=50 percent reduction in AHI compared to control group (63 percent versus 4 percent, $p < 0.001$).[19]

The applicant noted that patient symptoms and quality of life were improved with the remedē® System therapy. The mean Epworth Sleepiness Scale (ESS) score significantly decreased in remedē® System patients, indicating less daytime sleepiness.[20] Adverse events associated with remedē® System insertion and therapy included lead dislodgement/dislocation, hematoma, migraine, atypical chest pain, pocket perforation, pocket infection, extra-respiratory stimulation,

[17] Costanzo, M.R., et al., Mechanisms and Clinical Consequences of Untreated Central Sleep Apnea in Heart Failure. *Journal of the American College of Cardiology,* 2015. 65(1): p. 72–84.

[18] Costanzo, M.R., et al. (2016). Transvenous neurostimulation for central sleep apnoea: a randomised controlled trial. *The Lancet, 388(10048):* p. 974–982.

[19] Goldberg, L.R., et al. (2017). In Heart Failure Patients with CSA, Stimulation of the Phrenic Nerve Improves Sleep and Quality of Life. *Journal of Cardiac Failure, 23(8):* p. S15.

[20] Costanzo, M.R., et al. (2016). Transvenous neurostimulation for central sleep apnoea: a randomised controlled trial. *The Lancet, 388(10048):* p. 974–982.

concomitant device interaction, and elevated transaminases.[21] There were no patient deaths that were related to the device implantation or therapy.

One concern regarding the remedē® System is the potential for complications in patients with coexisting cardiac devices, such as pacemakers or ICDs, given that the remedē® System device requires lead placement and generation of electric impulses. Another concern with the evidence of substantial clinical improvement is that there is limited long-term data on patients with remedē® System implants. The pivotal trial included only 6 months of follow-up. Also, while the applicant reported a reduction in AHI in the treatment group, the applicant did not establish that that level of change was biologically meaningful in the population(s) being studied. The applicant did not conduct a power analysis to determine the necessary size of the study population and the necessary duration of the study to detect both early and late events.

In addition, patients in the pivotal study were not characterized by the use of cardiac devices. Cardiac resynchronization therapy (CRT), in particular, is known to improve chronic sleep apnea in addition to its primary effects on heart failure, and central apnea is a marker of the severity of the congestive heart failure. The applicant did not conduct subset analyses to assess the impact of cardiac resynchronization therapy.

Lastly, while evaluation of AHI and quality of life metrics show improvement with the remedē® System, the translation of those effects to mortality benefit is yet to be determined. Further studies of the remedē® System are likely needed to determine long-term effects of the device, and as well as its efficacy compared to existing treatments of CPAP or medications.

Based on the evidence submitted with the application, we have insufficient evidence that the remedē® System provides a substantial clinical improvement over other similar products. We are inviting public comments on whether the remedē® System meets the substantial clinical improvement criterion.

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that the remedē® System would be reported with CPT code 0424T. CPT code 0424T is assigned to APC 5464 (Level 4 Neurostimulator and Related Procedures). To meet the cost criterion for device pass-through payment, a device must pass all three tests of the cost criterion for at least one APC. For our calculations, we used APC 5464, which had a CY 2017 payment rate of $27,047.11 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 0424T had a device offset amount of $11,089 at the time the application was received. According to the applicant, the cost of the remedē® System was $34,500. 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 $34,500 for the remedē® System exceeds 127 percent of the applicable APC payment amount for the service related to the category of devices of $27,047.11 ($34,500/$27,047.11 × 100 = 127.5 percent). Therefore, we believe the remedē® System meets the first cost significance test.

The second cost significance test, 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 $34,500 for the remedē® System exceeds the cost of the device-related portion of the APC payment amount for the related service of $11,089 by 311 percent ($34,500/$11,089) × 100 = 311 percent). Therefore, we believe that the remedē® System meets the second cost significance test.

The third cost significance test, at § 419.66(d)(3), requires 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 $34,500 for the remedē® System and the portion of the APC payment amount for the device of $11,089 exceeds the APC payment amount for the related service of $27,047.11 by 87 percent (($34,500 − $11,089)/$27,047.11 × 100 = 86.6 percent). Therefore, we believe that the remedē® System meets the third cost significance test.

We are inviting public comments on whether the remedē® System meets the device pass-through payment criteria discussed in this section, including the cost criteria for device pass-through payment.

(6) Restrata® Wound Matrix

Acera Surgical, Inc. submitted an application for a new device category for transitional pass-through payment status for Restrata® Wound Matrix. Restrata® Wound Matrix is a sterile, single-use product intended for use in local management of wounds. According to the applicant, Restrata® Wound Matrix is a soft, white, conformable, non-friable, absorbable matrix that works as a wound care management product by acting as a protective covering for wound defects, providing a moist environment for the body's natural healing process to occur. Restrata® Wound Matrix is made from synthetic biocompatible materials and was designed with a nanoscale non-woven fibrous structure with high porosity, similar to native extracellular matrix. Restrata® Wound Matrix allows for cellular infiltration, new tissue formation, neovascularization, and wound healing before completely degrading via hydrolysis. The product permits the ingress of cells and soft tissue formation in the defect space/wound bed. Restrata® Wound Matrix can be used to manage wounds, including: Partial and full-thickness wounds, pressure sores/ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (for example, donor site/grafts, post-laser surgery, post-Mohs surgery, podiatric wounds, wound dehiscence), trauma wounds (for example, abrasions, lacerations, partial thickness burns, skin tears), and draining wounds.

With respect to the newness criterion at § 419.66(b)(1), the applicant received FDA clearance for Restrata® Wound Matrix through the premarket notification section 510(k) process on April 26, 2017 and its February 27, 2018 application for pass-through payment status was within 3 years of FDA clearance. We are inviting public

[21] Costanzo, M.R., et al. (2016).Transvenous neurostimulation for central sleep apnoea: a randomised controlled trial. *The Lancet, 388(10048):* p. 974–982.

comment on whether Restrata® Wound Matrix meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, Restrata® Wound Matrix is a product that is integral to the service provided, is used for one patient only, comes in contact with human skin, and is surgically inserted into the patient. The description of Restrata® Wound Matrix shows the product meets the device eligibility requirements of § 419.66(b)(4) because Restrata® Wound Matrix is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material. We are inviting public comment on whether Restrata® Wound Matrix meets the eligibility criteria.

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 category that describes Restrata® Wound Matrix. The applicant proposed a new device category descriptor of ''Nanofiber Skin Substitute'' for Restrata® Wound Matrix. We are inviting public comments on this issue.

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 regard to the substantial clinical improvement criterion, the applicant submitted three clinical studies about Restrata® to address this criterion. The largest study is non-randomized, non-blinded, uncontrolled single site retrospective analysis of 70 patients with 82 wounds. This study has not been published but has been submitted to a journal. The study included different types of wounds including diabetic wounds, venous wounds, and other wounds. The study asserted that the wounds had not responded to other wound care treatments, but provides little information on the reasons for the failure of previous treatments.

The study had no power analysis of the results. There were no corrections for multiple comparisons or peeks at the data, and the study did not address if participants dropped out or why there was a lack of drop-outs. The conclusions were descriptive statistics and were compared to the findings in another study where the average wound duration was nearly twice as long as in the original study. There was no previously established endpoint for the most important aspect of functionality, which would be the proportion of wounds with total closure that remained closed after six months despite weight bearing.

The other two studies were extremely small. One study was performed on two non-human subjects (pigs) with a competitor skin matrix product compared to Restrata®. The results of the study were mixed with Restrata® performing better on some measures and the competitor product performing better on other measures. The other study was a case series of six patients that was non-randomized without a control group. It was not clear how the results of these non-randomly selected pre-treated patients relate to the larger population of ulcer patients.

Based on the evidence submitted, we believe there is insufficient data to determine whether Restrata® offers a substantial clinical improvement over other treatments for wound care. We are inviting public comments on whether Restrata® meets the substantial clinical improvement criterion.

The third criterion for establishing a device category, at § 419.66(c)(3), requires CMS 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. Restrata® Wound Matrix would be reported with CPT codes 15271 through 15278, which cover the application of skin substitute grafts to different areas of the body for high-cost skin substitutes. To meet the cost criterion for device pass-through payment, a device must pass all three tests of the cost criterion for at least one APC. CPT codes 15271 through 15278 are assigned to either APC 5054 (Level 4 Skin Procedures), with a proposed CY 2019 payment rate of $1,593.38 and a device offset of $4.62, or APC 5055 (Level 5 Skin Procedures), with a proposed CY 2019 payment rate of $2,811.13 and a device offset of $37.11. According to the applicant, the highest retail cost of Restrata® Wound Matrix is $11,718.

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 $11,718 for Restrata® Wound Matrix exceeds the applicable APC amount for the service related to the category of devices of $1,593.38 by 735.42 percent ($11,718/$1,593.38 × 100 percent = 735.42 percent). Therefore, it appears that Restrata® Wound Matrix meets the first cost significance test.

The second cost significance test, 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 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 $11,718 for Restrata® Wound Matrix exceeds the device-related portion of the APC payment amount for the related service of $4.62 by 253,636.36 percent ($11,718/$4.62 × 100 percent = 253,636.36 percent). Therefore, it appears that Restrata® Wound Matrix meets the second cost significance test.

Section 419.66(d)(3), the third cost significance test, requires 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 $11,718 for Restrata® Wound Matrix and the portion of the APC payment amount for the device of $4.62 exceeds 10 percent at 735.13 percent (($11,718 − $4.62)/$1,593.38 × 100 percent = 735.13 percent). Therefore, it appears that Restrata® Wound Matrix meets the third cost significance test. Based on the costs submitted by the applicant and the calculations noted earlier, we believe that Restrata® Wound Matrix appears to meet the cost criterion at § 419.66(c)(3) for new device categories. We are inviting public comments on whether Restrata® Wound Matrix meets the device pass-through payment criteria discussed in this section, including the cost criteria.

(7) SpaceOAR® System

Augmenix, Inc. submitted an application for a new device category for transitional pass-through payment status for the SpaceOAR® System. According to the applicant, the

SpaceOAR® System is a polyethylene glycol hydrogel spacer that temporarily positions the anterior rectal wall away from the prostate to reduce the radiation delivered to the anterior rectum during prostate cancer radiotherapy treatment. The applicant stated that the SpaceOAR® System reduces some of the side effects associated with radiotherapy, which are collectively known as ''rectal toxicity'' (diarrhea, rectal bleeding, painful defecation, and erectile dysfunction, among other conditions). The applicant also stated that the SpaceOAR® is implanted several weeks before radiotherapy; the hydrogel maintains space between the prostate and rectum for the entire course of radiotherapy and is completely absorbed by patient's body within 6 months.

With respect to the newness criterion at § 419.66(b)(1), FDA granted a De Novo request classifying the SpaceOAR® System as a class II device under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act on April 1, 2015. We received the application for a new device category for transitional pass-through payment status for the SpaceOAR® System on June 1, 2017, which is within 3 years of the date of the initial FDA approval or clearance. We are inviting public comments on whether the SpaceOAR® System meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the SpaceOAR® 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 SpaceOAR® System meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service.

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 SpaceOAR® System. The applicant proposed a category descriptor for the SpaceOAR® System of ''Absorbable perirectal spacer''. We are inviting public comments on this issue.

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 studies which generally discussed the benefits and techniques for using hydrogel spacers to limit radiation exposure to the rectum in prostate radiotherapy. The applicant also submitted several studies that specifically examined the effect that the SpaceOAR® System had on mitigating outcomes such as rectal dose, toxicity, and quality of life declines after image guided intensity modulated radiation therapy for prostate cancer. Articles by Hamstra et al.[22] and Mariados et al.[23] discussed the results of a single-blind phase III trial of image guided intensity modulated radiation therapy with 3 years of follow up. A total of 222 men were randomized 2:1 to the spacer or control group and received 79.2 Gy in 1.8-Gy fractions to the prostate with or without the seminal vesicles. The results of this study showed that after 3 years, compared with the control group, the participants who received the SpaceOAR® System injection had a statistically significant smaller volume of the rectum receiving a threshold radiation exposure, which was the primary effectiveness endpoint. The results also showed that in an extended follow up period, the control group experienced larger declines in bowel and urinary quality of life compared to participants who received the SpaceOAR® System treatment. Lastly, in an extended follow-up period, the probability of grade ≥1 rectal toxicity was decreased in the SpaceOAR® System arm (9 percent control group, 2 percent SpaceOAR® System group, $p<.03$) and no ≥ grade 2 rectal toxicity was observed in the SpaceOAR® System arm. However, the control arm had low rates of rectal toxicity in general. The results of this 3-year follow-up of these participants showed that the differences identified in the 15-month follow-up study were maintained or increased.[24]

The applicant also included a secondary analysis of the phase III trial data which showed that participants who received lower radiation doses to the penile bulb, associated with the SpaceOAR® System injection, reported similar erectile function compared with the control group based on patient-reported sexual quality of life.[25] A 2017 retrospective cohort study by Pinkawa et al.[26] evaluated quality of life changes up to 5 years after RT for prostate cancer with the SpaceOAR® System and showed that 5 years after radiation therapy, no patients who received the SpaceOAR® System reported moderate/big problems with bowel urgency, losing control of stools, or with bowel habits overall. However, there were no statistically significant differences in mean score changes for urinary, bowel, or sexual bother between the percentage of participants in the SpaceOAR® System and control groups at either 1.5 or 5 years post radiation therapy. Concerns regarding the phase III trial include inclusion of only low to moderate risk prostate cancer in the study population and failing to use a clinical outcome as a primary endpoint, although the purpose of the spacer is to reduce the side effects of undesired radiation to the rectum including bleeding, diarrhea, fistula, pain, and/or stricture. Notwithstanding acknowledgement that rectal complications may be reduced using biodegradable biomaterials placed to increase the distance between the rectum and the prostate, it is not clear that SpaceOAR® System is superior to existing alternative biodegradable biomaterials currently utilized for spacing in the context of prostate radiotherapy.

Based on the evidence submitted with the application, we have insufficient evidence that the SpaceOAR® System provides a substantial clinical improvement over other similar products. We are inviting public comments on whether the SpaceOAR® System meets the substantial clinical improvement criterion.

[22] Hamstra DA, et al. (2017). Continued Benefit to Rectal Separation for Prostate Radiation Therapy: Final Results of a Phase III Trial. *Int J Radiat Oncol Biol PhysApr 1;97(5)*:976–985. Epub 2016 Dec 23. PMID:28209443.

[23] Mariados N, et al. (2015). Hydrogel Spacer Prospective Multicenter Randomized Controlled Pivotal Trial: Dosimetric and Clinical Effects of Perirectal Spacer Application in Men Undergoing Prostate Image Guided Intensity Modulated Radiation Therapy. *Int J Radiat Oncol Biol Phys.92(5)*:971–977. Epub 2015 Apr 23. PMID: 26054865.

[24] Ibid.

[25] Hamstra, DA et al. (2018) Sexual quality of life following prostate intensity modulated radiation therapy (IMRT) with a rectal/prostate spacer: secondary analysis of a phase 3 trial. *Practical Radiation Oncology, 8,* e7–e15.

[26] Pinkawa, M. et al. (2017). Quality of Life after Radiation Therapy for Prostate Cancer With a Hydrogel Spacer: Five Year Results. *Int J Radiat Oncol Biol Phys., Vol. 99, No. 2,* pp. 374e377.

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 SpaceOAR® System would be reported with CPT code 0438T (which was deleted and replaced with CPT code 55874, effective January 1, 2018). CPT code 0438T was assigned to APC 5374 (Level 4 Urology and Related Services). To meet the cost criterion for device pass-through payment, a device must pass all three tests of the cost criterion for at least one APC. For our calculations, we used APC 5374, which had a CY 2017 payment rate of $2,542.56 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 0438T had device offset amount of $587.07 at the time the application was received. According to the applicant, the cost of the SpaceOAR® System was $2,850.

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 $2,850 for the SpaceOAR® System exceeds 112 percent of the applicable APC payment amount for the service related to the category of devices of $2,542.56 ($2850/$2,542.56 × 100 = 112 percent). Therefore, we believe the SpaceOAR® system meets the first cost significance test.

The second cost significance test, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $2,850 for the SpaceOAR® System exceeds the cost of the device-related portion of the APC payment amount for the related service of $587.07 by 485 percent ($2,850/$587.07) × 100 = 485 percent). Therefore, we believe that the SpaceOAR® System meets the second cost significance test.

The third cost significance test, at § 419.66(d)(3), requires 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 $2,850 for the SpaceOAR® System and the portion of the APC payment amount for the device of $587.07 exceeds the APC payment amount for the related service of $2,542.56 by 89 percent (($2,850–$587.07)/$2,542.56 × 100 = percent). Therefore, we believe that the SpaceOAR® System meets the third cost significance test.

We are inviting public comments on whether the SpaceOAR® System meets the device pass-through payment criteria discussed in this section, including the cost criteria.

B. Proposed 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) applied to device-intensive APCs and is discussed in detail in section IV.B.4. of this 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 given 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 an 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 employed 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 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 this 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. Proposed Changes to the Device-Intensive Procedure Policy for CY 2019

As part of CMS' effort to better capture costs for procedures with significant device costs, for CY 2019, we are proposing to modify our criteria for device-intensive procedures. We have heard from stakeholders that the current criteria exclude some procedures that stakeholders believe 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 nonetheless qualify as device-intensive procedures, regardless of whether the device remains in the patient's body after the conclusion of the procedure. We agree that a broader definition of device-intensive procedures is warranted, and are proposing two modifications to the current criteria. First, we are proposing to allow 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, because we no longer believe that whether a device remains in the patient's body should affect its designation as a device-intensive procedure because such devices could, nonetheless, comprise a large cost of the applicable procedure. Second, we are proposing to modify 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 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, this proposed 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 are proposing 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.

In addition, to further align the device-intensive policy with the criteria used for device pass-through status, we are proposing to specify, 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 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:

(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).

As part of this proposal, we also are soliciting public comment on these proposed revised criteria, including whether there are any devices that are not capital equipment that commenters believe should be deemed part of device-intensive procedures that would not meet the proposed definition of single-use devices. In addition, we are soliciting public comments on the full list of proposed CY 2019 OPPS device-intensive procedures provided in Addendum P to this proposed rule, which is available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html.* Specifically, we are inviting public comment on whether any procedures proposed to receive device-intensive status for CY 2019 should not receive device-intensive status according to the proposed criteria, or if we did not assign device-intensive status for CY 2019 to any procedures commenters believed should receive device-intensive status based on the proposed criteria.

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 do 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 is not calculated from claims data; instead, it is applied as a default until claims data are 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 is to ensure ASC access for new procedures until claims data become available.

In accordance with our proposal 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 are proposing to modify this

policy and 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 proposal to lower the default device offset from 41 percent to 31 percent, we are proposing to continue 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 will be 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, we are clarifying that since the adoption of our current policy, 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 are proposing to 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. Clinically related and similar procedures for purposes of this policy are procedures that have little to 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 proposal, claims data from clinically related and similar codes will be 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 are proposing to 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 believe that claims data for HCPCS codes describing procedures that have very minor differences from the procedures described by new HCPCS codes would provide an accurate depiction of the cost relationship between the procedure and the device(s) that are used, and would be appropriate to use to set a new code's device offset percentage, in the same way that predecessor codes are used. For instance, for CY 2019, we are proposing to use the claims data from existing CPT code 36568 (Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump; younger than 5 years of age), for which the description as of January 1, 2019 is changing to ''(Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump, without imaging guidance; younger than 5 years of age)'', to determine the appropriate device offset percentage for new CPT code 36X72 (Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump, including all imaging guidance, image documentation, and all associated radiological supervision and interpretation required to perform the insertion; younger than 5 years of age). We believe that although CPT code 36568 is not identified as a predecessor code by CPT, the procedure described by new CPT code 36X72 was previously described by CPT code 36568 and, therefore, CPT code 36X72 is clinically related and similar to CPT code 36568, and the device offset percentage for CPT code 36568 can be accurately applied to both codes. 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 will be 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 will be used to determine whether the new HCPCS code qualifies for device-intensive status.

Additional information for our consideration of an offset percentage higher than the proposed 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.

The full listing of proposed CY 2019 device-intensive procedures is included in Addendum P to this 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.

We are not proposing any changes to this policy for CY 2019.

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 existing 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. Proposed 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.

For CY 2019 and subsequent years, we are proposing to apply our no cost/full credit and partial credit device policies to all procedures that qualify as device-intensive under our proposed modified criteria discussed in section IV.B.2. of this 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 note 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), and 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 approximately $21,302, and the median cost was approximately $19,521. The final CY 2018 payment rate (calculated using the median cost) was approximately $17,560.

For CY 2019, we are proposing to continue with 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 based on calculations using the median cost instead of the geometric mean cost. For CY 2019, there are no procedures to which this policy would apply. Due to the proposed change in APC assignment for CPT code 0308T to APC 5493 (Level 3 Intraocular Procedures) from APC 5495 (Level 5 Intraocular Procedures), our payment policy for low-volume device-intensive procedures would not apply to CPT code 0308T for CY 2019 because there are now more than 100 total claims for the APC to which CPT code 0308T is assigned. For more information on the proposed APC assignment change for CPT code 0308T, we refer readers to section III.D.4. of this proposed rule.

V. Proposed OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals

A. Proposed OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals

1. Background

Section 1833(t)(6) of the Act provides for temporary additional payments or ''transitional pass-through payments'' for certain drugs and biologicals. Throughout this 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 this proposed rule includes (but is not necessarily limited to) a ''biological product'' or a ''biologic'' as defined in 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, 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 2019 pass-through drugs and biologicals and their designated APCs are assigned status indicator ''G'' in Addenda A and B to this 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 this 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.

3. Proposed Drugs and Biologicals With Expiring Pass-Through Payment Status in CY 2018

We are proposing that the pass-through payment status of 23 drugs and biologicals would expire on December 31, 2018, as listed in Table 19 below. All of these drugs and biologicals will have received OPPS pass-through payment for at least 2 years and no more than 3 years by December 31, 2018. These drugs and biologicals were approved for pass-through payment status on or before January 1, 2017. 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 $125 for CY 2019), as discussed further in section V.B.2. of this proposed rule. We are proposing 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 are proposing to provide separate payment at the applicable relative ASP-based payment amount (which is proposed at ASP+6 percent for CY 2019, as discussed further in section V.B.3. of this proposed rule).

TABLE 19—PROPOSED DRUGS AND BIOLOGICALS FOR WHICH PASS–THROUGH PAYMENT STATUS EXPIRES DECEMBER 31, 2018

CY 2018 HCPCS code	CY 2018 long descriptor	CY 2018 status indicator	CY 2018 APC	Pass-through payment effective date
A9515	Choline C 11, diagnostic, per study dose	G	9461	04/01/2016
C9460	Injection, cangrelor, 1 mg	G	9460	01/01/2016
C9482	Injection, sotalol hydrochloride, 1 mg	G	9482	10/01/2016
J1942	Injection, aripiprazole lauroxil, 1 mg	G	9470	04/01/2016
J2182	Injection, mepolizumab, 1 mg	G	9473	04/01/2016
J2786	Injection, reslizumab, 1 mg	G	9481	10/01/2016
J2840	Injection, sebelipase alfa, 1 mg	G	9478	07/01/2016
J7202	Injection, Factor IX, albumin fusion protein (recombinant), Idelvion, 1 i.u.	G	9171	10/01/2016
J7207	Injection, Factor VIII (antihemophilic factor, recombinant) PEGylated, 1 I.U.	G	1844	04/01/2016
J7209	Injection, Factor VIII (antihemophilic factor, recombinant) (Nuwiq), per i.u.	G	1846	04/01/2016
J7322	Hyaluronan or derivative, Hymovis, for intra-articular injection, 1 mg	G	9471	04/01/2016
J7342	Instillation, ciprofloxacin otic suspension, 6 mg	G	9479	07/01/2016
J7503	Tacrolimus, extended release, (envarsus xr), oral, 0.25 mg	G	1845	04/01/2016
J9022	Injection, atezolizumab, 10 mg	G	9483	10/01/2016
J9145	Injection, daratumumab, 10 mg	G	9476	07/01/2016
J9176	Injection, elotuzumab, 1 mg	G	9477	07/01/2016
J9205	Injection, irinotecan liposome, 1 mg	G	9474	04/01/2016
J9295	Injection, necitumumab, 1 mg	G	9475	04/01/2016
J9325	Injection, talimogene laherparepvec, 1 million plaque forming units (PFU)	G	9472	04/01/2016
J9352	Injection, trabectedin, 0.1 mg	G	9480	07/01/2016
Q5101	Injection, filgrastim-sndz, biosimilar, (zarxio), 1 microgram	G	1822	07/01/2015
Q9982	Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries	G	9459	01/01/2016
Q9983	Florbetaben F18, diagnostic, per study dose, up to 8.1 millicuries	G	9458	01/01/2016

The proposed packaged or separately payable status of each of these drugs or biologicals is listed in Addendum B to this proposed rule (which is available via the internet on the CMS website).

4. Proposed Drugs, Biologicals, and Radiopharmaceuticals With New or Continuing Pass-Through Payment Status in CY 2019

We are proposing to continue pass-through payment status in CY 2019 for 45 drugs and biologicals. These drugs and biologicals, which were approved for pass-through payment status between January 1, 2017, and July 1, 2018, are listed in Table 20 below. The APCs and HCPCS codes for these drugs and biologicals approved for pass-through payment status through December 31, 2018 are assigned status indicator ''G'' in Addenda A and B to this 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 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). Because of this requirement, these drugs and biologicals are also included in Table 20, which brings the total number of drugs and biologicals with proposed pass-through payment status in CY 2019 to 49. The requirements of section 1301 of Pub. L. 115–141 are described in further detail in section V.A.5. of this proposed rule.

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 2019, we are proposing 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 2019. We are proposing that a $0 pass-through payment amount would be paid for pass-through drugs and biologicals under the CY 2019 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 are proposing that their pass-through payment amount would be equal to ASP+6 percent for CY 2019 minus a payment offset for any predecessor drug products contributing to the pass-through payment as described in section V.A.6. of this 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 are proposing to continue to update pass-through payment rates on a quarterly basis on the CMS website during CY 2019 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 2019, consistent with our CY 2018 policy for diagnostic and therapeutic radiopharmaceuticals, we are proposing 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 2019, we are proposing 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 are proposing to provide pass-through payment at WAC+3 percent (consistent with our proposed policy in section V.B.2.b. of this proposed rule), the equivalent payment provided to pass-through payment drugs and biologicals without ASP information. If WAC information also is not available, we are proposing to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

The 49 drugs and biologicals that we are proposing to continue to have pass-through payment status for CY 2019 or have been granted pass-through payment status as of July 2018 are shown in Table 20 below.

TABLE 20—PROPOSED DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS IN CY 2019

CY 2018 HCPCS code	CY 2019 HCPCS code	CY 2019 long descriptor	Proposed CY 2019 status indicator	Proposed CY 2019 APC	Pass-through payment effective date
A9586	A9586	Florbetapir f18, diagnostic, per study dose, up to 10 millicuries.	G	9084	10/01/2018
A9587	A9587	Gallium ga-68, dotatate, diagnostic, 0.1 millicurie	G	9056	01/01/2017
A9588	A9588	Fluciclovine f-18, diagnostic, 1 millicurie	G	9052	01/01/2017
C9014	C9014	Injection, cerliponase alfa, 1 mg	G	9014	01/01/2018
C9015	C9015	Injection, c-1 esterase inhibitor (human), Haegarda, 10 units.	G	9015	01/01/2018
C9016	C9016	Injection, triptorelin extended release, 3.75 mg	G	9016	01/01/2018
C9024	C9024	Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine.	G	9302	01/01/2018
C9028	C9028	Injection, inotuzumab ozogamicin, 0.1 mg	G	9028	01/01/2018
C9029	C9029	Injection, guselkumab, 1 mg	G	9029	01/01/2018
C9030	C9030	Injection, copanlisib, 1 mg	G	9030	07/01/2018
C9031	C9031	Lutetium Lu 177, dotatate, therapeutic, 1 mCi	G	9067	07/01/2018
C9032	C9032	Injection, voretigene neparvovec-rzyl, 1 billion vector genome.	G	9070	07/01/2018
C9447	C9447	Injection, phenylephrine and ketorolac, 4 ml vial	G	9083	10/01/2018
C9462	C9462	Injection, delafloxacin, 1 mg	G	9462	04/01/2018
C9463	C9463	Injection, aprepitant, 1 mg	G	9463	04/01/2018
C9465	C9465	Hyaluronan or derivative, Durolane, for intra-articular injection, per dose.	G	9465	04/01/2018
C9466	C9466	Injection, benralizumab, 1 mg	G	9466	04/01/2018
C9467	C9467	Injection, rituximab and hyaluronidase, 10 mg	G	9467	04/01/2018
C9468	C9468	Injection, factor ix (antihemophilic factor, recombinant), glycopegylated, Rebinyn, 1 i.u..	G	9468	04/01/2018
C9469	C9469	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg.	G	9469	04/01/2018
C9488	C9488	Injection, conivaptan hydrochloride, 1 mg	G	9488	04/01/2017
C9492	C9492	Injection, durvalumab, 10 mg	G	9492	10/01/2017
C9493	C9493	Injection, edaravone, 1 mg	G	9493	10/01/2017
J0565	J0565	Injection, bezlotoxumab, 10 mg	G	9490	07/01/2017
J0570	J0570	Buprenorphine implant, 74.2 mg	G	9058	01/01/2017

TABLE 20—PROPOSED DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS IN CY 2019—Continued

CY 2018 HCPCS code	CY 2019 HCPCS code	CY 2019 long descriptor	Proposed CY 2019 status indicator	Proposed CY 2019 APC	Pass-through payment effective date
J0606	J0606	Injection, etelcalcetide, 0.1 mg	G	9031	01/01/2018
J1428	J1428	Injection, eteplirsen, 10 mg	G	9484	04/01/2017
J1627	J1627	Injection, granisetron extended release, 0.1 mg	G	9486	04/01/2017
J2326	J2326	Injection, nusinersen, 0.1 mg	G	9489	07/01/2017
J2350	J2350	Injection, ocrelizumab, 1 mg	G	9494	10/01/2017
J3358	J3358	Ustekinumab, for Intravenous Injection, 1 mg	G	9487	04/01/2017
J7179	J7179	Injection, von willebrand factor (recombinant), (Vonvendi), 1 i.u. vwf:rco.	G	9059	01/01/2017
J7210	J7210	Injection, factor viii, (antihemophilic factor, recombinant), (afstyla), 1 i.u.	G	9043	01/01/2017
J7328	J7328	Hyaluronan or derivative, gelsyn-3, for intra-articular injection, 0.1 mg.	G	1862	01/01/2016
J7345	J7345	Aminolevulinic acid hcl for topical administration, 10% gel, 10 mg.	G	9301	01/01/2018
J9023	J9023	Injection, avelumab, 10 mg	G	9491	10/01/2017
J9034	J9034	Injection, bendamustine hcl (Bendeka), 1 mg	G	1861	01/01/2017
J9203	J9203	Injection, gemtuzumab ozogamicin, 0.1 mg	G	9495	01/01/2018
J9285	J9285	Injection, olaratumab, 10 mg	G	9485	04/01/2017
Q2040	Q2040	Tisagenlecleucel, up to 250 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per infusion.	G	9081	01/01/2018
Q2041	Q2041	Axicabtagene Ciloleucel, up to 200 Million Autologous Anti-CD19 CAR T Cells, Including Leukapheresis And Dose Preparation Procedures, Per Infusion.	G	9035	04/01/2018
Q4172	Q4172	PuraPly, and PuraPly Antimicrobial, any type, per square centimeter.	G	9082	10/01/2018
Q5103	Q5103	Injection, infliximab-dyyb, biosimilar, (inflectra), 10 mg	G	1847	04/01/2018
Q5104	Q5104	Injection, infliximab-abda, biosimilar, (renflexis), 10 mg	G	9036	04/01/2018
Q9950	Q9950	Injection, sulfur hexafluoride lipid microsphere, per ml	G	9085	10/01/2018
Q9991	Q9991	Injection, buprenorphine extended-release (Sublocade), less than or equal to 100 mg.	G	9073	07/01/2018
Q9992	Q9992	Injection, buprenorphine extended-release (Sublocade), greater than 100 mg.	G	9239	07/01/2018
Q9993	Q9993	Injection, rolapitant, 0.5 mg	G	9464	04/01/2018
Q9995	Q9995	Injection, emicizumab-kxwh, 0.5 mg	G	9257	07/01/2018

5. Proposed 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 drugs and biologicals pass-through payment status ended on December 31, 2017. These products are listed in Table 21 below. For CY 2019, we are proposing to continue pass-through payment status for the drugs and biologicals listed in Table 21 (we note that these drugs and biologicals are also listed in Table 20 above). 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 this proposed rule (which are available via the internet on the CMS website).

In addition, new section 1833(t)(6)(H) of the Act specifies that the payment amount for such drug or biological under this subsection that is furnished during the period beginning on October 1, 2018, and ending on March 31, 2019, shall be the greater of: (i) The payment amount that would otherwise apply under section 1833(t)(6)(D)(i) of the Act for such drug or biological during such period; or (ii) the payment amount that applied under section 1833(t)(6)(D)(i) of the Act for such drug or biological on December 31, 2017. We intend to address pass-through payment for these drugs and biologicals for the last quarter of CY 2018 through program instruction. For January 1, 2019 through March 31, 2019, we are proposing that pass-through payment for these four drugs and biologicals would be the greater of: (1) ASP+6 percent based on current ASP data; or (2) the payment rate for the drug or biological on December 31, 2017. We also are proposing for the period of April 1, 2019 through December 31, 2019 that the pass-through payment amount for these drugs and biologicals would be the amount that applies under section 1833(t)(6)(D)(i) of the Act.

We are proposing to continue to update pass-through payment rates for these four drugs and biologicals on a quarterly basis on the CMS website during CY 2019 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. 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).

The four drugs and biologicals that we are proposing would have pass-through payment status for CY 2019 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 21 below. Included as one of the four drugs and biologicals with pass-through payment status for CY 2019 is HCPCS code Q4172 (PuraPly, and PuraPly Antimicrobial, any type, per square centimeter). PuraPly is a skin substitute product that was 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 was approved for pass-through payment status through the drug and biological pass-through payment pathway, we are proposing to consider PuraPly to be a drug or biological 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 2019.

TABLE 21—PROPOSED DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS IN CY 2019 IN ACCORDANCE WITH PUBLIC LAW 115–141

CY 2018 HCPCS code	CY 2019 HCPCS code	CY 2019 long descriptor	Proposed CY 2019 status indicator	Proposed CY 2019 APC	Pass-through payment effective date
A9586	A9586	Florbetapir f18, diagnostic, per study dose, up to 10 millicuries.	G	9084	10/01/2018
C9447	C9447	Injection, phenylephrine and ketorolac, 4 ml vial	G	9083	10/01/2018
Q4172	Q4172	PuraPly, and PuraPly Antimicrobial, any type, per square centimeter.	G	9082	10/01/2018
Q9950	Q9950	Injection, sulfur hexafluoride lipid microsphere, per ml	G	9085	10/01/2018

6. Proposed 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 2019, as we did in CY 2018, we are proposing 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 22 below.

TABLE 22—PROPOSED APCS TO WHICH A POLICY-PACKAGED DRUG OR RADIOPHARMACEUTICAL OFFSET MAY BE APPLICABLE IN CY 2019

Proposed CY 2019 APC	Proposed CY 2019 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 are proposing 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. Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Payment Status

1. Proposed Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals

a. Proposed 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 $120 for CY 2018 (82 FR 59343).

Following the CY 2007 methodology, for this CY 2019 OPPS/ASC proposed rule, we used the most recently available four quarter moving average PPI levels to trend the $50 threshold forward from the third quarter of CY 2005 to the third quarter of CY 2019 and rounded the resulting dollar amount ($126.03) to the nearest $5 increment, which yielded a figure of $125. 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. Based on these calculations, we are proposing a packaging threshold for CY 2019 of $125.

b. Proposed 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 2019 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 2017 and were paid (via packaged or separate payment) under the OPPS. We used data from CY 2017 claims processed before January 1, 2018 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 this proposed rule, or for the following policy-packaged items that we are proposing to continue to package in CY 2019: 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 2019, 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 are proposing for separately payable drugs and biologicals for CY 2019, as discussed in more detail in section V.B.2.b. of this proposed rule) to calculate the CY 2019 proposed rule per day costs. We used the manufacturer submitted ASP data from the fourth quarter of CY 2017 (data that were used for payment purposes in the physician's office setting, effective April 1, 2018) to determine the proposed rule per day cost. As is our standard methodology, for CY 2019, we are proposing to use payment rates based on the ASP data from the first quarter of CY 2018 for budget neutrality estimates, packaging determinations, impact analyses, and completion of Addenda A and B to this 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 this proposed rule. These data also were the basis for drug payments in the physician's office setting, effective April 1, 2018. 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 2017 hospital claims data to determine their per day cost.

We are proposing to package items with a per day cost less than or equal to $125, and identify items with a per day cost greater than $125 as separately payable unless they are policy-packaged. Consistent with our past practice, we cross-walked historical OPPS claims data from the CY 2017 HCPCS codes that were reported to the CY 2018 HCPCS codes that we display in Addendum B to this proposed rule (which is available via the internet on the CMS website) for proposed payment in CY 2019.

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 2019 OPPS/ASC proposed rule, we are proposing to use ASP data from the fourth quarter of CY 2017, 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, 2018, along with updated hospital claims data from CY 2017. We note that we also are proposing to use these data for budget neutrality estimates and impact analyses for this CY 2019 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 2018. 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, 2018. These payment rates would then be updated in the January 2019 OPPS update, based on the most recent ASP data to be used for physician's office and OPPS payment as of January 1, 2019. For items that do not currently have an ASP-based payment rate, we are proposing to recalculate their mean unit cost from all of the CY 2017 claims data and updated cost report information available for the CY 2019 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 this 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. Under such circumstances, we are proposing 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 cost fluctuates relative to the proposed CY 2019 OPPS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2018. 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 2019, consistent with our historical practice, we are proposing 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 2018 and that were proposed for separate payment in CY 2019, and that then have per day costs equal to or less than the CY 2019 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2019 final rule, would continue to receive separate payment in CY 2019.
- HCPCS codes for drugs and biologicals that were packaged in CY 2018 and that were proposed for separate payment in CY 2019, and that then have per day costs equal to or less than the CY 2019 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2019 final rule, would remain packaged in CY 2019.
- HCPCS codes for drugs and biologicals for which we proposed packaged payment in CY 2019 but then have per day costs greater than the CY 2019 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2019 final rule, would receive separate payment in CY 2019.

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).

d. Proposed 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 2018, the payment rate for APC 5053 (Level 3 Skin Procedures) was $488.20, the payment rate for APC 5054 (Level 4 Skin Procedures) was $1,568.43, and the payment rate for APC 5055 (Level 5 Skin Procedures) was $2,710.48. This information also is available in Addenda A and B of the CY 2018 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 are proposing to continue it for CY 2019. 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 2019, as with our policy since CY 2016, we are proposing 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 2019, as for CY 2018, we are proposing 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 2019, as for CY 2018, we are proposing 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 2019, we are proposing that any skin substitute product that was assigned to the high cost group in CY 2018 would be assigned to the high cost group for CY 2019, regardless of whether it exceeds or falls below the CY 2019 MUC or PDC threshold.

For this CY 2019 OPPS/ASC proposed rule, consistent with the methodology as established in the CY 2014 through CY 2017 final rules with comment period, we analyzed CY 2017 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 proposed CY 2019 MUC threshold is $49 per cm^2 (rounded to the nearest $1) and the proposed CY 2019 PDC threshold is $895 (rounded to the nearest $1).

For CY 2019, we are proposing to continue to assign skin substitutes with pass-through payment status to the high cost category. We are proposing 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 are proposing 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 are proposing to use WAC+3 percent instead of WAC+6 percent to conform to our proposed policy described in section V.B.2.b. of this 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 2019 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), for CY 2018, 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 is 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 requests 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. We have identified four potential methodologies that have been raised to us that we encourage the public to review and provide comments on. We are 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 are 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. We intend to explore the full array of public comments on these ideas for the CY 2020 rulemaking, and we will consider the feedback received in response to this proposed rule in developing proposals for CY 2020.

• *Establish a lump-sum ''episode-based'' payment for a wound care episode.* Under this option, a hospital would receive a lump sum payment for all wound care services involving procedures using skin substitutes. The payment would be made for a wound care ''episode'' (such as 12 weeks) for one wound. The lump sum payment could be the same for all skin substitutes or could vary based on the estimated number of applications for a given skin substitute during the wound care episode. Under this option, payment to the provider could be made at the start of treatment, or at a different time, and could be made once or split into multiple payments. Quality metrics, such as using the recommended number of treatments for a given skin substitute during a treatment episode, and establishing a plan of care for patients who do not experience 30-percent wound healing after 4 weeks, could be established to ensure the beneficiary receives appropriate care while limiting excessive additional applications of skin substitute products.

• *Eliminate the high cost/low cost categories for skin substitutes and only have one payment category and set of procedure codes for all skin substitute products.* This option would reduce the financial incentives to use expensive skin substitutes and would provide incentives to use less costly skin substitute products that have been shown to have similar efficacy treating wounds as more expensive skin substitute products. A single payment category would likely have a payment rate that is between the current rates paid for high cost and low cost skin substitute procedures. Initially, a single payment category may lead to substantially higher payment for skin graft procedures performed with cheaper skin substitutes as compared to their costs. However, over time, payment for skin graft procedures using skin substitutes might reflect the lower cost of the procedures.

• *Allow for the payment of current add-on codes or create additional procedure codes to pay for skin graft services between 26 cm² and 99 cm² and substantially over 100 cm².* Under this option, payment for skin substitutes would be made more granularly based on the size of the skin substitute product being applied. This option also would reduce the risk that hospitals may not use enough of a skin substitute to save money when performing a procedure. However, such granularity in the use of skin substitutes could conflict with the goals of a prospective payment system, which is based on a system of averages. Specifically, it is expected that some skin graft procedures will be less than 25 cm² or around 100 cm² and will receive higher payments compared to the cost of the services. Conversely, services between 26 cm² and 99 cm² or those that are substantially larger than 100 cm² will receive lower payments compared to the cost of the services, but the payments will average over many skin graft procedures to an appropriate payment rate for the provider.

• *Keep the high cost/low cost skin substitute categories, but change the threshold used to assign skin substitutes in the high-cost or low-cost group.* Consider using other benchmarks that would establish more stable thresholds for the high cost and low cost groups. Ideas include, but are not limited to, fixing the MUC or PDC threshold at amount from a prior year, or setting global payment targets for high cost and low cost skin substitutes and establishing a threshold that meets the payment targets. Establishing different thresholds for the high cost and low cost groups could allow for the use of a mix of lower cost and higher cost skin substitute products that acknowledges that a large share of skin substitutes products used by Medicare providers are higher cost products but still providing substantial cost savings for skin graft procedures. Different thresholds may also reduce the number of skin substitute products that switch between the high cost and low cost groups in a given year to give more payment stability for skin substitute products.

To allow stakeholders time to analyze and comment on the potential ideas raised above, for CY 2019, we are proposing to continue our policy established in CY 2018 to assign skin substitutes to the low cost or high cost group. However, for CY 2020, we may revise our policy to reflect one of the potential new methodologies discussed above or a new methodology included in public comments in response to this proposed rule. Specifically, for CY 2019, we are proposing 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 2018, in which case we will assign the product to the high cost group for CY 2019, regardless of whether it exceeds the CY 2019 MUC or PDC threshold. We also are proposing to assign to the high cost group any skin substitute product that exceeds the CY 2019 MUC or PDC threshold and assign to the low cost group any skin substitute product that does not exceed the CY 2019 MUC or PDC thresholds and were not assigned to the high cost group in CY 2018. We are proposing 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 2019 MUC. In addition, we are proposing to use WAC+3 percent instead of WAC+6 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 2019 MUC. We also are proposing to retain our established policy to assign new skin substitute products with pricing information to the low cost group.

Table 23 below displays the proposed CY 2019 high cost or low cost category assignment for each skin substitute product.

TABLE 23—PROPOSED SKIN SUBSTITUTE ASSIGNMENTS TO HIGH COST AND LOW COST GROUPS FOR CY 2019

CY 2019 HCPCS code	CY 2019 short descriptor	CY 2018 high/low assignment	Proposed CY 2019 high/low 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.

TABLE 23—PROPOSED SKIN SUBSTITUTE ASSIGNMENTS TO HIGH COST AND LOW COST GROUPS FOR CY 2019—Continued

CY 2019 HCPCS code	CY 2019 short descriptor	CY 2018 high/low assignment	Proposed CY 2019 high/low assignment
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.
Q4131	Epifix	High	High.
Q4132	Grafix core and grafixpl core, per square centimeter	High	High.
Q4133	Grafix prime and grafixpl prime, per square centimeter	High	High.
Q4134	hMatrix	Low	Low.
Q4135	Mediskin	Low	Low.
Q4136	Ezderm	Low	Low.
Q4137	Amnioexcel or Biodexcel, 1cm	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 cord 1k, neox cord rt, or clarix cord 1k, per square centimeter	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.
Q4154	Biovance 1 square cm	High	High.
Q4156	Neox 100 or clarix 100, per square centimeter	High	High.
Q4157	Revitalon 1 square cm	High	High.*
Q4158	Kerecis omega3, per square centimeter	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 square centimeter	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 square cm	High	High.*
Q4170	Cygnus, per square cm	Low	Low.
Q4172+	PuraPly, PuraPly antimic	High	High.
Q4173	Palingen or palingen xplus, per sq cm	High	High.
Q4175	Miroderm, per square cm	High	High.
Q4176	Neopatch, per square centimeter	Low	Low.
Q4178	Floweramniopatch, per square centimeter	High	High.
Q4179	Flowerderm, per square centimeter	Low	Low.
Q4180	Revita, per square centimeter	High	High.
Q4181	Amnio wound, per square centimeter	Low	Low.
Q4182	Transcyte, per square centimeter	Low	Low.

*These products do not exceed either the MUC or PDC threshold for CY 2019, but are assigned to the high cost group because they were assigned to the high cost group in CY 2018.

+Pass-through payment status in CY 2019.

e. Proposed 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 believed 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 are proposing 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 2019.

For CY 2019, 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 2017 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 2019 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 2017 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 2019 drug packaging threshold of $125 (so that all HCPCS codes for the same drug or biological would be packaged) or greater than the proposed CY 2019 drug packaging threshold of $125 (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 2019 is displayed in Table 24 below.

TABLE 24—PROPOSED HCPCS CODES TO WHICH THE CY 2019 DRUG-SPECIFIC PACKAGING DETERMINATION METHODOLOGY WOULD APPLY

CY 2019 HCPCS code	CY 2019 long descriptor	Proposed CY 2019 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. Proposed Payment for Drugs and Biologicals Without Pass-Through Status That Are Not Packaged

a. Proposed Payment for Specified Covered Outpatient Drugs (SCODs) and Other Separately Payable and Packaged 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.[27]

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 2019 OPPS/ASC proposed rule, we are proposing 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 continued this policy of paying for separately payable drugs and biologicals at the statutory default for CYs 2014 through 2018.

b. Proposed CY 2019 Payment Policy

For CY 2019, we are proposing 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 are proposing to continue to pay for separately payable nonpass-through drugs acquired with a 340B discount at a rate of ASP minus 22.5 percent. We refer readers to section V.A.7. of this proposed rule 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 proposed rule, under section 1847A(c)(4), although payments may be based on WAC, unlike section 1847A(b) of the Act (which specifies that certain payments 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 partial quarter WAC-based pricing. Consistent with section 1847A(c)(4) of the Act, in the CY 2019 PFS proposed rule, we are proposing that, effective January 1, 2019, WAC-based payments for Part B drugs made under section 1847A(c)(4) of the Act would utilize a 3-percent add-on in place of the 6-percent add-on that is currently being used. For the OPPS, we also are proposing 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 apply this provision to non-SCOD separately payable drugs. Because we are proposing 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 are proposing 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

[27] 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.*

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 proposed rule for additional background on this anticipated proposal.

We are proposing 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 are proposing that the budget neutral weight scalar is not 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 this proposed rule (available via the internet on the CMS website), which illustrate the proposed CY 2019 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, 2018, or WAC, AWP, or mean unit cost from CY 2017 claims data and updated cost report information available for this proposed rule. In general, these published payment rates are not the same as the actual January 2019 payment rates. This is because payment rates for drugs and biologicals with ASP information for January 2019 will be determined through the standard quarterly process where ASP data submitted by manufacturers for the third quarter of CY 2018 (July 1, 2018 through September 30, 2018) will be used to set the payment rates that are released for the quarter beginning in January 2019 near the end of December 2018. In addition, payment rates for drugs and biologicals in Addenda A and B to this proposed rule for which there was no ASP information available for April 2018 are based on mean unit cost in the available CY 2017 claims data. If ASP information becomes available for payment for the quarter beginning in January 2019, 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 this proposed rule (reflecting April 2018 ASP data) that do not have ASP information available for the quarter beginning in January 2019. These drugs and biologicals would then be paid based on mean unit cost data derived from CY 2017 hospital claims. Therefore, the proposed payment rates listed in Addenda A and B to this proposed rule are not for January 2019 payment purposes and are only illustrative of the proposed CY 2019 OPPS payment methodology using the most recently available information at the time of issuance of this 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 will be based on 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 will be eligible for pass-through payment and not just the first biosimilar biological product for a reference product. For CY 2019, we are proposing 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 ASP (of the biosimilar) minus 22.5 percent of the reference product (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's product ASP. Biosimilars that do not have pass-through payment status and are not acquired under the 340B Program also are paid their own ASP+6 percent of the reference product's ASP.

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 agree 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, and 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, for CY 2019, we are proposing 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 are proposing 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.

3. Proposed Payment Policy for Therapeutic Radiopharmaceuticals

For CY 2019, we are proposing 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 2019. Therefore, we are proposing for CY 2019 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 are proposing to rely on CY 2017 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 2019 payment rates for nonpass-through, separately payable therapeutic radiopharmaceuticals are included in Addenda A and B to this proposed rule (which are available via the internet on the CMS website).

4. Proposed Payment Adjustment Policy for Radioisotopes Derived From Non-Highly Enriched Uranium Sources

Radioisotopes are widely used in modern medical imaging, particularly for cardiac imaging and predominantly for the Medicare population. Some of the Technetium-99 (Tc-99m), the radioisotope used in the majority of such diagnostic imaging services, is produced in legacy reactors outside of the United States using highly enriched uranium (HEU).

The United States would like to eliminate domestic reliance on these reactors, and is promoting the conversion of all medical radioisotope production to non-HEU sources. Alternative methods for producing Tc-99m without HEU are technologically and economically viable, and conversion to such production has begun. We expect that this change in the supply source for the radioisotope used for modern medical imaging will introduce new costs into the payment system that are not accounted for in the historical claims data.

Therefore, beginning in CY 2013, we finalized a policy to provide an additional payment of $10 for the marginal cost for radioisotopes produced by non-HEU sources (77 FR 68323). Under this policy, hospitals report HCPCS code Q9969 (Tc-99m from non-highly enriched uranium source, full cost recovery add-on per study dose) once per dose along with any diagnostic scan or scans furnished using Tc-99m as long as the Tc-99m doses used can be certified by the hospital to be at least 95 percent derived from non-HEU sources (77 FR 68321).

We stated in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68321) that our expectation is that this additional payment will be needed for the duration of the industry's conversion to alternative methods to producing Tc-99m without HEU. We also stated that we would reassess, and propose if necessary, on an annual basis whether such an adjustment continued to be necessary and whether any changes to the adjustment were warranted (77 FR 68316). A 2016 report from the National Academies of Sciences, Engineering, and Medicine anticipates the conversion of Tc-99m production from non-HEU sources will not be complete until the end of 2019.[28] In addition, one of the manufacturers of Tc-99m generators supports continuing the payment adjustment at the current level because approximately 30 percent of Tc-99m continues to be produced from non-HEU sources. We also received comments from a trade group of nuclear pharmacies and cyclotron operators supporting an increase in the payment adjustment by the rate of inflation to cover more of the cost of Tc-99m from non-HEU sources.

We appreciate the feedback from stakeholders. However, we continue to believe that the current adjustment is sufficient for the reasons we have outlined in this and prior rulemakings. The information from stakeholders and the National Academies of Sciences, Engineering, and Medicine indicates that the conversion of the production of Tc-99m from non-HEU sources may take more than 1 year after CY 2018. Therefore, for CY 2019 and subsequent years, we are proposing to continue to provide an additional $10 payment for radioisotopes produced by non-HEU sources. We intend to reassess this payment policy once conversion to non-HEU sources is closer to completion or has been completed.

5. Proposed Payment for Blood Clotting Factors

For CY 2018, 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 (82 FR 59353). That is, for CY 2018, 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 2018 updated furnishing fee was $0.215 per unit.

For CY 2019, we are proposing to pay for blood clotting factors at ASP+6 percent, consistent with our proposed payment policy for other nonpass-through, separately payable drugs and biologicals, and to continue our policy for payment of the furnishing fee using an updated amount. Our policy to pay for a furnishing fee for blood clotting factors under the OPPS is consistent with the methodology applied in the physician's office and in the inpatient hospital setting. These methodologies were first articulated in the CY 2006 OPPS final rule with comment period (70 FR 68661) and later discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765). The proposed furnishing fee update is based on the percentage increase in the Consumer Price Index (CPI) for medical care for the 12-month period ending with June of the previous year. Because the Bureau of Labor Statistics releases the applicable CPI data after the PFS and OPPS/ASC proposed rules are published, we are not able to include the actual updated furnishing fee in the proposed rules. Therefore, in accordance with our policy, as finalized in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765), we are proposing to announce the actual figure for the percent change in the

[28] National Academies of Sciences, Engineering, and Medicine. 2016. Molybdenum-99 for Medical Imaging. Washington, DC: The National Academies Press. Available at: *https://doi.org/10.17226/23563.*

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.*

6. Proposed Payment for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals With HCPCS Codes But Without OPPS Hospital Claims Data

For CY 2019, we are proposing to continue to use the same payment policy as in CY 2018 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 2019 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 proposed rule, which is available via the internet on the CMS website.

7. CY 2019 Proposed 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 appropriately, reflect the resources and acquisition costs that these hospitals incur. We believed that such changes would allow Medicare beneficiaries (and the Medicare program) to pay less 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. Our goal is 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 (CAHs) 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 (SCHs), 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.

Another topic that has been 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 is 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 have since heard from stakeholders that there has been some confusion about this issue. We want to clarify that the 340B payment adjustment does apply 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.

Data limitations inhibit 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 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 CAHs 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 SCHs, 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''.

For CY 2019, we are proposing to continue the 340B Program policies that were implemented in CY 2018 with the exception of the way we are calculating payment for 340B-acquired biosimilars. We are proposing, 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 the 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 ''L'' or ''M'') and drugs with OPPS transitional pass-through payment status (assigned status indicator ''G''). As discussed in section V.A.2.c. of this proposed rule, we are proposing to pay nonpass-through biosimilars acquired under the 340B Program at ASP minus 22.5 percent of the biosimilar's ASP. We also are proposing 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 are proposing 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 are proposing for CY 2019 that rural sole community hospitals (SCHs), children's hospitals, and PPS-exempt cancer hospitals continue to be excepted from the 340B payment adjustment. We are proposing that these hospitals be required to report informational modifier ''TB'' for 340B-acquired drugs, and continue to be paid ASP+6 percent.

VI. Proposed 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 2019 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 2019. 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 2018 or beginning in CY 2019. The sum of the proposed CY 2019 pass-through spending estimates for these two groups of device categories equals the proposed total CY 2019 pass-through spending estimate for device categories with pass-through payment status. We base 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 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 this proposed rule, we are proposing 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 2019, we also are proposing 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 2019 for this group of items is $0, as discussed below, because we are proposing to pay for most nonpass-through separately payable drugs and biologicals under the CY 2019 OPPS at ASP+6 percent (with the exception of 340B-acquired separately payable drugs, for which we do not yet have sufficient data to estimate a share of total drug payments), and because we are proposing to pay for CY 2019 pass-through payment drugs and biologicals at ASP+6 percent, as we discuss in section V.A. of this proposed rule.

Furthermore, payment for certain drugs, specifically diagnostic radiopharmaceuticals and contrast agents without pass-through payment status, is packaged into payment for the associated procedures, and these products will not be separately paid. In addition, we policy-package all 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 this proposed rule. We are proposing 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 2019. Therefore, our proposed estimate of pass-through payment for policy-packaged drugs and biologicals with pass-through payment status approved prior to CY 2019 is not $0, as discussed below. In section V.A.5. of this 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 are proposing 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 are proposing 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 2019. 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 2018 or beginning in CY 2019. The sum of the CY 2019 pass-through spending estimates for these two groups of drugs and biologicals equals the total CY 2019 pass-through spending estimate for drugs and biologicals with pass-through payment status.

B. Proposed Estimate of Pass-Through Spending

We are proposing to set the applicable pass-through payment percentage limit at 2.0 percent of the total projected OPPS payments for CY 2019, consistent with section 1833(t)(6)(E)(ii)(II) of the Act and our OPPS policy from CY 2004 through CY 2018 (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 2019, there are no active categories for CY 2019. Because there are no active device categories for CY 2019, we are proposing an estimate for the first group of devices of $0. In estimating our proposed CY 2019 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 2019; additional device categories that we estimated could be approved for pass-through status subsequent to the development of the proposed rule and before January 1, 2019; and contingent projections for new device categories established in the second through fourth quarters of CY 2019. We are proposing 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 this proposed rule, the proposed estimate of CY 2019 pass-through spending for this second group of device categories is $10 million.

To estimate proposed CY 2019 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 CY 2019, we are proposing 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 2019 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 2019, 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 at ASP+6 percent, which is zero 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 are proposing to include in the CY 2019 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. For this proposed rule, using the proposed methodology described above, we calculated a CY 2019 proposed spending estimate for this first group of drugs and biologicals of approximately $61.5 million.

To estimate proposed CY 2019 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 this proposed rule were newly eligible for pass-through payment in CY 2019, additional drugs and biologicals that we estimated could be approved for pass-through status subsequent to the development of this proposed rule and before January 1, 2018, and projections for new drugs and biologicals that could be initially eligible for pass-through payment in the second through fourth quarters of CY 2019), we are proposing 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 2019 pass-through payment estimate. We also are proposing to consider the most recent OPPS experience in approving new pass-through drugs and biologicals. Using our proposed methodology for estimating CY 2019 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 $55.2 million.

In summary, in accordance with the methodology described earlier in this section, for this proposed rule, 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 2019 and those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2019 is approximately $126.7 million (approximately $10 million for device categories and approximately $116.7 million for drugs and biologicals) which represents 0.18 percent of total projected OPPS payments for CY 2019 (approximately $70 billion). Therefore, we estimate that pass-through spending in CY 2019 would not amount to 2.0 percent of total projected OPPS CY 2019 program spending.

VII. Proposed OPPS Payment for Hospital Outpatient Visits and Critical Care Services

As we did in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59373), for CY 2019, we are proposing 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 are proposing to continue our payment policy for critical care services for CY 2019. 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 this proposed rule, we are seeking public comments on any changes to these codes that we should consider for future rulemaking cycles. We continue to encourage those commenters to provide the data and analysis necessary to justify any suggested changes.

In section X.V. of this proposed rule, we are proposing 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 (MPFS)-equivalent payment rate for the hospital outpatient clinic visit (HCPCS code G0463) when it is furnished by excepted off-campus provider-based departments. For a full discussion of this proposal as well as the comment solicitation on potential methods to control for unnecessary increases in the volume of covered outpatient department services, we refer readers to section X.B. of this proposed rule.

VIII. Proposed 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. Because 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). Furthermore, 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 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 5 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 0172, 0173, 0175, and 0176, to 5851, 5852, 5861, and 5862, 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 implemented an 8-percent outlier cap for CMHCs to mitigate potential outlier billing vulnerabilities by limiting the impact of inflated CMHC charges on outlier payments. We will continue to monitor the trends in outlier payments

and consider policy adjustments as necessary.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59373 through 59381), 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 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.

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).

B. Proposed PHP APC Update for CY 2019

1. Proposed PHP APC Geometric Mean per Diem Costs

For CY 2019, in this CY 2019 OPPS/ASC proposed rule, we are proposing to continue 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. Specifically, we are proposing 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)). We are proposing to continue to calculate the geometric mean per diem costs for CY 2019 for APC 5853 for CMHCs using only CY 2017 CMHC claims data and the most recent CMHC cost data, and the CY 2019 geometric mean per diem costs for APC 5863 for hospital-based PHPs using only CY 2017 hospital-based PHP claims data and the most recent hospital cost data.

2. Development of the Proposed PHP APC Geometric Mean per Diem Costs

In this CY 2019 OPPS/ASC proposed rule, we are proposing that for CY 2019 and subsequent years, to follow 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 determine the PHP APCs' proposed geometric mean per diem costs and to calculate the proposed payment rates for APCs 5853 and 5863, incorporating the modifications made in our 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 proposed geometric mean per diem cost for hospital-based PHP APC 5863 would be based upon actual hospital-based PHP claims and costs for PHP service days providing 3 or more services. Similarly, the proposed geometric mean per diem cost for CMHC APC 5853 would be based upon actual CMHC claims and costs for CMHC service days providing 3 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 per diem costs, after applying the OPPS budget neutrality adjustments described in section II.A.4. of this proposed rule.

We are proposing to apply our established methodologies in developing the CY 2019 proposed 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 2019 proposed rule, prior to calculating the proposed geometric mean per diem cost for CMHC APC 5853, we prepared the data by first applying trims and data exclusions, and assessing CCRs as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70463 through 70465), so that ratesetting 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 exclude any data from a CMHC for ratesetting purposes when the CMHC's geometric mean cost per day is more than ±2 standard deviations from the geometric mean cost per day for all CMHCs. By applying this trim for CY 2019 ratesetting, in this proposed rule, we excluded 4 CMHCs with geometric mean costs per day below the trim's lower limit of $53.33 and 4 CMHCs with geometric mean costs per day above the trim's upper limit of $274.43 from the proposed ratesetting for CY 2019. This standard deviation trim removed 8 providers from the ratesetting whose data would have skewed the calculation of the proposed geometric mean per diem costs for CMHCs.

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 2019 proposed rule ratesetting, no CMHCs were missing wage index data for all of their service days. Therefore, we did not exclude any CMHCs due to the lack of wage index data.

In addition to our trims and data exclusions, before determining the proposed 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 1 to the statewide hospital ancillary CCR (80 FR 70457). For this CY 2019 proposed rule ratesetting, we identified 3 CMHCs that had CCRs greater than 1. These CMHCs' CCRs were 1.053, 1.009, and 1.025, and each was defaulted to its appropriate statewide hospital ancillary CCR for CY 2019 ratesetting purposes.

In summary, these data preparation steps adjusted the CCR for 3 CMHCs by defaulting to the appropriate statewide hospital ancillary CCR and excluded 8 CMHCs, resulting in the inclusion of a total of 36 CMHCs (44 total—8 excluded) in our CY 2019 proposed rule ratesetting modeling. The trims removed 645 CMHC claims out of a total of 13,152 CMHC claims, resulting in 12,507 CMHC claims used for ratesetting purposes. We believe that excluding providers with extremely low or high geometric mean costs per day or extremely low or high CCRs protects CMHCs from having that data inappropriately skew the calculation of the proposed CMHC APC geometric mean per diem cost. Moreover, we believe that these trims, exclusions, and adjustments help prevent inappropriate fluctuations in the proposed PHP APC geometric mean per diem payment rates.

After applying all of the above 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 the proposed PHP APC geometric mean per diem cost.[29]

[29] Each revenue code on the CMHC claim must have a HCPCS code and charge associated with it.

The proposed CY 2019 geometric mean per diem cost for all CMHCs for providing 3 or more services per day (CMHC PHP APC 5853) is $119.51.

b. Hospital-Based PHP Data Preparation: Data Trims and Exclusions

For this CY 2019 proposed rule, we followed a data preparation process for hospital-based PHP providers that is similar to that used for CMHCs by applying trims and data exclusions as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70463 through 70465) so that our ratesetting is not skewed by providers with extreme data. Before any trimming or exclusions were applied, there were 394 hospital-based PHP providers in the CY 2017 PHP claims data used in this CY 2019 OPPS/ASC proposed rule.

For hospital-based PHP providers, we applied a trim on hospital service days when the CCR was greater than 5 at the cost center level. This trim removed hospital-based PHP service days that use a CCR greater than 5 to calculate costs for at least one of their component services. Unlike the ±2 standard deviation trim, which excluded CMHC providers that failed the trim, the CCR greater than 5 trim excluded any hospital-based PHP service day where any of the services provided on that day were associated with a CCR greater than 5 (in other words, 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 from our proposed rule ratesetting affected service days from 4 hospital-based PHP providers with CCRs ranging from 5.2024 to 13.1952. However, 100 percent of the service days for 3 of these affected hospital-based PHP providers had at least 1 service associated with a CCR greater than 5, so the trim removed these 3 providers entirely from our proposed rule ratesetting. The fourth provider remained in the ratesetting data, but with affected service days trimmed out. In addition, 16 hospital-based PHPs reported zero daily costs and, therefore, were removed for having no days with PHP payment; no hospital-based PHPs were removed for missing wage index data; and 1 hospital-based PHP was removed by the OPPS ±3 standard deviation trim on costs per day.

Therefore, we excluded 20 hospital-based PHP providers [(3 with CCRs greater than 5) + (16 with zero daily costs) + (1 after applying the ±3 standard deviation trim)], resulting in 374 (394 total—20 excluded) hospital-based PHP providers in the data used for proposed rule ratesetting. In addition, 5 hospital-based PHP providers were defaulted to using their overall hospital ancillary CCRs due to outlier cost center CCR values, which ranged from 0.0331 to 72.7320. After completing these data preparation steps, we calculated the proposed CY 2019 geometric mean per diem cost for hospital-based PHP APC 5863 for hospital-based PHP 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) to calculate the geometric mean per diem cost.[30] The proposed CY 2019 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 $220.52.

The proposed CY 2019 PHP APC geometric mean per diem costs for CMHC PHP APC 5853 are $119.51 and for hospital-based PHP APC 5863 are $220.52, as stated above and shown in Table 25. The proposed PHP APCs payment rates, which are derived from these proposed PHP APCs geometric mean per diem costs, are included in Addendum A to this proposed rule (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*).[31]

TABLE 25—CY 2019 PROPOSED PHP APC GEOMETRIC MEAN PER DIEM COSTS

CY 2019 APC	Group title	Proposed PHP APC geometric mean per diem costs
5853	Partial Hospitalization (3 or more services per day) for CMHCs	$119.51
5863	Partial Hospitalization (3 or more services per day) for hospital-based PHPs	220.52

We multiply each claim service line's charges by the CMHC's overall CCR (or statewide ancillary 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 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 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.

[30] 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; that CCR is determined by using the OPPS 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 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 geometric mean per diem cost for hospital-based PHP APC 5863.

[31] As discussed in section II.A. of this CY 2019 OPPS/ASC proposed rule, OPPS APC geometric mean per diem costs (including PHP APC geometric mean per diem costs) are divided by the geometric mean per diem costs for APC 5012 (Clinic Visits and Related Services) to calculate each PHP APC's unscaled relative payment weight. An unscaled relative payment weight is one that is not yet adjusted for budget neutrality. Budget neutrality is required under section 1833(t)(9)(B) of the Act, and ensures that the estimated aggregate weight under the OPPS for a calendar year is neither greater than nor less than the estimated aggregate weight that would have been made without the changes. To adjust for budget neutrality (that is, to scale the weights), we compare the estimated aggregated weight using the scaled relative payment weights from the previous calendar year at issue. We refer readers to the ratesetting procedures described in Part 2 of the OPPS Claims Accounting narrative and in section II. of this proposed rule for more information on scaling the weights, and for details on the final steps of the process that lead to 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.*

3. Proposed Changes to the Revenue-Code-to-Cost Center Crosswalk

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79691), we received public comments identifying an issue that may have contributed to a decreased PHP median [sic] cost for hospital-based PHPs. The commenters noted that the lack of a required standardized PHP cost center on the Medicare cost report may be creating some cost-finding nuances in the cost report itself—that hospital-based PHP costs are combined with the costs of less expensive non-PHP outpatient mental health services during CCR calculation, thus ''diluting'' the CCR values. We agreed with the commenters that, if PHP costs are combined with other less intensive outpatient mental health treatment costs in the same cost center, the CCR values could be diluted, leading to lower geometric mean per diem costs being calculated. We stated in response that we would consider adding a cost center to the hospital cost report for PHP costs only.

On November 17, 2017, in Transmittal No. 12, we added a new cost center, ''Partial Hospitalization Program,'' on Line 93.99 of Worksheet A (Line 93.99 is also displayed on Worksheets B, Parts I and II, B–1; and C, Parts I and II) for hospital-based PHPs, for cost reporting periods ending on or after August 31, 2017 (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R12P240.pdf*). On January 30, 2018, in Transmittal No. 13, we changed the implementation date from cost reporting periods ending on or after August 31, 2017, to cost reporting periods ending on or after September 30, 2017 (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R12P240.pdf*). The instructions for this new PHP cost center (Line 93.99) indicate that effective for cost reporting periods ending on or after September 30, 2017, the provider is to enter the costs of providing hospital-based partial hospitalization program (PHP) services as defined in section 1861(ff) of the Act. Therefore, this cost center is to include all costs associated with providing PHP services, as defined in the statute (for example, occupational therapy, individual and group therapy, among others). It should not include costs for non-PHP outpatient mental health services, such as costs from what providers refer to as ''Intensive Outpatient Programs.''

During current hospital-based-PHP ratesetting, costs are estimated by multiplying revenue code charges on the claim by the appropriate cost center-level CCR from the hospital cost report (80 FR 70465). Each PHP revenue code is associated with particular cost centers on the cost report (80 FR 70464). The appropriate cost center-level CCR is identified by using the OPPS Revenue-Code-to-Cost-Center crosswalk; the current crosswalk is discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59228) and is available on the CMS website at: *https://www.cms.gov/apps/ama/license.asp?file=/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CMS–1678-FC-2018-OPPS-FR-Revenue-Code-to-Cost-Center-Crosswalk.zip.* The Revenue-Code-to-Cost-Center crosswalk identifies the primary, secondary (if any), and tertiary (if any) cost centers that are associated with each PHP revenue code, and which are the source for the CCRs used in PHP ratesetting. As discussed in the CY 2002 OPPS interim final rule (66 FR 59885), hospital-based PHP CCRs are assessed by applying the existing OPPS ±3 standard deviation trim to hospital-based PHP CCRs within each cost center and to the overall hospital ancillary CCR. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70464), we stated that, if the primary cost center has no CCR or if it fails the ±3 standard deviation trim, the ratesetting system will look for a CCR in the secondary cost center. If the secondary cost center has no CCR or if it fails the ±3 standard deviation trim, the system will move to the tertiary cost center to look for a CCR. If the tertiary cost center has no CCR or if it fails the ±3 standard deviation trim, the ratesetting system will default to using the hospital's overall ancillary CCR. If the hospital's overall ancillary CCR fails the ±3 standard deviation trim, we exclude the hospital from ratesetting. While the hierarchy requires a primary cost center to be associated with a given revenue code, it is optional for there to be secondary or tertiary cost centers.

With the new PHP cost center, the crosswalk must be updated for hospital-based PHP cost estimation to correctly match hospital-based PHP revenue code charges with the PHP cost center CCR for future ratesetting. However, because the PHP-allowable revenue codes are also used for reporting non-PHP mental health services, we could not designate the PHP cost center as the primary cost center in the existing OPPS Revenue-Code-to-Cost-Center crosswalk. Therefore, we are proposing to create a separate PHP-only Revenue-Code-to-Cost-Center crosswalk for use in CY 2019 and subsequent years, which would provide a more accurate and operationally simpler method of matching hospital-based PHP charges to the correct hospital-based PHP cost center CCR without affecting non-PHP ratesetting. We note that, because CMHCs have their own cost reports, we use each CMHC's overall CCR in estimating costs for PHP ratesetting (80 FR 70463 and 70464). As such, CMHCs do not have a crosswalk and, therefore, this proposal to create a PHP-only crosswalk does not apply to CMHCs. Therefore, we are proposing that, for CY 2019 and subsequent years, hospital-based PHPs would follow a new Revenue-Code-to-Cost-Center crosswalk that only applies to hospital-based PHPs. We are proposing that this new PHP-only Revenue-Code-to-Cost-Center crosswalk would be comprised of the existing PHP allowable revenue codes and would map each of those PHP-allowable revenue codes to the new PHP cost center Line 93.99 as the primary cost center source for the CCR. We also are proposing to designate as the new secondary cost center the cost center that is currently listed as the existing primary cost center, and to designate as the new tertiary cost center the cost center that is listed as the existing secondary cost center.

In addition, we are proposing one exception to this policy for the mapping for revenue code 0904, which is the only PHP-allowable revenue code in the existing crosswalk with a tertiary cost center source for the CCR. We are proposing that for revenue code 0904, the secondary cost center for CY 2019 and subsequent years would be the existing secondary cost center 3550 (''Psychiatric/Psychological Services''). Similarly, we are proposing that for revenue code 0904, the tertiary cost center for CY 2019 and subsequent years would be existing tertiary cost center 9000 (''Clinic''). We considered expanding the Revenue-Code-to-Cost-Center crosswalk hierarchy to add a 4th or quaternary level to the hierarchy, before the system would default to the overall hospital ancillary CCR. However, we evaluated the usage of the current hierarchy for revenue code 0904 for the CY 2017, CY 2018, and CY 2019 PHP ratesetting modelling, and found that expanding the hierarchy would not be necessary. Our analysis showed that the existing primary cost center 3580 (''Recreational Therapy'') for revenue code 0904 had not been used during any of the past 3 years.

Our current and proposed PHP-only Revenue-Code-to-Cost-Center Crosswalks are shown in Table 26 below.

TABLE 26—CURRENT AND PROPOSED PHP-ONLY REVENUE—CODE-TO-COST-CENTER CROSSWALKS

PHP allowable revenue code	Current hierarchy (applicable in CY 2018)			Proposed new PHP-only hierarchy (applicable in CY 2019 and beyond)		
	Primary cost center source for CCR	Secondary cost center source for CCR	Tertiary cost center source for CCR	Primary cost center source for CCR	Secondary cost center source for CCR	Tertiary cost center source for CCR
0430	6700 Occupational Therapy.			9399 (PHP)	6700 Occupational Therapy.	
0431	6700 Occupational Therapy.			9399 (PHP)	6700 Occupational Therapy.	
0432	6700 Occupational Therapy.			9399 (PHP)	6700 Occupational Therapy.	
0433	6700 Occupational Therapy.			9399 (PHP)	6700 Occupational Therapy.	
0434	6700 Occupational Therapy.			9399 (PHP)	6700 Occupational Therapy.	
0435	RESERVED.					
0436	RESERVED.					
0437	RESERVED.					
0438	RESERVED.					
0439	6700 Occupational Therapy.			9399 (PHP)	6700 Occupational Therapy.	
0900	3550 (Psychiatric/Psychological Services.	9000 (Clinic)		9399 (PHP)	3550 (Psychiatric/Psychological Services).	9000 (Clinic).
0904	3580 (Recreational Therapy).	3550 (Psychiatric/Psychological Services.	9000 (Clinic)	9399 (PHP)	3550 (Psychiatric/Psychological Services).	9000 (Clinic).
0914	3550 (Psychiatric/Psychological Services.	9000 (Clinic)		9399 (PHP)	3550 (Psychiatric/Psychological Services).	9000 (Clinic).
0915	3550 (Psychiatric/Psychological Services.	9000 (Clinic)		9399 (PHP)	3550 (Psychiatric/Psychological Services).	9000 (Clinic).
0916	3550 (Psychiatric/Psychological Services.	9000 (Clinic)		9399 (PHP)	3550 (Psychiatric/Psychological Services).	9000 (Clinic).
0918	3550 (Psychiatric/Psychological Services.	9000 (Clinic)		9399 (PHP)	3550 (Psychiatric/Psychological Services).	9000 (Clinic).
0942	9000 (Clinic)			9399 (PHP)	9000 (Clinic)	

4. PHP Service Utilization Updates

While we are not proposing any changes to this policy, we will continue to monitor the provision of days with only 3 services. 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 2017 claims data used for this CY 2019 proposed rule revealed some changes in the provision of individual therapy compared to CY 2016 and CY 2015 claims data as shown in the table below.

TABLE 27—PROVISION OF INDIVIDUAL THERAPY, BY PROVIDER TYPE AND CLAIMS YEAR

	Percent of days with 3 services only	Percent of days with 4 or more services
CMHCs:		
CY 2015 Claims	7.9	4.4
CY 2016 Claims	8.5	5.0
CY 2017 Claims	4.8	4.2
Hospital-based PHPs:		
CY 2015 Claims	4.0	6.2
CY 2016 Claims	4.7	5.8
CY 2017 Claims	4.1	12.2

As shown in Table 27, CMHCs have decreased the provision of individual therapy, based on the CY 2017 claims used for this proposed rule. In contrast, the CY 2017 claims data show that hospital-based PHPs have greatly increased the provision of individual therapy.

In the CY 2018 OPPS/ASC proposed rule and final rule with comment period (82 FR 33640 and 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 4 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 APC 5853 and APC 5863 for providing 3 or more PHP services per day, we are continuing to monitor utilization of days with only 3 PHP services. Table 28 below shows the utilization findings based on the most recent claims data.

TABLE 28—PERCENTAGE OF PHP DAYS BY SERVICE UNIT FREQUENCY

	CY 2015 (%)	CY 2016 * (%)	CY 2017 * (%)	% Change ** (%)
CMHCs:				
Percent of Days with 3 services	4.7	4.8	4.8	0.0
Percent of Days with 4 services	62.9	70.3	76.3	8.5
Percent of Days with 5 or more services	32.4	24.9	18.9	−24.1
Hospital-based PHPs:				
Percent of Days with 3 services	12.4	10.95	9.3	−14.7
Percent of Days with 4 services	69.8	64.9	56.1	−13.6
Percent of Days with 5 or more services	17.8	24.1	34.6	43.6

* May not sum to 100 percent by provider type due to rounding.
** (CY 2017–CY 2016)/CY 2016.

As shown in Table 28, the CY 2017 claims data used for this proposed rule showed that PHPs maintained an appropriately low utilization of 3 service days compared to CY 2016 and CY 2015. Compared to CY 2016, hospital-based PHPs have provided fewer days with 3 services only, fewer days with 4 services only, and more days with 5 or more services. Compared to CY 2016, CMHCs have remained steady in providing an appropriately low level of 3 service days, increased their provision of days with 4 services, but have decreased their provision of days with 5 or more services.

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 in place for providing 3 or more services per day to CMHCs and hospital-based PHPs, respectively. The CY 2017 data are the first year of claims data to reflect the change to the single-tier PHP APCs, and the level of utilization of days with 3 services only indicates providers are not reducing care for this patient population by providing more days with only 3 services.

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).

C. Outlier Policy for CMHCs

In this proposed rule, for CY 2019, we are proposing 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 below. We refer readers to section II.G. of this proposed rule for our general policies for hospital outpatient outlier payments.

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). For CMHCs, we set our projected target for aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS (82 FR 59267). 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 below. As previously stated, we are proposing to continue to calculate the CMHC outlier percentage according to previously established policies, and we are not proposing any changes to our current methodology for calculating the CMHC outlier percentage for CY 2019. To calculate the CMHC outlier percentage, we follow three steps:

- *Step 1:* We multiply 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 estimate 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 proposed rule). That threshold is determined by multiplying the provider's estimated paid days by 3.4 times the CMHC PHP APC payment rate. If the provider's costs exceed the threshold, we multiply that excess by 50 percent, as described in section VIII.C.3. of this proposed rule, to determine the estimated outlier payments for that provider. CMHC outlier payments are capped at 8 percent of the provider's estimated total per diem payments (including the beneficiary's copayment), as described in section VIII.C.5. of this proposed rule, so any provider's costs that exceed the CMHC outlier cap would have its payments adjusted downward. After accounting for the CMHC outlier cap, we sum 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 > 0, then (A × 0.50) = Estimated CMHC Outlier Payment (before cap) = B. If B > (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 determine 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 2018, we designated approximately 0.03 percent of that estimated 1.0 percent hospital outpatient outlier threshold for CMHCs (82 FR 59381), based on this methodology. In this proposed rule, we are proposing to continue to use the same methodology for CY 2019. Therefore, based on our CY 2019 payment estimates, CMHCs are projected to receive 0.02 percent of total hospital outpatient payments in CY 2019, excluding outlier payments. We are proposing 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 above.

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). This cutoff point is sometimes called a multiplier threshold (70 FR 68550). For CY 2018, the highest CMHC PHP APC payment rate is the payment rate for CMHC PHP APC 5853. In addition, in 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))].

In this proposed rule, for CY 2019, in accordance with our existing policy, we are proposing 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 2019, if a CMHC's cost for partial hospitalization services paid under CMHC PHP APC 5853 exceeds 3.4 times the proposed payment rate for CMHC APC 5853, the outlier payment would be calculated as [0.50 × (CMHC Cost − (3.4 × APC 5853 rate))].

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. The main vulnerability in the OPPS outlier payment system is the time lag between the update of the CCRs that are based on the latest settled cost report and the current charges that creates the potential for hospitals and CMHCs to set their own charges to exploit the delay in calculating new CCRs. 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.

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*).

In this proposed rule, we are proposing to continue these policies for CY 2019.

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, 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 2018, we continued this policy in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59381).

In this proposed rule, we are proposing to continue this policy for CY 2019, such that the CMHC outlier payment cap would be 8 percent of the CMHC's total per diem payments.

6. Fixed-Dollar Threshold

Finally, 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).

In this proposed rule, we are proposing to continue this policy for CY 2019.

IX. Proposed Procedures That Would 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 would be paid by Medicare in CY 2019 as inpatient only procedures is included as Addendum E to this proposed rule (which is available via the internet on the CMS website).

B. Proposed Changes to the Inpatient Only (IPO) List

1. Methodology for Identifying Appropriate Changes to IPO List

In this proposed rule, for CY 2019, we are proposing 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:

1. Most outpatient departments are equipped to provide the services to the Medicare population.

2. The simplest procedure described by the code may be performed in most outpatient departments.

3. The procedure is related to codes that we have already removed from the IPO list.

4. A determination is made that the procedure is being performed in numerous hospitals on an outpatient basis.

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.

Using the above-listed criteria, for the CY 2019 OPPS, we have identified two procedures described by the following codes that we are proposing to remove from the IPO list for CY 2019: CPT code 31241 (Nasal/sinus endoscopy, surgical; with ligation of sphenopalatine artery) and CPT code 01402 (Anesthesia for open or surgical arthroscopic procedures on knee joint; total knee arthroplasty). We also are proposing to add to the IPO list for CY 2019 the procedure described by HCPCS code C9606 (Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel). The procedures that we are proposing to remove from the IPO list for CY 2019 and subsequent years, including the HCPCS codes, long descriptors, and the proposed CY 2019 payment indicators, are displayed in Table 29 of this proposed rule.

As noted earlier, we are proposing to remove the procedure described by CPT code 31241 from the IPO list for CY 2019. After reviewing the clinical characteristics of the procedure described by CPT code 31241 and consulting with stakeholders and our clinical advisors regarding this procedure, we believe that this procedure meets criterion 3—the procedure is related to codes that we have already removed from the IPO list. We are proposing that the procedure described by CPT code 31241 be assigned to C–APC 5153 (Level 3 Airway Endoscopy) with a status indicator of ''J1''. We are seeking comment on whether the public believes that the procedure described by CPT code 31241 meets criterion 3 and whether the procedure meets any of the other five criteria for removal from the IPO list.

We also are proposing to remove the procedure described by CPT code 01402 from the IPO list. After reviewing the clinical characteristics of the procedure described by CPT code 01402, we believe that this procedure meets criteria 3 and 4. This procedure is typically billed with the procedure described by CPT code 27447 (Arthroplasty, knee, condyle and plateau; medical and lateral compartments with or without patella resurfacing (total knee arthroplasty)), which was removed from the IPO list for CY 2018 (82 FR 52526). We are seeking public comment on whether the procedure described by CPT code 01402 meets criteria 3 and 4 and whether the procedure meets any of the other five criteria for removal from the IPO list.

In addition, we are proposing to add the procedure described by HCPCS code C9606 (Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when

performed, single vessel) to the IPO list for CY 2019. The IPO list specifies those procedures and services for which the hospital will be paid only when the procedures are provided in the inpatient setting because of the nature of the procedure, the underlying physical condition of the patient, or the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged (76 FR 74353). After evaluating the procedure described by HCPCS code C9606 against the criteria described above, we believe that the procedure should be added to the IPO list because this procedure is performed during acute myocardial infarction and it is similar to the procedure described by CPT code 92941 (Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of intracoronary stent, artherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel), which was added to the IPO list for CY 2018 (82 FR 52526). We are seeking public comment on whether the procedure described by HCPCS code C9606 should be added to the IPO list for CY 2019.

2. Solicitation of Public Comments on the Potential Removal of Procedure Described by CPT Code 0266T From the IPO List

CPT code 0266T describes the 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). The procedure described by CPT code 0266T has been included on the IPO list since the procedure code became effective in CY 2011.

There are several codes that describe procedures that are similar to the procedure described by CPT code 0266T that are not on the IPO list, including: CPT code 0267T (Implantation or replacement of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed)) and CPT code 0268T (Implantation or replacement of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)). The device that is billed with these two procedures has been granted a Category B Investigational Device Exemption (IDE) from FDA.[32] Currently, there is limited information available to determine the typical site of service and the ability for the procedure to be safely performed in the outpatient setting. At this time, we do not believe that we have adequate information to determine whether the procedure described by CPT code 0266T should be removed from the IPO list. Therefore, we are seeking public comments on the removal of the procedure described by CPT code 0266T from the IPO list. Specifically, we are seeking public comments on whether the procedure described by CPT code 0266T meets any of the criteria to be removed from the IPO list and the APC assignment and status indicator for this code.

TABLE 29—PROPOSED CHANGES TO THE INPATIENT ONLY LIST FOR CY 2019

CY 2019 CPT code	CY 2019 long descriptor	Proposed action	Proposed CY 2019 OPPS APC assignment	Proposed CY 2019 OPPS status indicator
31241	Nasal/sinus endoscopy, surgical; with ligation of sphenopalatine artery	Remove from IPO list.	5153	J1
01402	Anesthesia for open or surgical arthroscopic procedures on knee joint; total knee arthroplasty.	Remove from IPO list.	N/A	N
C9606	Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel.	Add to IPO list	N/A	C

The complete list of codes (the IPO list) that are proposed to be placed on the IPO list for CY 2019 are included as Addendum E to this proposed rule (which is available via the internet on the CMS website).

X. Proposed Nonrecurring Policy Changes

A. Collecting Data on Services Furnished in Off-Campus Provider-Based Emergency Departments

The June 2017 Report to Congress [33] by the Medicare Payment Advisory Commission (MedPAC) states that, in recent years, there has been significant growth in the number of health care facilities located apart from hospitals that are devoted primarily to emergency department services. This includes both off-campus provider-based emergency departments that are eligible for payment under the OPPS and independent freestanding emergency departments not affiliated with a hospital that are not eligible for payment under the OPPS. Since 2010, we have observed a noticeable increase in the number of hospital outpatient emergency department visits furnished under the OPPS. MedPAC and other entities have expressed concern that services may be shifting to the higher acuity and higher cost emergency department setting due to: (1) Higher payment rates for services performed in off-campus provider-based emergency departments compared to similar services provided in other settings (that is, physician offices or urgent care clinics); and (2) the exemption for services provided in an emergency department included under section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–25), whereby all items and services (emergency and nonemergency) furnished in an emergency department are excepted from the payment implications of section 603, as long as the department maintains its status as an emergency department under the regulation at 42 CFR 489.24(b).

MedPAC and other entities are concerned that these payment

[32] Available at: *https://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies.html.*

[33] Available at: *http://www/medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf.*

incentives may be a key contributing factor to the growth in the number of emergency departments located off-campus from a hospital. MedPAC recommended in its March 2017 [34] and June 2017 Reports to Congress that CMS require hospitals to append a modifier to claims for all services furnished in off-campus provider-based emergency departments, so that CMS can track the growth of OPPS services provided in this setting.

In order to participate in Medicare as a hospital, the facility must meet the statutory definition of a hospital at section 1861(e) of the Act, which requires a facility to be primarily engaged in providing care and services to inpatients. In addition, 42 CFR 482.55 requires hospital emergency department services (to include off-campus provider-based emergency departments) to be fully integrated with departments and services of the hospital. The integration must be such that the hospital can immediately make available the full extent of its patient care resources to assess and furnish appropriate care for an emergency patient. Such services would include, but are not limited to, surgical services, laboratory services, and radiology services, among others. The emergency department must also be integrated with inpatient services, which means the hospital must have a sufficient number of inpatient beds and nursing units to support the volume of emergency department patients that could require inpatient services. The provision of services, equipment, personnel and resources of other hospital departments and services to emergency department patients must be within timeframes that protect the health and safety of patients and is within acceptable standards of practice.

We agree with MedPAC's recommendation and believe we need to develop data to assess the extent to which OPPS services are shifting to off-campus provider-based emergency departments. Therefore, we are announcing in this proposed rule that we are implementing through the subregulatory HCPCS modifier process a new modifier for this purpose effective beginning January 1, 2019.

We will create a HCPCS modifier (ER—Items and services furnished by a provider-based off-campus emergency department) that is to be reported with every claim line for outpatient hospital services furnished in an off-campus provider-based emergency department. The modifier would be reported on the UB–04 form (CMS Form 1450) for hospital outpatient services. Critical access hospitals (CAHs) would not be required to report this modifier.

B. Proposal and Comment Solicitation on Method To Control for Unnecessary Increases in the Volume of Outpatient Services

When the Medicare program was first implemented, payment for hospital services (inpatient and outpatient) was based on hospital-specific reasonable costs attributable to furnishing services to Medicare beneficiaries. Although payment for most Medicare hospital inpatient services became subject to a prospective payment system (PPS) under section 1886(d) of the Act in 1983, Medicare hospital outpatient services continued to be paid based on hospital-specific costs. This methodology for payment provided little incentive for hospitals to furnish such outpatient services efficiently and in a cost effective manner. At the same time, advances in medical technology and changes in practice patterns were bringing about a shift in the site of medical care from the hospital inpatient setting to the hospital outpatient setting.

In the Omnibus Budget Reconciliation Act of 1986 (OBRA 1986) (Pub. L. 99–509), the Congress paved the way for development of a PPS for hospital outpatient services. Section 9343(g) of OBRA 1986 mandated that fiscal intermediaries require hospitals to report claims for services under the Healthcare Common Procedure Coding System (HCPCS). Section 9343(c) of OBRA 1986 extended the prohibition against unbundling of hospital services under section 1862(a)(14) of the Act to include outpatient services as well as inpatient services. The codes under the HCPCS enabled us to determine which specific procedures and services were billed, while the extension of the prohibition against unbundling ensured that all nonphysician services provided to hospital outpatients were reported on hospital bills and captured in the hospital outpatient data that were used to develop an outpatient PPS.

The brisk increase in hospital outpatient services further led to an interest in creating payment incentives to promote more efficient delivery of hospital outpatient services through a Medicare outpatient PPS. Section 9343(f) of OBRA 1986 and section 4151(b)(2) of the Omnibus Budget Reconciliation Act of 1990 (OBRA 1990) (Pub. L. 101–508) required that we develop a proposal to replace the existing hospital outpatient payment system with a PPS and submit a report to the Congress on a new proposed system. The statutory framework for the Outpatient Prospective Payment System (OPPS) was established by section 4523 of the Balanced Budget Act (BBA) of 1997 (Pub. L. 105–33), which amended section 1833 of the Act by adding subsection (t), which establishes a PPS for hospital outpatient department services, and by section 201 of the Balanced Budget Reconciliation Act (BBRA) of 1999 (Pub. L. 106–113), which amended section 1833(t) of the Act to require outlier and transitional pass-through payments. At the onset of the OPPS, there was significant concern over observed increases in the volume of outpatient services and corresponding rapidly growing beneficiary coinsurance. Accordingly, most of the focus was on finding ways to address those issues.

When section 4523 of the BBA of 1997 established the OPPS, it included specific authority under section 1833(t)(2)(F) of the Act that requires the Secretary to develop a method for controlling unnecessary increases in the volume of covered outpatient department (OPD) services.[35] In the initial rule that proposed to implement the OPPS (63 FR 47585 through 47587), we discussed several possible approaches for controlling the volume of covered outpatient department services furnished in subsequent years, solicited comments on those options, and stated that the agency would propose an appropriate ''volume control'' mechanism for services furnished in CY 2001 and beyond after completing further analysis. For the CY 2000 OPPS, we proposed to implement a method that was similar to the one used under the Medicare Physician Fee Schedule (PFS) (known as the sustainable growth rate or ''SGR''), which would be triggered when expenditure targets, based on such factors as volume, intensity, and beneficiary enrollment, were exceeded (63 FR 47586 through 47587). However, as we discussed in the CY 2001 OPPS final rule (65 FR 18503) and the CY 2002 OPPS final rule (66 FR 59908), we delayed the implementation of the proposed volume control method as suggested by the ''President's Plan to Modernize and Strengthen Medicare for the 21st Century'' to give hospitals time to adjust to the OPPS and CMS time to continue to examine methods to control unnecessary increases in the volume of covered OPD services.

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66611 through 66612), we noted that we had

[34] Available at: *http://medpac.gov/docs/default-souce/reports/mar17_entirereport.pdf.*

[35] Available at: *https://www.ssa.gov/OP_Home/ssact/title18/1833.htm.*

significant concerns about the growth in program expenditures for hospital outpatient services, and that while the OPPS was developed in order to address some of those concerns, its implementation had not generally slowed that growth in expenditures. To address some of those concerns, we established a set of packaging policies beginning in the CY 2008 that would explicitly encourage efficiency in the provision of services in the hospital outpatient setting and potentially control future growth in the volume of OPPS services (72 FR 66612). Specifically, in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66580), we adopted a policy to package seven categories of items and services into the payment for the primary diagnostic or therapeutic modality to which we believe these items are typically ancillary or supportive.

Similarly, in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74925 through 74948), we expanded our packaging policies to include more categories of packaged items and services as part of a broader initiative to make the OPPS more like a prospective payment system and less like a per service fee schedule. Packaging can encourage hospitals to furnish services efficiently while also enabling hospitals to manage their resources with the maximum flexibility, thereby encouraging long-term cost containment, which is an essential component of a prospective payment system. While most of the packaging policies established in the CY 2014 OPPS focused on ancillary services that were part of a primary procedure, we also introduced the concept of comprehensive APCs (C–APCs) (78 FR 74861 through 74910), which were implemented beginning in the CY 2015 OPPS (79 FR 66798 through 66810). Comprehensive APCs package payment for adjunctive and secondary items, services, and procedures into the most costly primary procedure under the OPPS at the claim level.

While we have developed many payment policies with these goals in mind, growth in program expenditures for hospital outpatient services paid under the OPPS continues. As illustrated in Table 30 below, total spending has been growing at a rate of roughly 8 percent per year under the OPPS, and 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. We continue to be concerned with this rate of increase in program expenditures under the OPPS for several reasons. The OPPS was originally designed to manage Medicare spending growth. What was once a cost-based system was mandated by law to become a prospective payment system, which arguably should have slowed the increases in program spending. To the contrary, the OPPS has been the fastest growing sector of Medicare payments out of all payment systems under Medicare Parts A and B. Furthermore, we are concerned that the rate of growth suggests that payment incentives, rather than patient acuity or medical necessity, may be affecting site-of-service decision-making. This site-of-service selection has an impact on not only the Medicare program, but also on Medicare beneficiary out-of-pocket spending. Therefore, to the extent that there are lower-cost sites-of-service available, we believe that beneficiaries and the physicians treating them should have that choice and not be encouraged to receive or provide care in higher paid settings solely for financial reasons. For example, to provide for easier comparisons between hospital outpatient departments and ASCs, as previously discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59389), we also will make available a website that provides comparison information between the OPPS and ASC payment and copayment rates, as required under section 4011 of the 21st Century Cures Act (Pub. L. 114–255). Making this information available can help beneficiaries and their physicians determine the cost and appropriateness of receiving care at different sites of service. Although resources such as this website will help beneficiaries and physicians select a site of service, we do not believe this information alone is enough to control unnecessary volume increases. The growth in OPPS expenditures and the increase in the volume and intensity of hospital outpatient services are illustrated in Tables 30 and 31 below, respectively.

TABLE 30—GROWTH IN EXPENDITURES UNDER OPPS FROM CY 2010 THROUGH CY 2019 *

[In millions]

Calendar year (CY)	Incurred cost	Percent increase
CY 2010	$36,774	.....
CY 2011	39,781	8.2
CY 2012	43,154	8.5
CY 2013	46,462	7.7
CY 2014	52,425	12.8
CY 2015	56,274	7.3
CY 2016	59,896	6.4
CY 2017	64,770	8.1
CY 2018	69,642	7.5
CY 2019 (Estimated)	75,315	8.1

* Includes Medicare Part B Drug Expenditures.

TABLE 31—PERCENTAGE INCREASE IN VOLUME AND INTENSITY OF HOSPITAL OUTPATIENT SERVICES *

Calendar year (CY)	Percentage increase
CY 2011	3.7
CY 2012	5.1
CY 2013	5.5
CY 2014	8.0
CY 2015	3.5

TABLE 31—PERCENTAGE INCREASE IN VOLUME AND INTENSITY OF HOSPITAL OUTPATIENT SERVICES *—Continued

Calendar year (CY)	Percentage increase
CY 2016	6.5
CY 2017	5.8
CY 2018	5.4
CY 2019 (Estimated)	5.3

* Includes Medicare Part B Drug Expenditures.

As noted in its March 2018 Report to Congress, 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.[36] 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 unnecessary shift of services from (lower cost) physician offices to (higher cost) HOPDs''.[37] We would consider these shifts in the sites of service unnecessary if the beneficiary can safely receive the same services in a lower cost setting but instead receives care in a higher cost setting.

As noted in MedPAC's March 2017 Report to Congress, ''from 2014 to 2015, the use of outpatient services increased by 2.2 percent per Medicare FFS beneficiary. Over the decade ending in 2015, volume per beneficiary grew by 47 percent. One-third of the growth in outpatient volume from 2014 to 2015 was due to an increase in the number of evaluation and management (E&M) visits billed as outpatient services. This growth in part reflects hospitals purchasing freestanding physician practices and converting the billing from the Physician Fee Schedule to higher paying hospital outpatient department (HOPD) visits. The conversions shift market share from freestanding physician offices to HOPDs. From 2012 to 2015, hospital-based E&M visits per beneficiary grew by 22 percent, compared with a 1-percent decline in physician office-based visits.'' [38]

MedPAC has documented how the billing for these services has shifted from physician offices to higher-cost outpatient sites of care for several years. At the same time, MedPAC has repeated its recommendation that the difference in payment rates between hospital outpatient departments and physician offices should be reduced or eliminated. It specifically recommended in its 2012 Report to Congress that the payment rates for E&M visits provided in hospital outpatient departments be reduced so that total payment rates for these visits are the same, whether the service is provided in a hospital outpatient department or a physician office. In its 2014 Report to Congress, MedPAC recommended that Congress direct the Secretary to reduce or eliminate differences in payment rates between hospital outpatient departments and physician offices for selected APCs. Both of these recommendations were reiterated in MedPAC's March 2017 Report to Congress.

As previously noted, in addition to the concern that the difference in payment is leading to unnecessary increases in the volume of covered outpatient department services, we also are 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 freestanding physician offices. For example, MedPAC estimates that ''the Medicare program spent $1.0 billion more in 2009, $1.3 billion more in 2014, and $1.6 billion more in 2015 than it would have if payment rates for E&M office visits in HOPDs were the same as freestanding office rates. Relatedly, beneficiaries' cost-sharing was $260 million higher in 2009, $325 million higher in 2014, and $400 million higher in 2015 than it would have been because of the higher rates paid in HOPD settings.'' [39] We believe that this volume growth and the resulting increase in beneficiary cost-sharing is unnecessary because it appears to have been incentivized by the difference in payment for each setting rather than patient acuity. If there was not a difference in payment rates, we believe that we would not have seen the increase in beneficiaries' cost-sharing and the shift in site-of-service.

In the CY 2015 OPPS/ASC proposed rule (79 FR 41013), we stated that we continued to seek a better understanding of how the growing trend toward hospital acquisition of physicians' offices and subsequent treatment of those locations as off-campus provider-based departments (PBDs) of hospitals affects payments under the PFS and the OPPS, as well as beneficiary cost-sharing obligations. We noted that MedPAC continued to question the appropriateness of increased Medicare payment and beneficiary cost-sharing when physicians' offices become hospital outpatient departments and that MedPAC recommended that Medicare pay selected hospital outpatient services at PFS rates (MedPAC March 2012 and June 2013 Reports to Congress).

To understand how this trend was affecting Medicare, we explained that we needed information on the extent to which this shift was occurring. To that end, during the CY 2014 OPPS/ASC rulemaking cycle, we sought public comment regarding the best method for collecting information and data that would allow us to analyze the frequency, type, and payment for physicians' services and hospital outpatient services furnished in off-campus PBDs of hospitals (78 FR 75061 through 75062 and 78 FR 74427 through 74428). Based on our analysis of the public comments we received, we believed that the most efficient and equitable means of gathering this important information across two different payment systems would be to create a HCPCS modifier to be reported with every code for physicians' services and hospital outpatient services furnished in an off-campus PBD of a hospital on both the CMS–1500 claim form for physicians' services and the UB–04 form (CMS Form 1450 and OMB Control Number 0938–0997) for hospital outpatient services. We noted that a main provider may treat an off-campus facility as provider-based if certain requirements at 42 CFR 413.65 are satisfied, and we define a ''campus'' at 42 CFR 413.65(a)(2) to be the physical

[36] Available at: *http://www.medpac.gov/docs/default-source/reports/mar18_medpac_entirereport_sec.pdf?sfvrsn=0.*

[37] *http://www.medpac.gov/docs/default-source/reports/mar18_medpac_entirereport_sec.pdf?sfvrsn=0.*

[38] Available at: *http://www.medpac.gov/docs/default-source/reports/mar17_medpac_ch3.pdf?sfvrsn=0.*

[39] Ibid.

area immediately adjacent to the provider's main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by the CMS regional office, to be part of the provider's campus.

In 2015, the Congress took steps to address the higher Medicare payments for services furnished by certain off-campus provider-based departments (PBDs) that may be associated with hospital acquisition of physicians' offices through section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74), enacted on November 2, 2015. In the CY 2017 OPPS/ASC proposed rule, we discussed the provision of section 603 of the Bipartisan Budget Act of 2015, which amended section 1833(t) of the Act. For the full discussion of our initial implementation of this provision, we refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699 through 79719) and interim final rule with comment period (79720 through 79729).

Section 603 of the Bipartisan Budget Act of 2015 (Section 603) amended section 1833(t) of the Act by amending paragraph (1)(B) and adding a new paragraph (21). As a general matter, under sections 1833(t)(1)(B)(v) and (t)(21) of the Act, applicable items and services furnished by certain off-campus outpatient departments of a provider on or after January 1, 2017 are not considered covered OPD services as defined under section 1833(t)(1)(B) of the Act for purposes of payment under the OPPS and are instead paid ''under the applicable payment system'' under Medicare Part B if the requirements for such payment are otherwise met. We note that, in order to be considered part of a hospital, an off-campus department of a hospital must meet the provider-based criteria established under 42 CFR 413.65.

Section 603 amended section 1833(t)(1)(B) of the Act by adding a new clause (v), which excludes from the definition of ''covered OPD services'' applicable items and services (defined in paragraph (21)(A) of the section) that are furnished on or after January 1, 2017, by an off-campus PBD, as defined in paragraph (21)(B) of the section. Section 603 also added a new paragraph (21) to section 1833(t) of the Act, which defines the terms ''applicable items and services'' and ''off-campus outpatient department of a provider,'' requires the Secretary to make payments for such applicable items and services furnished by an off-campus PBD under an applicable payment system (other than the OPPS), provides that hospitals shall report on information as needed for implementation of the provision, and establishes a limitation on administrative and judicial review of the Secretary's determinations of applicable items and services, applicable payment system, whether a department meets the definition of an off-campus outpatient department of a provider, and information hospitals are required to report. In defining the term ''off-campus outpatient department of a provider,'' section 1833(t)(21)(B)(i) of the Act specifies that the term means a department of a provider (as defined at 42 CFR 413.65(a)(2) as that regulation was in effect on November 2, 2015, the date of enactment of Pub. L. 114–74) that is not located on the campus of such provider, or within the distance from a remote location of a hospital facility. Section 1833(t)(21)(B)(ii) of the Act excepts from the definition of ''off-campus outpatient department of a provider,'' for purposes of paragraphs (1)(B)(v) and (21)(B) of the section, an off-campus PBD that was billing under section 1833(t) of the Act with respect to covered OPD services furnished prior to the date of enactment of the Bipartisan Budget Act of 2015, that is, November 2, 2015. We note that the definition of ''applicable items and services'' specifically excludes items and services furnished by a dedicated emergency department as defined at 42 CFR 489.24(b) and the definition of ''off-campus outpatient department of a provider'' does not include PBDs located on the campus of a hospital or within the distance (described in the definition of campus at § 413.65(a)(2)) from a remote location of a hospital facility; the items and services furnished by these excepted off-campus PBDs on or after January 1, 2017 continued to be paid under the OPPS.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699 through 79720), we established a number of policies to implement section 603 of the Bipartisan Budget Act of 2015. Broadly, we: (1) Defined applicable items and services in accordance with section 1833(t)(21)(A) of the Act for purposes of determining whether such items and services are covered OPD services under section 1833(t)(1)(B)(v) of the Act or whether payment for such items and services will instead be made under the applicable payment system designated under section 1833(t)(21)(C) of the Act; (2) defined off-campus PBD for purposes of sections 1833(t)(1)(B)(v) and (t)(21) of the Act; and (3) established policies for payment for applicable items and services furnished by an off-campus PBD (nonexcepted items and services) under section 1833(t)(21)(C) of the Act. To do so, we finalized policies that define whether certain items and services furnished by a given off-campus PBD may be considered excepted and, thus, continue to be paid under the OPPS; established the requirements for the off-campus PBDs to maintain excepted status (both for the excepted off-campus PBDs and for the items and services furnished by such excepted off-campus PBDs); and described the applicable payment system for nonexcepted items and services (generally, the PFS).

As part of developing policies to implement the section 603 amendments to section 1833(t) of the Act, we solicited public comments on information collection requirements for implementing this provision in accordance with section 1833(t)(21)(D) of the Act (81 FR 45686; 81 FR 79709 through 79710). In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79719 and 79725), we created modifier ''PN'' to collect data for purposes of implementing section 603 but also to trigger payment under the newly adopted PFS rates for nonexcepted items and services.

While the changes required by the section 603 amendments to section 1833(t) of the Act address some of the concerns related to shifts in settings of care and overutilization in the hospital outpatient setting, the majority of hospital off-campus departments continue to receive full OPPS payment (including off-campus emergency departments and excepted off-campus departments of a hospital), which is often higher than the payment that would have been made if a similar service had been furnished in the physician office setting. Therefore, the current site-based payment creates an incentive for the misallocation of capital toward higher cost sites of care that could result in higher costs for providers, taxpayers, beneficiaries, and the Medicare program. Likewise, the differences in payment rates have unnecessarily shifted services away from the physician's office to the higher paying hospital outpatient department. We believe that the higher payment that is made under the OPPS, as compared to payment under the PFS, is likely to be incentivizing providers to furnish care in the hospital outpatient setting rather than the physician office setting. In 2012, Medicare was paying approximately 80 percent more for a 15-minute office visit in a hospital outpatient department than in a

freestanding physician office.[40] Under current policy, Medicare still pays more using the G-code for a clinic visit than it would under the PFS. In the CY 2017 OPPS/ASC interim final rule, we noted that the most frequently billed service with the ''PO'' modifier was described by HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient), which is paid under APC 5012 (Clinic Visits and Related Services); the total number of CY 2017 claim lines for this service was approximately 10.7 million as of May 2017. When services are furnished in the hospital outpatient setting, an additional payment for the professional services is generally made under the PFS using the ''facility'' rate. For example, in CY 2017, the OPPS payment rate for APC 5012, which is the APC to which the outpatient clinic visit code was assigned, was $106.56. The CY 2017 PFS ''facility'' payment rate for a Level 3 visit, a service that commonly corresponds to the OPPS clinic visit, was $77.88 for a new patient and $51.68 for an established patient.

However, when services are furnished in the physician office setting, only one payment is made—typically, the ''nonfacility'' rate under the PFS. The CY 2017 PFS nonfacility payment rates for a Level 3 visit, a commonly billed service under the PFS, was $109.46 for a new patient and $73.93 for an established patient. Therefore, the total Medicare Part B payment rate (for the hospital and professional service) for a new patient when the service was furnished in the hospital outpatient setting was $184.44 ($106.56 + $77.88) compared to $109.46 in the physician office setting, or for an established patient, $158.24 ($106.56 + $51.68) in the hospital outpatient setting compared to $73.93 in the physician office setting. Under these examples, the payment rate was approximately $75 to $85 more for the same service when furnished in the hospital outpatient setting instead of the physician office setting, 20 percent of which was the responsibility of the beneficiary.

We have heard that many off-campus departments converted from physicians' offices to hospital outpatient departments, without a change in either the physical location or a change in the acuity of the patients seen. 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 difference in payment for these services is a significant factor in the shift in services from the physician's office to the hospital outpatient department, thus unnecessarily increasing hospital outpatient department volume and Medicare program and beneficiary expenditures.

We consider the shift of services from the physician office to the hospital outpatient department unnecessary if the beneficiary can safely receive the same services in a lower cost setting but is instead receiving services in the higher paid setting due to payment incentives. We believe the increase in the volume of clinic visits 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 capping 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. In particular, we believe this method of capping payment will control unnecessary volume increases as manifested both in terms of numbers of covered outpatient department services furnished and costs of those services.

Therefore, given the unnecessary increases in the volume of clinic visits in hospital outpatient departments, for the CY 2019 OPPS, we are proposing to use our authority under section 1833(t)(2)(F) of the Act to apply 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) 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). Off-campus PBDs that are not excepted from section 603 (departments that bill the modifier ''PN'') already receive a PFS-equivalent payment rate for the clinic visit. In CY 2019, for an individual Medicare beneficiary, the standard unadjusted Medicare OPPS proposed payment for the clinic visit is approximately $116, with approximately $23 being the average copayment. The proposed PFS equivalent rate for Medicare payment for a clinic visit would be approximately $46 and the copayment would be approximately $9. This would save beneficiaries an average of $14 per visit. Under this proposal, an excepted off-campus PBD would continue to bill HCPCS code G0463 with the ''PO'' modifier in CY 2019, but the payment rate for services described by HCPCS code G0463 when billed with modifier ''PO'' would now be equivalent to the payment rate for services described by HCPCS code G0463 when billed with modifier ''PN''. For a discussion of the PFS relativity adjuster that will now also be used to pay for all outpatient clinic visits provided at all off-campus PBDs, we refer readers to the CY 2018 PFS final rule (82 FR 53023 through 53024), as well as the CY 2019 PFS proposed rule.

In addition, we are proposing to implement this proposed method in a non-budget neutral manner. Specifically, while section 1833(t)(9)(B) of the Act generally requires that changes made under the OPPS be made in a budget neutral manner, we note that this section does not apply to the volume control method under section 1833(t)(2)(F) of the Act. In particular, 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

[40] Available at: *http://www.medpac.gov/docs/default-source/reports/march-2012-report-to-the-congress-medicare-payment-policy.pdf.*

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 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.

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 the movement of the volume within the OPPS system in the aggregate, a concern similar to the one we discussed in the CY 2008 OPPS final rule with comment period (72 FR 66613). This estimated payment impact is displayed in Column 5 of Table 42—Estimated Impact of the Proposed Changes for the Hospital Outpatient Prospective Payment System in this proposed rule. An estimate that includes the effects of estimated changes in enrollment, utilization, and case-mix based on the FY 2019 President's budget approximates the estimated savings at $760 million, with $610 million of the savings accruing to Medicare, and $150 million saved by Medicare beneficiaries in the form of reduced copayments. 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 reallocate expenditures that are unnecessary within the OPPS, we believe that this method must be adopted in a non-budget neutral manner. The impact associated with this proposal is further described in section XXI. of this proposed rule.

While we are developing a method to systematically control for unnecessary increases in the volume of other hospital outpatient department services, we continue to recognize the importance of not impeding development or beneficiary access to new innovations. We are soliciting public comments on how to maintain access to new innovations while controlling for unnecessary increases in the volume of covered hospital OPD services.

In addition, we are soliciting public comments on how to expand the application of the Secretary's statutory authority under section 1833(t)(2)(F) of the Act to additional items and services paid under the OPPS that may represent unnecessary increases in OPD utilization. Therefore, we are seeking public comment on the following:

- How might Medicare define the terms ''unnecessary'' and ''increase'' for services (other than the clinic visit) that can be performed in multiple settings of care? Should the method to control for unnecessary increases in the volume of covered OPD services include consideration of factors such as enrollment, severity of illness, and patient demographics?
- While we are proposing to pay the PFS payment rate for clinic visits beginning in CY 2019, we also are interested in other methods to control for unnecessary increases in the volume of outpatient services. Prior authorization is a requirement that a health care provider obtain approval from the insurer prior to providing a given service in order for the insurer to cover the service. Private health insurance plans often require prior authorization for certain services. Should prior authorization be considered as a method for controlling overutilization of services?
- For what reasons might it ever be appropriate to pay a higher OPPS rate for services that can be performed in lower cost settings?
- Several private health plans use utilization management as a cost-containment strategy. How might Medicare use the authority at section 1833(t)(2)(F) of the Act to implement an evidence-based, clinical support process to assist physicians in evaluating the use of medical services based on medical necessity, appropriateness, and efficiency?

Could utilization management help reduce the overuse of inappropriate or unnecessary services?

- How should we account for providers that serve Medicare beneficiaries in provider shortage areas, which may include certain rural areas? With respect to rural providers, should there be exceptions from this policy, such as for providers who are at risk of hospital closure or that are sole community hospitals?
- What impact on beneficiaries and the health care market would such a method to control for unnecessary increases in the volume of covered OPD services have?
- What exceptions, if any, should be made if additional proposals to control for unnecessary increases in the volume of outpatient services are made?

C. Proposal To Apply the 340B Drug Payment Policy to Nonexcepted Off-Campus Departments of a Hospital

1. Historical Perspective

a. Section 603 of the Bipartisan Budget Act of 2015

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699), we discussed implementation of section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74), enacted on November 2, 2015, which amended section 1833(t) of the Act. Specifically, this provision amended section 1833(t) of the Act by amending paragraph (1)(B) and adding a new paragraph (21). As a general matter, under sections 1833(t)(1)(B)(v) and (t)(21) of the Act, applicable items and services furnished by certain off-campus outpatient departments of a provider on or after January 1, 2017 are not considered covered OPD services as defined under section 1833(t)(1)(B) of the Act for purposes of payment under the OPPS and will instead be paid ''under the applicable payment system'' under Medicare Part B if the requirements for such payment are otherwise met. We indicated that, in order to be considered part of a hospital, an off-campus department of a hospital must meet the provider-based criteria established under 42 CFR 413.65. Accordingly, we refer to an ''off-campus outpatient department of a provider,'' which is the term used in section 603 of the Bipartisan Budget Act of 2015, as an ''off-campus outpatient provider-based department'' or an ''off-campus PBD.'' For a detailed discussion of the legislative history and statutory authority related to payments under section 603 of the Bipartisan Budget Act of 2015, we refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699 through 79719) and interim final rule with comment period (81 FR 79720 through 79729).

b. Applicable Payment System

To implement the amendments made by section 603 of Public Law 114–74, we issued an interim final rule with comment period (81 FR 79720) which accompanied the CY 2017 OPPS/ASC final rule with comment period to establish the PFS as the ''applicable payment system'' that applies in most

cases, and we established payment rates under the PFS for those nonexcepted items and services furnished by nonexcepted off-campus PBDs. As we discussed in the CY 2017 OPPS/ASC interim final rule with comment period (81 FR 79718) and reiterated in the CY 2018 PFS final rule with comment period (82 FR 53028), payment for Medicare Part B drugs that would be separately payable under the OPPS (assigned a status indicator of ''K'') but are not payable under the OPPS because they are furnished by nonexcepted off-campus PBDs is made in accordance with section 1847A of the Act (generally, at a rate of ASP plus 6 percent), consistent with Part B drug payment policy for items or services furnished in the physician office (nonfacility) setting. We did not propose or make an adjustment to payment for 340B-acquired drugs in nonexcepted off-campus PBDs in CY 2018, but indicated we may consider doing so through future notice-and-comment rulemaking.

In the interim final rule with comment period that accompanied the CY 2017 OPPS/ASC final rule with comment period, we established payment policies under the PFS for nonexcepted items and services furnished by a nonexcepted off-campus PBD on or after January 1, 2017. In accordance with sections 1848(b) and (c) of the Act, PFS payment is based on the relative value of the resources involved in furnishing particular services (81 FR 79790). Resource-based relative values are established for each item and service (described by a HCPCS code) based on the work (time and intensity), practice expense (such as clinical staff, supplies and equipment, office rent, and overhead), and malpractice expense required to furnish the typical case of the service. Because Medicare makes separate payment under institutional payment systems (such as the OPPS) for the facility costs associated with many of the same services that are valued under the PFS, we establish two different PFS payment rates for many of these services—one that applies when the service is furnished in a location where a facility bills and is paid for the service under a Medicare payment system other than the PFS (the facility rate), and another that applies when the billing practitioner or supplier furnishes and bills for the entire service (the nonfacility rate). Consistent with the long-established policy under the PFS to make payment to the billing practitioner at the facility rate when Medicare makes a corresponding payment to the facility (under the OPPS, for instance) for the same service, physicians and nonphysician practitioners furnishing services in nonexcepted PBDs continue to report their services on a professional claim form and are paid for their services at the PFS facility rate.

Similarly, there are many (mostly diagnostic) services paid under the PFS that have two distinct portions of the service: A technical component (TC) and a professional component (PC). These components can be furnished independently in time or by different suppliers, or they may be furnished and billed together as a ''global'' service (82 FR 52981). Payment for these services can also be made under a combination of payment systems; for example, under the PFS for the professional component and the OPPS for the facility portion. For instance, for a diagnostic CT scan, the technical component relates to the portion of the service during which the image is captured and might be furnished in an office or HOPD setting, and the professional component relates to the interpretation and report by a radiologist.

In the CY 2017 interim final rule with comment period, we stated that we continue to believe that it is operationally infeasible for nonexcepted off-campus PBDs to bill directly under the PFS for the subset of PFS services for which there is a separately valued technical component (81 FR 79721). In addition, we explained that we believe hospitals that furnish nonexcepted items and services are likely to furnish a broader range of services than other provider or supplier types for which there is a separately valued technical component under the PFS. We stated that we therefore believe it is necessary to establish a new set of payment rates under the PFS that reflect the relative resource costs of furnishing the technical component of a broad range of services to be paid under the PFS that is specific to one site of service (the off-campus PBD of a hospital) with the packaging (bundling) rules that are significantly different from current PFS rules (81 FR 79721).

In continuing to implement the requirements of sections 1833(t)(1)(B) and (t)(21) of the Act, we recognize that there is no established mechanism for allowing hospitals to report and bill under the PFS for the portion of resources incurred in furnishing the full range of nonexcepted items and services. This is because hospitals with nonexcepted off-campus PBDs that furnish nonexcepted items and services generally furnish a broader range of services than other provider or supplier types for which there is a separately valued technical component under the PFS. As such, we established a new set of payment rates under the PFS that reflected the relative resource costs of furnishing the technical component of a broad range of services to be paid under the PFS specific to the nonexcepted off-campus PBDs of a hospital. Specifically, we established a PFS relativity adjuster that is applied to the OPPS rate for the billed nonexcepted items and services furnished in a nonexcepted off-campus PBD in order to calculate payment rates under the PFS. The PFS relativity adjuster reflects the estimated overall difference between the payment that would otherwise be made to a hospital under the OPPS for the nonexcepted items and services furnished in nonexcepted off-campus PBDs and the resource-based payment under the PFS for the technical aspect of those services with reference to the difference between the facility and nonfacility (office) rates and policies under the PFS. The current PFS relativity adjuster is set at 40 percent of the amount that would have been paid under the OPPS (82 FR 53028). These PFS rates incorporate the same packaging rules that are unique to the hospital outpatient setting under the OPPS, including the packaging of drugs that are unconditionally packaged under the OPPS. This includes packaging certain drugs and biologicals that would ordinarily be separately payable under the PFS when furnished in the physician office setting.

Nonexcepted off-campus PBDs continue to bill for nonexcepted items and services on the institutional claim utilizing a new claim line (modifier ''PN'') to indicate that an item or service is a nonexcepted item or service. For a detailed discussion of the current PFS relativity adjuster related to payments under section 603 of Public Law 114–74, we refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 52356 through 52637), the CY 2018 PFS final rule with comment period (82 FR 53019 through 53025), and the CY 2019 PFS proposed rule.

c. Section 340B of the Public Health Service Act

The 340B Program, which was established by section 340B of the Public Health Service Act by the Veterans Health Care Act of 1992, is administered by the Health Resources and Services Administration (HRSA) within HHS. The 340B Program allows participating hospitals and other health care providers to purchase certain ''covered outpatient drugs'' (as defined under section 1927(k) of the Act and interpreted by HRSA through various

guidance documents) at discounted prices from drug manufacturers.

In the CY 2018 OPPS/ASC proposed rule (82 FR 33632 through 33635), we proposed changes to the payment methodology under the OPPS for separately payable drugs and biologicals acquired under the 340B Program. We stated that these changes would better, and more appropriately, reflect the resources and acquisition costs that these hospitals incur. Such changes would allow Medicare beneficiaries (and the Medicare program) to pay less when hospitals participating in the 340B Program furnish drugs that are purchased under the 340B Program to Medicare beneficiaries. Subsequently, in the CY 2018 OPPS/ASC final rule with comment period, we finalized our proposal that separately payable, covered outpatient drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B Program will be paid ASP minus 22.5 percent, rather than ASP plus 6 percent, when billed by a hospital paid under the OPPS that is not excepted from the payment adjustment. CAHs are not subject to this 340B policy change because they are paid under section 1834(g) of the Act. Rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals are excepted from the alternative payment methodology for 340B-acquired drugs and biologicals. In addition, as stated in the CY 2018 OPPS/ASC final rule with comment period, this policy change does not apply to drugs with pass-through payment status, which are required to be paid based on the ASP methodology, or to vaccines, which are excluded from the 340B Program.

2. Proposal To Pay an Adjusted Amount for 340B-Acquired Drugs and Biologicals Furnished in Nonexcepted Off-Campus PBDs in CY 2019 and Subsequent Years

As noted in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79716), prior to the implementation of the payment adjustment under the OPPS for drugs and biologicals acquired under the 340B program, separately payable drugs and biologicals were paid the same rate at both excepted and nonexcepted off-campus departments of a hospital. The policy we finalized in the CY 2018 OPPS/ASC final rule with comment period, in which we adjust 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 ASP plus 6 percent to ASP minus 22.5 percent, applies to separately payable drugs and biologicals paid under the OPPS (81 FR 59353 through 59369). Under sections 1833(t)(1)(B)(v) and (t)(21) of the Act, however, nonexcepted items and services furnished by nonexcepted off-campus PBDs are no longer covered outpatient department services and, therefore, are not payable under the OPPS. This means that nonexcepted off-campus PBDs are not subject to the payment changes finalized in the CY 2018 OPPS/ASC final rule with comment period that apply to hospitals and PBDs paid under the OPPS. Because the separately payable drugs and biologicals acquired under the 340B Program and furnished in nonexcepted off campus PBDs are no longer covered outpatient department services, these drugs and biologicals are currently paid in the same way Medicare Part B drugs are paid in the physician office and other nonhospital settings—typically at ASP plus 6 percent—regardless of whether they are acquired under the 340B Program.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59367 through 59368), we discussed public comments that we received that noted that the alternative payment methodology for 340B-acquired drugs and biologicals did not apply to nonexcepted off-campus PBDs of a hospital and could result in behavioral changes that may undermine CMS' policy goals of reducing beneficiary cost-sharing liability and undercut the goals of section 603 of the Public Law 114–74. Commenters recommended that, if CMS adopted a final policy to establish an alternative payment methodology for 340B drugs in CY 2018, CMS should also apply the same adjustment to payment rates for drugs furnished in nonexcepted off-campus PBDs of a hospital if such drugs were acquired under the 340B Program (82 FR 59367). While we did not propose to adjust payment for 340B-acquired drugs in nonexcepted off-campus PBDs in CY 2018, we indicated that we would consider adopting such a policy in future rulemaking.

The current PFS payment policies for nonexcepted items and services incorporate a significant number of payment policies and adjustments made under the OPPS (81 FR 79726; 82 FR 53024 through 53025). In establishing these policies in prior rulemaking, we pointed out that the adoption of these policies was necessary in order to maintain the integrity of the PFS relativity adjuster because it adjusts payment rates developed under the OPPS (81 FR 79726). For example, it is necessary to incorporate OPPS packaging rules into the site-specific PFS rate because the PFS relativity adjuster is applied to OPPS rates that were developed based on those packaging rules. In addition, many of the OPPS policies and adjustments are replicated under the nonexcepted off-campus PBD site-specific PFS rates because they are specifically applicable to hospitals as a setting of care. For example, we adopted the geographic adjustments used for hospitals instead of the adjustments developed for the PFS localities, which reflect cost differences calculated for professionals and suppliers rather than hospitals (81 FR 79726).

We agree with commenters that the difference in the payment amounts for 340B-acquired drugs furnished by hospital outpatient departments—excepted off-campus PBDs versus nonexcepted off-campus PBDs—creates an incentive for hospitals to move drug administration services for 340B-acquired drugs to nonexcepted off-campus PBDs to receive a higher payment amount for these drugs, thereby undermining our goals of reducing beneficiary cost-sharing for these drugs and biologicals and moving towards site neutrality through the section 603 amendments to section 1833(t) of the Act. Therefore, for CY 2019, we are proposing changes to the Medicare Part B drug payment methodology for drugs and biologicals furnished and billed by nonexcepted off-campus departments of a hospital that were acquired under the 340B Program. Specifically, for CY 2019 and subsequent years, we are proposing to pay under the PFS the adjusted payment amount of ASP minus 22.5 percent for separately payable drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B Program when they are furnished by nonexcepted off-campus PBDs of a hospital. Furthermore, in this CY 2019 OPPS/ASC proposed rule, we are proposing to except rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals from this payment adjustment. We believe that our proposed payment policy would better reflect the resources and acquisition costs that nonexcepted off-campus PBDs incur for these drugs and biologicals.

We note that, ordinarily, Medicare pays for drugs and biologicals furnished in the physician's office setting at ASP plus 6 percent. This is because section 1842(o)(1)(A) of the Act provides that if a physician's, supplier's, or any other person's bill or request for payment for services includes a charge for a drug or biological for which payment may be

made under Medicare Part B and the drug or biological is not paid on a cost or prospective payment basis as otherwise provided in this part, the amount for the drug or biological is equal to the following: The amount provided under section 1847, section 1847A, section 1847B, or section 1881(b)(13) of the Act, as the case may be for the drug or biological.

Generally, in the hospital outpatient department setting, low-cost drugs and biologicals are packaged into the payment for other services billed under the OPPS. Separately payable drugs (1) have pass-through payment status, (2) have a cost per day exceeding a threshold, or (3) are not policy-packaged or packaged in a C–APC. As described in section V.A.1. of this proposed rule, section 1847A of the Act establishes the 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 WAC, and the AWP (82 FR 59337). As noted in section V.B.2.b. of this proposed rule, since CY 2013, our policy has been to pay for separately payable drugs and biologicals at ASP plus 6 percent in accordance with section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default) (82 FR 59350). Consequently, in the case of services furnished in a hospital outpatient department, Medicare pays ASP plus 6 percent for separately payable Part B drugs and biologicals unless those drugs or biologicals are acquired under the 340B Program, in which case they are paid at ASP minus 22.5 percent. For a detailed discussion of our current OPPS drug payment policies, we refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59343 through 59371).

As a general matter, in the nonexcepted off-campus PBD setting, we pay hospitals under the PFS for all drugs and biologicals that are packaged under the OPPS based on a percentage of the OPPS payment rate, which is determined using the PFS relativity adjuster. Because OPPS packaging rules apply to the PFS payments to nonexcepted off-campus PBDs, the PFS payment for some nonexcepted items and services that are packaged includes payment for some drugs and biologicals that would be separately billable under the PFS if a similar service had been furnished in the office-based setting. As we noted in the CY 2017 final rule with comment period, in analyzing the term ''applicable payment system,'' we considered whether and how the requirements for payment could be met under alternative payment systems in order to pay for nonexcepted items and services, and considered several payment systems under which payment is made for similar items and services (81 FR 79712). Because the PFS relativity adjuster that is applied to calculate payment to hospitals for nonexcepted items and services furnished in nonexcepted off-campus PBDs is based on a percentage (40 percent) of the amount determined under the OPPS for a particular item or service, and the OPPS is a prospective payment system, we believe that items and services furnished by nonexcepted off-campus PBDs paid under the PFS are payable on a prospective payment basis. Therefore, we believe we have flexibility to pay for separately-payable drugs and biologicals furnished in nonexcepted off-campus PBDs at an amount other than the amount dictated by sections 1842(o)(1)(C) and 1847A of the Act.

As we discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59354), several recent studies and reports on Medicare Part B payments for 340B-acquired drugs highlight a difference in Medicare Part B drug spending between 340B hospitals and non-340B hospitals as well as varying differences in the amount by which the Part B payment exceeds the drug acquisition cost. When we initially developed the policy for nonexcepted off-campus PBDs, most separately payable drugs and biologicals were paid, both in the OPPS and in other Part B settings, such as physician offices, through similar methodologies under section 1847A/1842(o) of the Act. For drugs and biologicals that are packaged in the OPPS, we adopted similar packaging payment policies for purposes of making the site-specific payment under the PFS for nonexcepted off-campus PBDs. 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 upon where (for example, excepted or nonexcepted PBD) 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 drug 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, our current payment policy could undermine the validity of the use of the OPPS payment structure in nonexcepted off campus PBDs. In order to avoid such perverse incentives and the resulting distortions, we are proposing, pursuant to our authority at section 1833(t)(21)(C) of the Act 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 believe this proposed change in policy would eliminate the significant incongruity between the payment amounts for these drugs, depending upon whether they are furnished by excepted off-campus PBDs or nonexcepted off-campus PBDs, which we believe is an unnecessary difference in payment where the 340B Program does not differentiate between PBDs paid under the OPPS and PBDs paid under the PFS using the PFS relativity adjuster.

D. Expansion of Clinical Families of Services at Excepted Off-Campus Departments of a Provider

1. Background

a. Section 603 of the Bipartisan Budget Act of 2015

We refer readers to section X.C.1.a. of this proposed rule for a discussion of the provisions of section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74), as implemented in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699 through 79719). As discussed in the CY 2017 OPPS/ASC final rule with comment period, we adopted the PFS as the applicable payment system for nonexcepted items and services furnished and billed by off-campus PBDs. In addition, we indicated that, in order to be considered part of a hospital, an off-campus department of a hospital must meet the provider-based criteria established under 42 CFR 413.65. For a detailed discussion of the history and statutory authority related to payments under section 603 of Public Law 114–74, we refer readers to the CY 2017 OPPS/ASC final rule with

comment period (81 FR 79699 through 79719) and the interim final rule with comment period (81 FR 79720 through 79729).

b. Expansion of Services at an Off-Campus PBD Excepted Under Section 1833(t)(21)(B)(ii) of the Act

In the CY 2017 OPPS/ASC proposed rule (81 FR 45685), we noted that we had received questions from some hospitals regarding whether an excepted off-campus PBD could expand the number or type of services the department furnishes and maintain excepted status for purposes of paragraphs (1)(B)(v) and (21) of section 1833(t) of the Act. We indicated that we were concerned that if excepted off-campus PBDs could expand the types of services provided at the excepted off-campus PBDs and also be paid OPPS rates for these new types of services, hospitals may be able to purchase additional physician practices and expand services furnished by existing excepted off-campus PBDs as a result (81 FR 45685). This could result in newly purchased physician practices furnishing services that are paid at OPPS rates, which we believed these amendments to section 1833(t) of the Act were intended to address (81 FR 45685). We believed section 1833(t)(21)(B)(ii) of the Act excepted off-campus PBDs and the items and services that are furnished by such excepted off-campus PBDs for purposes of paragraphs (1)(B)(v) and (21) of section 1833(t) of the Act as they were being furnished on the date of enactment of section 603 of the Bipartisan Budget Act of 2015, as guided by our regulatory definition at § 413.65(a)(2) of a department of a provider (81 FR 45685). Thus, in the CY 2017 OPPS/ASC proposed rule, we proposed that if an excepted off-campus PBD furnished items and services from a clinical family of services (clinical families of services were identified in Table 21 of the CY 2017 proposed rule (81 FR 45685 through 45686)) that it did not furnish prior to November 2, 2015, and thus did not also bill for, services from these new expanded clinical families of services would not be covered OPD services, and instead would be subject to paragraphs (1)(B)(v) and (21) of section 1833(t) of the Act as described in section X.A.1.c. of the proposed rule. In addition, in that rule, we proposed not to limit the volume of excepted items and services within a clinical family of services that an excepted off-campus PBD could furnish (81 FR 45685).

The majority of commenters, including several hospital associations, regional health systems, and medical equipment manufacturers opposed the proposals primarily because they believed: (1) CMS exceeded its statutory authority, as the statutory language included in section 603 does not address changes in service mix by excepted off-campus PBDs; (2) CMS' proposal does not account for evolving technologies and would hinder beneficiary access to those innovative technologies; (3) the term ''clinical families of service'' appeared to be a new term created by CMS for the purpose of implementing section 603 and it would be difficult for CMS and hospitals to manage changes in the composition of APCs and HCPCS code changes contained in those APCs; and (4) the proposal created significant operational challenges and administrative burden for both CMS and hospitals because commenters believed it was unnecessarily complex (81 FR 79706 through 79707).

In addition, MedPAC explained in its comment letter that the proposal was unnecessarily complex and instead suggested that CMS adopt a different approach by determining how much the Medicare program had paid an excepted off-campus PBD for services billed under the OPPS during a 12-month baseline period that preceded November 2, 2015 and to cap the OPPS payment made to the off-campus PBD at the amount paid during the baseline period.[41] Some commenters, including physician group stakeholders, supported CMS' intent to monitor service line expansion and changes in billing patterns by excepted off-campus PBDs. These commenters urged CMS to work to operationalize a method that would preclude an excepted off-campus PBD from expanding the excepted services for which it is paid under the OPPS into wholly new clinical areas, as they believed an excepted, off-campus PBD should only be able to bill under the OPPS for those items and services for which it submitted claims prior to November 2, 2015 (82 FR 33647).

In response to public comments, we did not finalize our proposal to limit the expansion of excepted services at excepted off-campus PBDs. However, we stated our intent to monitor this issue and expressed interest in additional feedback to help us consider whether excepted off-campus PBDs that expand the types of services offered after November 2, 2015 should be paid for furnishing those items and services under the applicable payment system (that is, the PFS) instead of the OPPS. Specifically, we requested comments on how either a limitation on volume or a limitation on lines of service would work in practice (81 FR 79707).

In addition, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79707), we sought public comments on how either a limitation on volume of services, or a limitation on lines of service, as we laid out in the CY 2017 OPPS/ASC proposed rule, could be implemented. Specifically, we stated that we were interested in what data were available or could be collected that would have allowed us to implement a limitation on the expansion of excepted services.

We provided a summary of and responses to comments received in response to the CY 2017 OPPS/ASC final rule with comment period in the CY 2018 OPPS/ASC proposed rule. As stated in that rule, several of the public comments received in response to the comment solicitation included in the CY 2017 OPPS/ASC final rule with comment period were repeated from the same stakeholders in response to the CY 2017 OPPS/ASC proposed rule. These commenters again expressed concern regarding CMS' authority to address changes in service-mix; that a limitation on service expansion or volume would stifle innovative care delivery and use of new technologies; and that limiting service line expansion using clinical families of service was not workable. Because these commenters did not provide new information, we referred readers to the CY 2017 OPPS/ASC final rule with comment period for our responses to comments on statutory authority and concerns about hindering access to innovative technologies (81 FR 79707 and 82 FR 59388). A summary of and our responses to the other comments received in response to the comment solicitation included in the CY 2017 OPPS/ASC final rule with comment period were included in the CY 2018 OPPS/ASC proposed rule (82 FR 33645 through 33648).

In the CY 2018 OPPS/ASC proposed rule, we did not propose any policies related to clinical service line expansion or volume increases at excepted off-campus PBDs. However, we stated that we would continue to monitor claims data for changes in billing patterns and utilization, and we again invited public comments on the issue of service line expansion. In response to the CY 2018 comment solicitation, MedPAC largely reiterated the comments it submitted in response to the CY 2017 OPPS/ASC rulemaking and acknowledged the challenges of implementing its recommended approach as such

[41] Available at: *http://medpac.gov/docs/default-source/comment-letters/08172016_opps_asc_comment_2017_medpac_sec.pdf?sfvrsn=0.*

approach would necessitate CMS requiring hospitals to report the amount of OPPS payments received by each excepted off-campus PBD during the baseline period (such as November 2014 through November 2015) because CMS was not collecting data on payments made to each individual PBD during that period. In its comments, MedPAC recommended that, to help ensure the accuracy of these data, CMS could selectively audit hospitals.[42] Another commenter expressed support for CMS' efforts to continue to implement and expand site-neutral payment policies for services where payment differentials are not warranted, such as between HOPDs and ASCs or physician offices.

2. CY 2019 Proposal

As previously expressed in CYs 2017 and 2018 OPPS/ASC rulemaking, we continue to be concerned that if excepted off-campus PBDs are allowed to furnish new types of services that were not provided at the excepted off-campus PBDs prior to the date of enactment of the Bipartisan Budget Act of 2015 and can be paid OPPS rates for these new types of services, hospitals may be able to purchase additional physician practices and add those physicians to existing excepted off-campus PBDs. This could result in newly purchased physician practices furnishing services that are paid at OPPS rates, which we believe the section 603 amendments to section 1833(t) of the Act are intended to prevent. Of note, these statutory amendments ''came after years of nonpartisan economists, health policy experts, and providers expressing concern over the Medicare program's [OPPS] paying more for the same services provided at HOPDs than in other settings—such as an ambulatory surgery center, physician office, or community outpatient facility.'' [43] Experts raised concerns that this payment inequity drove the acquisition of ''standalone or independent practices and facilities by hospitals, resulted in higher costs for the Medicare system and taxpayers, and also resulted in beneficiaries needlessly facing higher cost-sharing in some settings than in others.'' [44] In addition, some experts argued that, ''to the extent this payment differential accelerated consolidation of providers, this would result in reduced competition among both hospitals and nonaffiliated outpatient service providers. This, in turn, could reduce large hospital systems' incentives to reduce costs, increase efficiency, or focus on patient outcomes.'' [45]

The Government Accountability Office (GAO) stated in its December 2015 Report to Congress that ''from 2007 through 2013, the number of vertically consolidated physicians nearly doubled, with faster growth in more recent years.'' GAO concluded that, ''regardless of what has driven hospitals and physicians to vertically consolidate, paying substantially more for the same service when performed in an HOPD rather than a physician office provides an incentive to shift services that were once performed in physician offices to HOPDs after consolidations have occurred.'' [46]

While there is no congressional record available for section 603 of the Bipartisan Budget Act of 2015, we do not believe that Congress intended to allow for new service lines to be paid OPPS rates because providing for such payment would allow for excepted off-campus PBDs to be paid higher rates for types of services they were not performing prior to enactment of the Bipartisan Budget Act of 2015 that would be paid at lower rates if performed in a nonexcepted PBD. Similarly, we are concerned that a potential shift of services from nonexcepted PBDs to excepted PBDs, or to excepted PBDs generally, may be occurring, given the higher payment rate in this setting. We believe that the growth of service lines in currently excepted off-campus PBDs may be an unintended consequence of our current policy, which allows continued full OPPS payment for any services furnished by excepted off-campus PBDs, including services in new service lines.

In prior rulemaking, and as discussed in section X.A. of this proposed rule, we noted our concerns and discussed our efforts to begin collecting data and monitoring billing patterns for off-campus PBDs. Specifically, as described in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66910 through 66914), we created HCPCS modifier ''PO'' (Services, procedures, and/or surgeries furnished at off-campus provider-based outpatient departments) for hospital claims to be reported with every code for outpatient hospital items and services furnished in an off-campus PBD of a hospital. Reporting of this new modifier was voluntary for CY 2015, with reporting required beginning on January 1, 2016. In addition, we established modifier ''PN'' (Nonexcepted service provided at an off-campus, outpatient, provider-based department of a hospital) to identify and pay nonexcepted items and services billed on an institutional claim. Effective January 1, 2017, nonexcepted off-campus PBDs of a hospital were required to report this modifier on each claim line for nonexcepted items and services to trigger payment under the PFS instead of the OPPS. As a conforming revision, effective January 1, 2017, the modifier ''PO'' descriptor was revised to ''excepted service provided at an off-campus, outpatient, provider-based department of a hospital'' and this modifier continued to be used to identify items and services furnished by an excepted off-campus PBD of a hospital.

As discussed in the CY 2018 OPPS/ASC proposed rule (82 FR 33647), a few commenters supported CMS' intent to monitor service line expansion and changes in billing patterns by excepted off-campus PBDs. These commenters urged CMS to work to operationalize a method that would preclude an excepted off-campus PBD from increasing its payment advantage under the OPPS by expanding into wholly new clinical areas (82 FR 33647). Moreover, a few commenters urged CMS to pursue a limitation on service line expansion to ensure designation as an excepted off-campus PBD is not ''abused'' (82 FR 33647). One commenter suggested that CMS evaluate outpatient claims with the ''PO'' modifier to develop a list of ''grandfathered'' items and services for which the excepted off-campus PBD may continue to be paid under the OPPS (82 FR 33647). In response to these comments, we stated that we were concerned with the practicality of developing a list of excepted items and services for each excepted off-campus PBD, given the magnitude of such a list (82 FR 33647). We noted in the CY 2018 OPPS/ASC final rule with comment period, however, that we continued to monitor claims data for changes in billing patterns and utilization, and invited comments on this issue (82 FR 59388).

In light of our prior stated concerns about the expansion of services in excepted off-campus PBDs, for CY 2019 and subsequent years, we are proposing that if an excepted off-campus PBD furnishes services from any clinical family of services (as clinical families of services are defined in Table 32 of this proposed rule) from which it did not

[42] Available at: *http://medpac.gov/docs/default-source/comment-letters/09082017_opps_asc_2018_medpac_comment_sec.pdf?sfvrsn=0.*

[43] Available at: *https://archives-energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/114/Letters/20160205SiteNeutralLetter%5b1%5d.pdf.*

[44] Ibid.

[45] Ibid.

[46] GA0–16–189, ''Increasing Hospital-Physician Consolidation Highlights Need for Payment Reform.'' Available at: *https://www.gao.gov/assets/680/674347.pdf.*

furnish an item or service during a baseline period from November 1, 2014 through November 1, 2015 (and subsequently bill under the OPPS for that item or service), items and services from these new clinical families of services would not be excepted items and services and, thus, would not be covered OPD services, and instead would be subject to paragraphs (1)(B)(v) and (21) of section 1833(t) of the Act and paid under the PFS. Furthermore, in this CY 2019 OPPS/ASC proposed rule, we are proposing to revise 42 CFR 419.48 to limit the definition of ''excepted items and services'' in accordance with this proposal. Generally, excepted items and services are items or services that are furnished on or after January 1, 2017 by an excepted off-campus PBD (as defined in § 419.48) that has not impermissibly relocated or changed ownership. Beginning on January 1, 2019, excepted items and services would be items or services that are furnished and billed by an excepted off-campus PBD (defined in § 419.48) only from the clinical families of services (described later in this section) for which the excepted off-campus PBD furnished (and subsequently billed under the OPPS) for at least one item or service from November 1, 2014 through November 1, 2015. Further, for purposes of this section, ''new clinical families of services'' would be items or services: (1) That are furnished and billed by an excepted off-campus PBD; (2) that are otherwise paid under the OPPS through one of the APCs included in Table 32 of this proposed rule; and (3) that belong to a clinical family listed in Table 32 from which the excepted off-campus PBD did not furnish an item or service during the baseline period from November 1, 2014 through November 1, 2015 (and subsequently bill for that service under the OPPS). In addition, for CY 2019, we are proposing that if an excepted off-campus PBD furnishes a new item or service from a clinical family of services listed in Table 32 from which the off-campus PBD furnished a service from November 1, 2014 through November 1, 2015, such service would continue to be paid under the OPPS because items and services from within a clinical family of services for which the nonexcepted off-campus PBD furnished an item or service during the baseline period would not be considered a ''service expansion.''

In order to determine the types of services provided at an excepted off-campus PBD, for purposes of OPPS payment eligibility, excepted off-campus PBDs will be required to ascertain the clinical families from which they furnished services from November 1, 2014 through November 1, 2015 (that were subsequently billed under the OPPS). In addition, items and services furnished by an excepted off campus PBD that are not identified below in Table 32 of this proposed rule must be reported with modifier ''PN''. We selected the year prior to the date of enactment of the Bipartisan Budget Act of 2015 as the baseline period because it is the most recent year preceding the date of enactment of section 603 and we believe that a full year of claims data would adequately reflect the types of service lines furnished and billed by an excepted off-campus PBD. We considered expanding the baseline period to include a timeframe prior to November 2014, but are not proposing this alternative due to the possibility that hospital claims data for an earlier time period may not be readily available and reviewing claims from a longer timeframe may impose undue burden. If an excepted off-campus PBD did not furnish services under the OPPS until after November 1, 2014, we are proposing that the 1-year baseline period begins on the first date the off-campus PBD furnished covered OPD services prior to November 2, 2015. For providers that met the mid-build requirement (as defined at section 1833(t)(21)(B)(v) of the Act), we are proposing to establish a 1-year baseline period that begins on the first date the off-campus PBDs furnished a service billed under the OPPS. We are proposing changes to our regulation at 42 CFR 419.48 to include these alternative baseline periods. For guidance on the implementation of sections 16001 and 16002 of the 21st Century Cures Act, we refer readers to the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/Sections-16001-16002.pdf.* We are concerned that a 1-year baseline may be unnecessarily long to the extent that such baseline would be, at least in part, a prospective period during which such departments would have time and an incentive to bill services from as many service lines as possible, thereby limiting the effect of this policy. We welcome public comment on whether a different baseline period, such as 3 or 6 months, should be used for off-campus PBDs that began furnishing services and billing after November 1, 2014, or that met the mid-build requirement.

We are aware of past stakeholder concern regarding limiting service line expansion for excepted off-campus PBDs using the 19 clinical families identified below in Table 32 of this proposed rule. However, we believe that the proposed clinical families recognize all clinically distinct service lines for which a PBD might bill under the OPPS, while at the same time allow for new services within a clinical family of services to be considered for designation as ''excepted items and services'', as defined in the regulations at 42 CFR 419.48 where the types of services within a clinical family expand due to new technology or innovation. We believe that requiring excepted off-campus PBDs to limit their services to the exact same services they furnished during the proposed baseline period would be too restrictive and administratively burdensome. We are requesting public comments on the proposed clinical families. We also are soliciting public comments on whether any specific groups of hospitals should be excluded from our proposal to limit the expansion of excepted services, such as certain rural hospitals (for example, rural sole community hospitals), in light of recent reports of hospital closures in rural areas.

In addition, we are soliciting public comments on alternate methodologies to limit the expansion of excepted services in excepted off-campus PBDs for CY 2019. Specifically, we are inviting public comments on the adoption and implementation of other methodologies, such as the approach recommended by MedPAC (discussed earlier in this section) in response to the CY 2017 and CY 2018 proposals whereby CMS would establish a baseline service volume for each applicable off-campus PBD, cap excepted services (regardless of clinical family) at that limit, and when the hospital reaches the annual cap for that location, additional services furnished by that off-campus PBD would no longer be considered covered OPD services and would instead be paid under the PFS (the annual cap could be updated based on the annual updates to the OPPS payment rates). Under such alternate approach, hospitals would need to report service volume for each off-campus PBD for the applicable period (such as November 1, 2014–November 1, 2015) and such applicable periods would be subject to audit.

TABLE 32—PROPOSED CLINICAL FAMILIES OF SERVICES FOR PURPOSES OF SECTION 603 IMPLEMENTATION

Clinical families	APCs
Airway Endoscopy	5151–5155.
Blood Product Exchange	5241–5244.
Cardiac/Pulmonary Rehabilitation	5771; 5791.
Diagnostic/Screening Test and Related Procedures	5721–5724; 5731–5735; 5741–5743.
Drug Administration and Clinical Oncology	5691–5694.
Ear, Nose, Throat (ENT)	5161–5166.
General Surgery and Related Procedures	5051–5055; 5061; 5071–5073; 5091–5094; 5361–5362.
Gastrointestinal (GI)	5301–5303; 5311–5313; 5331; 5341.
Gynecology	5411–5416.
Major Imaging	5523–5525; 5571–5573; 5593–5594.
Minor Imaging	5521–5522; 5591–5592.
Musculoskeletal Surgery	5111–5116; 5101–5102.
Nervous System Procedures	5431–5432; 5441–5443; 5461–5464; 5471.
Ophthalmology	5481, 5491–5495; 5501–5504.
Pathology	5671–5674.
Radiation Oncology	5611–5613; 5621–5627; 5661.
Urology	5371–5377.
Vascular/Endovascular/Cardiovascular	5181–5184; 5191–5194; 5200; 5211–5213; 5221–5224; 5231–5232.
Visits and Related Services	5012; 5021–5025; 5031–5035; 5041; 5045; 5821–5823.

XI. Proposed CY 2019 OPPS Payment Status and Comment Indicators

A. Proposed CY 2019 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 2019, we are not proposing to make any changes to the definitions of status indicators that were listed in Addendum D1 to the CY 2018 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-1656-FC.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending.*

The complete list of the payment status indicators and their definitions that would apply for CY 2019 is displayed in Addendum D1 to this proposed rule, which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

The proposed CY 2019 payment status indicator assignments for APCs and HCPCS codes are shown in Addendum A and Addendum B, respectively, to this proposed rule, which are available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

B. Proposed CY 2019 Comment Indicator Definitions

In this proposed rule, we are proposing to use four comment indicators for the CY 2019 OPPS. These comment indicators, ''CH'', ''NC'', ''NI'', and ''NP'', are in effect for CY 2018 and we are proposing to continue their use in CY 2019. The proposed CY 2019 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 proposed OPPS comment indicators for CY 2019 are listed in Addendum D2 to this proposed rule, which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

XII. Proposed 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 and 2018 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; and 82 FR 59401 through 59424, respectively).

2. Policies Governing Changes to the Lists of Codes and Payment Rates for ASC Covered Surgical Procedures and Covered Ancillary Services

Under 42 CFR 416.2 and 416.166 of the Medicare regulations, subject to certain exclusions, covered surgical procedures in an ASC are surgical procedures that are separately paid under the OPPS, that would not be expected to pose a significant risk to

beneficiary safety when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the 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. We define surgical procedures as those described by Category I CPT codes in the surgical range from 10000 through 69999 as well as those Category III CPT codes and Level II HCPCS codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that we have determined do not pose a significant safety risk, that we would not expect to require an overnight stay when performed in ASCs, and that are separately paid under the OPPS (72 FR 42478).

In the August 2, 2007 final rule (72 FR 42495), we also established our policy to make separate ASC payments for the following ancillary items and services when they are provided integral to ASC covered surgical procedures: (1) Brachytherapy sources; (2) certain implantable items that have pass-through payment status under the OPPS; (3) certain items and services that we designate as contractor-priced, including, but not limited to, procurement of corneal tissue; (4) certain drugs and biologicals for which separate payment is allowed under the OPPS; and (5) certain radiology services for which separate payment is allowed under the OPPS. In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66932 through 66934), we expanded the scope of ASC covered ancillary services to include certain diagnostic tests within the medicine range of 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 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, which we finalized in the CY 2012 OPPS/ASC final rule with comment period, is used to update HCPCS and CPT codes (76 FR 42291; 76 FR 74380 through 74381).

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 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 American Medical Association (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 are separately paid under the OPPS (72 FR 42478).

As we noted in the CY 2008 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).

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59402 through 59403), we noted that some stakeholders have suggested that certain procedures that are outside the CPT surgical range but that are similar to surgical procedures currently covered in an ASC setting should be ASC covered surgical procedures. For example, some stakeholders have recommended adding certain cardiovascular procedures to the ASC Covered Procedures List (CPL) due to their similarity to currently-covered peripheral endovascular procedures in the surgical code range for surgery and cardiovascular system. Further, stakeholders also noted that the AMA's CPT code manual states that the listing of a procedure in a specific section of the book may reflect historical or other considerations and should not be interpreted as strictly classifying the

procedure as ''surgery'' or ''not surgery'' for insurance purposes. As the CPT codebook states: ''It is equally important to recognize that as techniques in medicine and surgery have evolved, new types of services, including minimally invasive surgery, as well as endovascular, percutaneous, and endoscopic interventions have challenged the traditional distinction of Surgery vs Medicine. *Thus, the listing of a service or procedure in a specific section of this book should not be interpreted as strictly classifying the service or procedure as 'surgery' or 'not surgery' for insurance or other purposes.* The placement of a given service in a specific section of the book may reflect historical or other considerations (e.g., placement of the percutaneous peripheral vascular endovascular interventions in the Surgery/Cardiovascular System section, while the percutaneous coronary interventions appear in the Medicine/Cardiovascular section)'' (emphasis added) (CPT® 2018 Professional Edition, ''Instructions for Use of the CPT Code Book,'' page xii.). While we continue to believe that using the CPT code range to define surgery represents a logical, appropriate, and straightforward approach to defining a surgical procedure, we also believe it may be appropriate for us to use the CPT surgical range as a guide rather than a strict determinant as to whether a procedure is surgical, which would give us more flexibility to include ''surgery-like'' procedures on the ASC CPL.

We also are cognizant of the dynamic nature of ambulatory surgery and the continued shift of services from the inpatient setting to the outpatient setting over the past decade. In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59402 through 59403), we responded to public comments that we had solicited regarding services that are described by Category I CPT codes outside of the surgical range, or Level II HCPCS codes or Category III CPT codes that do not directly crosswalk and are not clinically similar to procedures in the CPT surgical range, but that nonetheless may be appropriate to include as covered surgical procedures that are payable when furnished in the ASC setting. Commenters offered mixed views for changing the current definition of surgery; however, most commenters were supportive of changing the definition. Some commenters recommended broadening the definition of surgery to include procedures not described by the CPT surgical range. Another commenter recommended making all surgical codes payable in a hospital outpatient department payable in an ASC and further suggested that CMS at least redefine surgical procedures to include invasive procedures such as percutaneous transluminal angioplasty and cardiac catheterization.

One commenter recommended using a definition of surgery developed by the AMA Specialty Society Relative Value Scale Update Society for use in the agency's Physician Fee Schedule (PFS) professional liability insurance relative values. In calculating the professional liability insurance relative values, certain cardiology codes outside the CPT surgical range are considered surgical codes for both the calculation and assignment of the surgery-specific malpractice risk factors. However, we note that the distinction between ''surgical'' and ''non-surgical'' codes developed by the AMA Specialty Society Relative Value Scale Update Society is used by CMS to calculate professional liability risk factors and not necessarily to define surgery. The codes considered surgeries by the AMA Society Relative Value Scale Update Society were most recently displayed on the CMS website for the CY 2018 MPFS final rule under the file ''Invasive Cardiology Services Outside of Surgical HCPCS Code Range Considered Surgery.'' We refer readers to that file, which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/CY2018-PFS-FR-Invasive-Cardiology.zip.*

After further consideration of comments we received in response to the CY 2018 OPPS/ASC final rule with comment period, we are proposing to revise our definition of ''surgery'' for CY 2019 to account for ''surgery-like'' procedures that are assigned codes outside the CPT surgical range (10000–69999). We believe it is appropriate to expand our definition of covered surgical procedures to include Category I CPT codes that are not in the Category I CPT surgical range but that directly crosswalk or are clinically similar to procedures in the Category I CPT code surgical range because, as commenters have noted, the CPT Codebook's classification of certain procedures as ''surgical'' should not be considered dispositive of whether a procedure is or is not surgery. We also believe that considering these codes for potential inclusion on the covered surgical procedures list is consistent with our policy for Level II HCPCS codes and Category III CPT codes.

For CY 2019, we are proposing that these newly-eligible ''surgery-like'' procedures are procedures that are described by Category I CPT codes that are not in the surgical range but, like procedures described by Level II HCPCS codes or by Category III CPT codes under our current policy, directly crosswalk or are clinically similar to procedures in the Category I CPT surgical range. These Category I CPT codes would be limited to those 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 are inviting comments on our proposal to revise the definition of surgery for the ASC prospective payment system. We also are soliciting comments on whether we should expand our definition of ''surgery'' to include procedures that fall outside the CPT surgical range, but fall within the definition of ''surgery'' developed by the AMA Specialty Society Relative Value Scale Update Society for use in the agency's Physician Fee Schedule (PFS) professional liability insurance relative values, that we determine 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.

B. Proposed Treatment of New and Revised Codes

1. Background on Current Process for Recognizing New and Revised Category I and Category III CPT Codes and Level II HCPCS Codes

Category I CPT, Category III CPT, and Level 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 and vaccine codes;
- Category III CPT codes, which describe new and emerging technologies, services, and procedures; and
- Level II HCPCS codes, which are used primarily to identify items, supplies, temporary procedures, and services not described by CPT codes.

We finalized a policy in the August 2, 2007 final rule (72 FR 42533 through 42535) to evaluate each year all new and revised Category I and Category III CPT codes and Level II HCPCS codes that describe surgical procedures, and to make preliminary determinations during the annual OPPS/ASC rulemaking process regarding whether

or not they meet the criteria for payment in the ASC setting as covered surgical procedures and, if so, whether or not they are office-based procedures. In addition, we identify new and revised codes as ASC covered ancillary services based upon the final payment policies of the revised ASC payment system. In prior rulemakings, we refer to this process as recognizing new codes. However, this process has always involved the recognition of new and revised codes. We consider revised codes to be new when they have substantial revision to their code descriptors that necessitate a change in the current ASC payment indicator. To clarify, we refer to these codes as new and revised in this CY 2018 OPPS/ASC proposed rule.

We have separated our discussion below based on when the codes are released and whether we are proposing to solicit public comments in this proposed rule (and respond to those comments in the CY 2019 OPPS/ASC final rule with comment period) or whether we will be soliciting public comments in the CY 2019 OPPS/ASC final rule with comment period (and responding to those comments in the CY 2020 OPPS/ASC final rule with comment period).

We note that we sought public comments in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59405 through 59406) on the new and revised Level II HCPCS codes effective October 1, 2017, or January 1, 2018. These new and revised codes, with an effective date of October 1, 2017, or January 1, 2018, were flagged with comment indicator ''NI'' in Addenda AA and BB to the CY 2018 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 2018 OPPS/ASC final rule with comment period. We will respond to public comments and finalize the treatment of these codes under the ASC payment system in the CY 2019 OPPS/ASC final rule with comment period.

In Table 33 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 OPPS.

TABLE 33—COMMENT AND FINALIZATION TIMEFRAMES FOR NEW OR REVISED HCPCS CODES

ASC quarterly update CR	Type of code	Effective date	Comments sought	When finalized
April 1, 2018	Level II HCPCS Codes	April 1, 2018	CY 2019 OPPS/ASC proposed rule.	CY 2019 OPPS/ASC final rule with comment period.
July 1, 2018	Level II HCPCS Codes	July 1, 2018	CY 2019 OPPS/ASC proposed rule.	CY 2019 OPPS/ASC final rule with comment period.
	Category I (certain vaccine codes) and III CPT codes.	July 1, 2018	CY 2019 OPPS/ASC proposed rule.	CY 2019 OPPS/ASC final rule with comment period.
October 1, 2018 ..	Level II HCPCS Codes	October 1, 2018 ..	CY 2019 OPPS/ASC final rule with comment period.	CY 2020 OPPS/ASC final rule with comment period.
January 1, 2019 ..	Category I and III CPT Codes ...	January 1, 2019 ..	CY 2019 OPPS/ASC proposed rule.	CY 2019 OPPS/ASC final rule with comment period.
	Level II HCPCS Codes	January 1, 2019 ..	CY 2019 OPPS/ASC final rule with comment period.	CY 2020 OPPS/ASC final rule with comment period.

Note: 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. We refer readers to section III.A.3. of this CY 2019 OPPS/ASC proposed rule for further discussion of this issue.

2. Proposed Treatment of New and Revised Level II HCPCS Codes Implemented in April 2018 for Which We Are Soliciting Public Comments in This Proposed Rule

In the April 2018 ASC quarterly update (Transmittal 3996, CR 10530, dated March 09, 2018), we added nine new Level II HCPCS codes to the list of covered surgical procedures and ancillary services. Table 34 below lists the new Level II HCPCS codes that were implemented April 1, 2018, along with their proposed payment indicators for CY 2019. The proposed payment rates, where applicable, for these April codes can be found in Addendum AA and Addendum BB to this proposed rule (which are available via the internet on the CMS website).

TABLE 34—NEW LEVEL II HCPCS CODES FOR COVERED SURGICAL PROCEDURES AND ANCILLARY SERVICES EFFECTIVE ON APRIL 1, 2018

CY 2018 HCPCS code	CY 2019 long descriptor	Proposed CY 2019 payment indicator
C9462	Injection, delafloxacin, 1 mg	K2
C9463	Injection, aprepitant, 1 mg	K2
C9464	Injection, rolapitant, 0.5 mg	K2
C9465	Hyaluronan or derivative, Durolane, for intra-articular injection, per dose	K2
C9466	Injection, benralizumab, 1 mg	K2
C9467	Injection, rituximab and hyaluronidase, 10 mg	K2
C9468	Injection, factor ix (antihemophilic factor, recombinant), glycopegylated, Rebinyn, 1 i.u	K2
C9469*	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg	K2
C9749	Repair of nasal vestibular lateral wall stenosis with implant(s)	J8

*HCPCS code C9469 (Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg), which was effective April 1, 2018, was deleted June 30, 2018 and replaced with HCPCS code Q9993 (Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg) effective July 1, 2018.

We are inviting public comments on these proposed payment indicators and the proposed payment rates for the new HCPCS codes that were recognized as ASC covered surgical procedures and ancillary services in April 2018 through the quarterly update CRs, as listed in Table 34 above. We are proposing to finalize their payment indicators and their payment rates in the CY 2019 OPPS/ASC final rule with comment period.

3. Proposed Treatment of New and Revised Level II HCPCS Codes Implemented in July 2018 for Which We Are Soliciting Public Comments in This Proposed Rule

In the July 2018 ASC quarterly update (Transmittal 4076, Change Request 10788, dated June 26, 2018), we added eight new Level II HCPCS codes to the list of covered ancillary services. Table 35 below lists the new HCPCS codes that are effective July 1, 2018. The proposed payment rates, where applicable, for these July codes can be found in Addendum BB to this proposed rule (which is available via the internet on the CMS website).

TABLE 35—NEW LEVEL II HCPCS CODES FOR COVERED ANCILLARY SERVICES EFFECTIVE ON JULY 1, 2018

CY 2018 HCPCS code	CY 2018 long descriptor	Proposed CY 2019 payment indicator
C9030	Injection, copanlisib, 1 mg	K2
C9032	Injection, voretigene neparvovec-rzyl, 1 billion vector genome	K2
Q5105	Injection, epoetin alfa, biosimilar, (Retacrit) (for esrd on dialysis), 100 units	K2
Q5106	Injection, epoetin alfa, biosimilar, (Retacrit) (for non-esrd use), 1000 units	K2
Q9991	Injection, buprenorphine extended-release (Sublocade), less than or equal to 100 mg	K2
Q9992	Injection, buprenorphine extended-release (Sublocade), greater than 100 mg	K2
Q9993*	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg	K2
Q9995	Injection, emicizumab-kxwh, 0.5 mg	K2

*HCPCS code C9469 (Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg), which was effective April 1, 2018, was deleted June 30, 2018 and replaced with HCPCS code Q9993 (Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg) effective July 1, 2018.

Through the July 2018 quarterly update CR, we are also implementing an ASC payment for one new Category III CPT code as an ASC covered ancillary service, effective July 1, 2018. This code is listed in Table 36 below, along with its proposed payment indicator. The CY 2019 proposed payment rate for this new Category III CPT code can be found in Addendum BB to this proposed rule (which is available via the internet on the CMS website).

TABLE 36—NEW CATEGORY III CPT CODE FOR COVERED ANCILLARY SERVICE EFFECTIVE ON JULY 1, 2018

CY 2018 HCPCS code	CY 2018 long descriptor	Proposed CY 2019 payment indicator
0508T	Pulse-echo ultrasound bone density measurement resulting in indicator of axial bone mineral density, tibia	Z2

We are inviting public comments on these proposed payment indicators and the proposed payment rates for the new Category III CPT code and Level II HCPCS codes that were or are expected to be newly recognized as ASC covered surgical procedures or covered ancillary services in July 2018 through the quarterly update CRs, as listed in Tables 34, 35 and 36 above. We are proposing to finalize their payment indicators and their payment rates in the CY 2019 OPPS/ASC final rule with comment period.

4. Proposed Process for New and Revised Level II HCPCS Codes That Will Be Effective October 1, 2018 and January 1, 2019 for Which We Will Be Soliciting Public Comments in the CY 2019 OPPS/ASC Final Rule With Comment Period

As has been our practice in the past, we incorporate those new and revised Level II HCPCS codes that are effective January 1 in the final rule with comment period, thereby updating the OPPS and the ASC payment system for the following calendar year. These codes are released to the public via the CMS HCPCS website, and also through the January OPPS quarterly update CRs. In the past, we also released new and revised Level II 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.

For CY 2019, consistent with our established policy, we are proposing that the Level II HCPCS codes that will be effective October 1, 2018, and January 1, 2019, would be flagged with comment indicator ''NI'' in Addendum B to the CY 2019 OPPS/ASC final rule with comment period to indicate that we have assigned the codes an interim OPPS payment status for CY 2019. We will invite public comments in the CY 2019 OPPS/ASC final rule with comment period on the interim status indicator and APC assignments, and payment rates for these codes that will be finalized in the CY 2020 OPPS/ASC final rule with comment period.

5. Proposed Process for Recognizing New and Revised Category I and Category III CPT Codes That Will Be Effective January 1, 2019 for Which We Are Soliciting Public Comments in This CY 2019 OPPS/ASC Proposed Rule

For new and revised CPT codes effective January 1, 2019, that were received in time to be included in this proposed rule, we are proposing APC and status indicator assignments. We will accept comments and finalize the APC and status indicator assignments in the OPPS/ASC final rule with comment period. For those new/revised CPT codes that are received too late for inclusion in this OPPS/ASC proposed rule, we may either make interim final assignments in the final rule with

comment period or possibly 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.

For the CY 2019 ASC update, the new and revised CY 2019 Category I and III CPT codes will be effective on January 1, 2019, and can be found in ASC Addendum AA and Addendum BB to this proposed rule (which are available via the internet on the CMS website). The new and revised CY 2019 Category I and III CPT codes are assigned to 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 and that comments will be accepted on the proposed payment indicator. Further, we remind readers that the CPT code descriptors that appear in Addendum AA and Addendum BB are short descriptors and do not describe the complete procedure, service, or item described by the CPT code.

Therefore, we include the 5-digit placeholder codes and their long descriptors for the new and revised CY 2019 CPT codes in Addendum O to this proposed rule (which is available via the internet on the CMS website) so that the public can comment on our proposed payment indicator assignments. The 5-digit placeholder codes can be found in Addendum O, specifically under the column labeled ''CY 2019 OPPS/ASC Proposed Rule 5-Digit Placeholder Code,'' to this proposed rule. The final CPT code numbers will be included in the CY 2019 OPPS/ASC final rule with comment period. We note that not every code listed in Addendum O is subject to comment. For the new/revised Category I and III CPT codes, we are requesting comments on only those codes that are assigned to comment indicator ''NP''.

In summary, we are soliciting public comments on the proposed CY 2019 payment indicators for the new and revised Category I and III CPT codes that will be effective January 1, 2019. The CPT codes are listed in Addendum AA and Addendum BB to this proposed rule with short descriptors only. We list them again in Addendum O to this proposed rule with long descriptors. We also are proposing to finalize the payment indicator for these codes (with their final CPT code numbers) in the CY 2019 OPPS/ASC final rule with comment period. The proposed payment indicator for these codes can be found in Addendum AA and Addendum BB to this proposed rule (which are available via the internet on the CMS website).

C. Proposed 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 list of covered surgical procedures 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 list of covered surgical procedures 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 list of 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 nonoffice-based, after taking into account updated volume and utilization data.

(2) Proposed Changes for CY 2019 to Covered Surgical Procedures Designated as Office-Based

In developing this 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 2017 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 2017, as well as for those procedures assigned one of the temporary office-based payment indicators, specifically ''P2'', ''P3'', or ''R2'' in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59406 through 59408).

Our review of the CY 2017 volume and utilization data resulted in our identification of 4 covered surgical procedures that we believe meet the criteria for designation as office-based. The data indicate that these procedures are performed more than 50 percent of the time in physicians' offices, and we believe that the services are of a level of complexity consistent with other procedures performed routinely in physicians' offices. The CPT codes that we are proposing to permanently designate as office-based for CY 2019 are listed in Table 37 below.

TABLE 37—ASC COVERED SURGICAL PROCEDURES PROPOSED TO BE NEWLY DESIGNATED AS PERMANENTLY OFFICE-BASED FOR CY 2019

CY 2019 CPT code	CY 2019 long descriptor	CY 2018 ASC payment indicator	Proposed CY 2019 ASC payment indicator *
31573	Laryngoscopy, flexible; with therapeutic injection(s) (*e.g.,* chemodenervation agent or corticosteroid, injected percutaneous, transoral, or via endoscope channel), unilateral.	G2	P3
36513	Therapeutic apheresis; for platelets	G2	R2
36902	Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, radiological supervision and interpretation and image documentation and report; with transluminal balloon angioplasty, peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty.	G2	P3
36905	Percutaneous transluminal mechanical thrombectomy and/or infusion for thrombolysis, dialysis circuit, any method, including all imaging and radiological supervision and interpretation, diagnostic angiography, fluoroscopic guidance, catheter placement(s), and intraprocedural pharmacological thrombolytic injection(s); with transluminal balloon angioplasty, peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty.	G2	P3

* Payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the MPFS proposed rates. Current law specifies a 0.25 percent update to the MPFS payment rates for CY 2019. For a discussion of the MPFS rates, we refer readers to the CY 2019 MPFS proposed rule.

We also reviewed CY 2017 volume and utilization data and other information for 10 procedures designated as temporary office-based in Tables 84 and 85 in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59408). Of these 10 procedures, there were very few claims in our data and no claims data for 4 procedures described by CPT codes 38222, 65785, 67229, and 0402T. Consequently, we are proposing to maintain the temporary office-based designations for these 4 codes for CY 2019. We list all of these codes for which we are proposing to maintain the temporary office-based designations for CY 2019 in Table 38 below. The procedures for which the proposed office-based designations for CY 2019 are temporary also were indicated by asterisks in Addendum AA to this proposed rule (which is available via the internet on the CMS website).

The volume and utilization data for the remaining six procedures that have a temporary office-based designation for CY 2018, described by CPT codes 10030, 36473, 36901, 64461, and 64463, and HCPCS code G0429, are sufficient to indicate that these procedures are performed predominantly in physicians' offices and, therefore, should be assigned an office-based payment indicator in CY 2018. Consequently, we are proposing to assign payment indicator ''P2'', ''P3'', or ''G2'' to these covered surgical procedure codes in CY 2019.

TABLE 38—PROPOSED CY 2019 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARY OFFICE-BASED IN THE CY 2018 OPPS/ASC FINAL RULE WITH COMMENT PERIOD

CY 2019 CPT/ HCPCS code	CY 2019 long descriptor	CY 2018 ASC payment indicator *	CY 2019 ASC proposed payment indicator **
38222	Diagnostic bone marrow; biopsy(ies) and aspiration(s)	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 ***
0402T	Collagen cross-linking of cornea (including removal of the corneal epithelium and intraoperative pachymetry when performed).	R2 *	R2 ***
10030	Image-guided fluid collection drainage by catheter (*e.g.,* abscess, hematoma, seroma, lymphocele, cyst), soft tissue (*e.g.,* extremity, abdominal wall, neck), percutaneous.	P2 *	G2
36473	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated.	P2 *	P3 **
36901	Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, radiological supervision and interpretation and image documentation and report.	P2 *	P3 **
64461	Paravertebral block (pvb) (paraspinous block), thoracic; single injection site (includes imaging guidance, when performed).	P3 *	G2
64463	Paravertebral block (pvb) (paraspinous block), thoracic; continuous infusion by catheter (includes imaging guidance, when performed).	P3 *	G2
G0429	Dermal filler injection(s) for the treatment of facial lipodystrophy syndrome (lds) (*e.g.,* as a result of highly active antiretroviral therapy).	P3 *	P3 **

* If designation is temporary.
** Payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the MPFS proposed rates. Current law specifies a 0.25 percent update to the MPFS payment rates for CY 2019. For a discussion of the MPFS rates, we refer readers to the CY 2019 MPFS proposed rule.

For CY 2019, we are proposing to designate 8 new CY 2019 CPT codes for ASC covered surgical procedures as temporary office-based, as displayed in Table 39 below. After reviewing the clinical characteristics, utilization, and volume of related procedure codes, we determined that the procedures described by the new CPT codes would be predominantly performed in physicians' offices. However, because we had no utilization data for the procedures specifically described by these new CPT codes, we are proposing 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 2019 is temporary are indicated by asterisks in Addendum AA to this proposed rule (which is available via the internet on the CMS website).

TABLE 39—PROPOSED CY 2019 PAYMENT INDICATORS FOR NEW CY 2019 CPT CODES FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARY OFFICE-BASED

CY 2019 OPPS/ ASC proposed rule 5-digit CMS placeholder code	CY 2019 long descriptor	Proposed CY 2019 ASC payment indicator **
06X1T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound.	R2 *
10X12	Fine needle aspiration biopsy, including ultrasound guidance; first lesion	P3 *
10X14	Fine needle aspiration biopsy, including fluoroscopic guidance; first lesion	P3 *
10X16	Fine needle aspiration biopsy, including CT guidance; first lesion	P2 *
10X18	Fine needle aspiration biopsy, including MR guidance; first lesion	R2 *
11X02	Tangential biopsy of skin (*e.g.,* shave, scoop, saucerize, curette); single lesion	P3 *
11X04	Punch biopsy of skin (including simple closure, when performed); single lesion	P3 *
11X06	Incisional biopsy of skin (*e.g.,* wedge) (including simple closure, when performed); single lesion	P3 *

* If designation is temporary.
** Payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the MPFS proposed rates. Current law specifies a 0.25 percent update to the MPFS payment rates for CY 2019. For a discussion of the MPFS rates, we refer readers to the CY 2019 MPFS proposed rule.

b. Proposed ASC Covered Surgical Procedures To Be Designated as Device-Intensive

(1) Background

As discussed in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79739 through 79740), we implemented a payment methodology for calculating the ASC payment rates for covered surgical procedures that are designated as device-intensive.

According to this ASC payment methodology, we apply 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.

We also finalized in the CY 2017 OPPS/ASC final rule that device-intensive procedures will be subject to all of the payment policies applicable to procedures designated as an ASC device-intensive procedure under our established methodology, including our policies on no cost/full credit and partial credit devices and discontinued procedures. In addition, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79739 through 79740), we adopted a policy for new HCPCS codes describing procedures involving the implantation of medical devices that do not yet have associated claims data, to designate these procedures as device-intensive with a default device offset set at 41 percent until claims data are available to establish the HCPCS code-level device offset for the procedures. This default device offset amount of 41 percent is not calculated from claims data; instead, it is applied as a default until claims data are 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 involve the implantation of medical devices would be to ensure ASC access for new procedures until claims data become available. However, in certain rare instances, for example, in the case of a very expensive implantable device, we indicated we might temporarily assign a higher offset percentage if warranted by additional information, such as pricing data from a device manufacturer. Once claims data are available for a new procedure involving the implantation of a medical device, the device-intensive designation is applied to the code if the HCPCS code device offset is greater than 40 percent, according to our policy of determining device-intensive status, by calculating the HCPCS code-level device offset.

(2) Proposed Changes to List of ASC Covered Surgical Procedures Designated as Device-Intensive for CY 2019

As discussed in section IV.B.2. of this proposed rule, for CY 2019 we are proposing to modify our criteria for device-intensive procedures to better capture costs for procedures with significant device costs. We are proposing to allow procedures that involve surgically inserted or implanted, high-cost, single-use devices to qualify as device-intensive procedures. In addition, we are proposing to modify our criteria to lower the device offset percentage threshold from 40 percent to 30 percent. Specifically, for CY 2019 and subsequent years, we are proposing 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 are proposing that the default device offset for new codes that describe procedures that involve the implantation of medical devices would 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 are proposing that the default device offset would be applied in the same manner as proposed in section IV.B.2 of this proposed rule.

In addition, as also proposed in section IV.B.2 of this proposed rule, to further align the device-intensive policy with the criteria used for device pass-through status, we are proposing to specify, 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 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:

(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).

In conjunction with our proposed modifications to the device-intensive criteria, we are proposing to amend § 416.171(b)(2) of the regulations to reflect the proposed new device criteria.

Based on our proposed modifications to our device-intensive criteria, for CY 2019, we are proposing to update the ASC list of covered surgical procedures that are eligible for payment according to our proposed device-intensive procedure payment methodology, reflecting the proposed individual HCPCS code device-offset percentages based on CY 2017 OPPS claims and cost report data available for this proposed rule.

The ASC covered surgical procedures that we are proposing to designate as device-intensive, and therefore subject to the device-intensive procedure payment methodology for CY 2019, are assigned payment indicator ''J8'' and are included in Addendum AA to this proposed rule (which is available on the CMS website). The CPT code, the CPT code short descriptor, and the proposed CY 2019 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 also are included in Addendum AA to this proposed rule. In addition, for CY 2019, we are proposing to only apply our proposed 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). Under this proposal, the payment rate under the ASC payment system for device-intensive procedures furnished without an implantable or inserted medical device would be calculated by applying the uniform ASC conversion factor to both the device portion and service (non-device) portion of the OPPS relative payment weight for the device-intensive procedure and summing both portions (device and service) to establish the ASC payment rate.

c. Proposed 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.

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 that 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.

For partial credit, we are proposing 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 would 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 would 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 policy to all device-intensive procedures.

d. Proposed Additions to the List of ASC Covered Surgical Procedures

As discussed in section XII.A.3. of this proposed rule, we are proposing to revise our definition of surgery for CY 2019 to include certain ''surgery-like'' procedures that are assigned codes outside the CPT surgical range. For CY 2019, we are proposing 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 are continuing to include in our definition of surgical procedures those described by Category I CPT codes in the surgical range from 10000 through 69999 as well as those Category III CPT codes and Level II HCPCS codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that we have determined do not pose a significant safety risk, that we would not expect to require an overnight stay when performed in ASCs, and that are separately paid under the OPPS.

We conducted a review of HCPCS codes that currently are paid under the OPPS, but not included on the ASC list of covered surgical procedures, and that meet our proposed definition of surgery to determine if changes in technology and/or medical practice affected the clinical appropriateness of these procedures for the ASC setting. Based on this review, we are proposing to update the list of ASC covered surgical procedures by adding 12 cardiac catheterization procedures to the list for CY 2019, as shown in Table 40 below. After reviewing the clinical characteristics of these procedures and consulting with stakeholders and our clinical advisors, we determined that these 12 procedures are separately paid under the OPPS, would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, and would not be expected to require active medical monitoring and care of the beneficiary at midnight following the procedure. Our regulation at 42 CFR 416.166(c) lists general exclusions from the list of ASC covered surgical procedures based 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 have assessed each of the proposed added procedures against the regulatory safety criteria and believe that these procedures meet each of the criteria. Although the proposed cardiac catheterization procedures may involve blood vessels that could be considered major, based on our review of the clinical characteristics of the procedures and their similarity to other procedures that are currently included on the ASC list of covered surgical procedures, we believe these procedures may be appropriately performed in an ASC. Therefore, we are proposing to include these 12 procedures on the list of ASC covered surgical procedures for CY 2019.

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). However, we are interested in hearing any specific safety concerns from stakeholders regarding these 12 cardiac catheterization procedures and are requesting comments on whether these procedures may be safely performed in an ASC in light of the regulatory criteria governing which procedures may be added to the ASC covered procedures list.

The procedures that we are proposing to add to the ASC list of covered surgical procedures, including the HCPCS code long descriptors and the proposed CY 2019 payment indicators, are displayed in Table 40 below.

TABLE 40—PROPOSED ADDITIONS TO THE LIST OF ASC COVERED SURGICAL PROCEDURES FOR CY 2019

CY 2019 CPT code	CY 2019 long descriptor	Proposed CY 2019 ASC payment indicator
93451	Right heart catheterization including measurement(s) of oxygen saturation and cardiac output, when performed.	G2
93452	Left heart catheterization including intraprocedural injection(s) for left ventriculography, imaging supervision and interpretation, when performed.	G2
93453	Combined right and left heart catheterization including intraprocedural injection(s) for left ventriculography, imaging supervision and interpretation, when performed.	G2
93454	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation.	G2
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.	G2
93456	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with right heart catheterization.	G2
93457	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 and right heart catheterization.	G2
93458	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed.	G2
93459	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed, catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) with bypass graft angiography.	G2
93460	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with right and left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed.	G2
93461	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with right and left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed, catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) with bypass graft angiography.	G2
93462	Left heart catheterization by transseptal puncture through intact septum or by transapical puncture (list separately in addition to code for primary procedure).	N1

e. Proposal To Review Recently-Added Procedures to the ASC Covered Procedures List

Section 1833(i)(1) of the Act requires us to specify, in consultation with appropriate medical organizations, surgical procedures that are appropriately performed on an inpatient basis in a hospital but that can be safely performed in an ASC, a CAH, or an HOPD and to review and update the list of ASC procedures at least every 2 years. As noted in section XII.C.1. of this proposed rule, we evaluate the ASC covered procedures list (ASC CPL) each year to determine whether procedures should be added or removed from the list, and changes to the list are often made in response to specific concerns raised by stakeholders. Often, when a procedure is added to the ASC CPL, the provider community has limited experience in performing the procedure on the Medicare population, even if providers have greater experience with other patient populations. Because ASCs generally provide a subset of items and services that are offered by hospitals and because Medicare beneficiaries tend to be frailer and exhibit a higher number of comorbidities than other populations, we believe it may be appropriate to reevaluate recently-added procedures.

Specifically, we are proposing to review all procedures that were added to the ASC CPL within the 3 calendar years prior to the year in which we are engaging in rulemaking to assess the safety, effectiveness, and beneficiary experience of these newly-added procedures when performed in the ASC setting. Our review will begin with procedures added to the ASC CPL in CYs 2015, 2016, and 2017, and assess whether newly-added procedures continue to meet our criteria, including whether they continue not to be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC and continue not to be expected to require active medical monitoring and care of the beneficiary at midnight following the procedure. This review would include taking into account recent clinical developments and available safety findings related to the recently-added procedures.

We are proposing to review all 38 procedures that were added to the ASC CPL for CYs 2015, 2016, and 2017. The 38 procedures that were added to the ASC CPL during this time are displayed in Table 41 below, along with their HCPCS code long descriptors, the CY 2018 payment indicators, and the calendar year that each procedure was added to the ASC CPL. We also are seeking comment about these recently-added procedures from members of the public, including Medicare beneficiaries, ASC facilities, and physicians performing these procedures in the ASC setting. In addition, we are seeking comment from the public on whether these procedures continue to meet the criteria to remain on the ASC CPL. We intend to evaluate each of these 38 procedures using all available data, including clinical characteristics, utilization reflected in ASC claims and pricing data, prevailing medical practice, and any public comments we receive to determine whether they continue to meet the criteria to be a covered surgical procedure.

In addition, we are soliciting comment regarding how our systematic review should be structured in the future, including the length of time procedures should be considered recently-added, how frequently reviews should be performed in light of the time required to accumulate meaningful data and whether any future reviews should examine procedures added during a period of time greater or less than the previous 3 completed calendar years.

TABLE 41—ADDITIONS TO THE LIST OF ASC COVERED SURGICAL PROCEDURES FOR CY 2015, 2016, AND 2017

CY 2019 CPT code	CY 2019 long descriptor	CY 2018 ASC payment indicator	Calendar year added to ASC CPL
0171T	Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar; single level.	J8	2016
0172T	Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar; each additional level.	N1	2016
20936	Autograft for spine surgery only (includes harvesting the graft); local (*e.g.,* ribs, spinous process, or laminar fragments) obtained from same incision (list separately in addition to code for primary procedure).	N1	2017
20937	Autograft for spine surgery only (includes harvesting the graft); morselized (through separate skin or fascial incision) (list separately in addition to code for primary procedure).	N1	2017
20938	Autograft for spine surgery only (includes harvesting the graft); structural, bicortical or tricortical (through separate skin or fascial incision) (list separately in addition to code for primary procedure).	N1	2017
22551	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below c2.	J8	2015
22552	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below c2, each additional interspace (list separately in addition to code for separate procedure).	N1	2017
22554	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); cervical below c2.	J8	2015
22612	Arthrodesis, posterior or posterolateral technique, single level; lumbar (with lateral transverse technique, when performed).	J8	2015
22614	Arthrodesis, posterior or posterolateral technique, single level; each additional vertebral segment (list separately in addition to code for primary procedure).	N1	2015
22840	Posterior non-segmental instrumentation (*e.g.,* harrington rod technique, pedicle fixation across 1 interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at c1, facet screw fixation) (list separately in addition to code for primary procedure).	N1	2017
22842	Posterior segmental instrumentation (*e.g.,* pedicle fixation, dual rods with multiple hooks and sublaminar wires); 3 to 6 vertebral segments (list separately in addition to code for primary procedure).	N1	2017
22845	Anterior instrumentation; 2 to 3 vertebral segments (list separately in addition to code for primary procedure).	N1	2017

TABLE 41—ADDITIONS TO THE LIST OF ASC COVERED SURGICAL PROCEDURES FOR CY 2015, 2016, AND 2017—Continued

CY 2019 CPT code	CY 2019 long descriptor	CY 2018 ASC payment indicator	Calendar year added to ASC CPL
22853	Insertion of interbody biomechanical device(s) (*e.g.,* synthetic cage, mesh) with integral anterior instrumentation for device anchoring (*e.g.,* screws, flanges), when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each interspace (list separately in addition to code for primary procedure).	N1	2017
22854	Insertion of intervertebral biomechanical device(s) (*e.g.,* synthetic cage, mesh) with integral anterior instrumentation for device anchoring (*e.g.,* screws, flanges), when performed, to vertebral corpectomy(ies) (vertebral body resection, partial or complete) defect, in conjunction with interbody arthrodesis, each contiguous defect (list separately in addition to code for primary procedure).	N1	2017
22859	Insertion of intervertebral biomechanical device(s) (*e.g.,* synthetic cage, mesh, methylmethacrylate) to intervertebral disc space or vertebral body defect without interbody arthrodesis, each contiguous defect (list separately in addition to code for primary procedure).	N1	2017
37241	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; venous, other than hemorrhage (*e.g.,* congenital or acquired venous malformations, venous and capillary hemangiomas, varices, varicoceles).	J8	2016
37242	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; arterial, other than hemorrhage or tumor (*e.g.,* congenital or acquired arterial malformations, arteriovenous malformations, arteriovenous fistulas, aneurysms, pseudoaneurysms).	J8	2016
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.	J8	2016
49406	Image-guided fluid collection drainage by catheter (*e.g.,* abscess, hematoma, seroma, lymphocele, cyst); peritoneal or retroperitoneal, percutaneous.	G2	2016
57120	Colpocleisis (le fort type)	G2	2016
57310	Closure of urethrovaginal fistula;	G2	2016
58260	Vaginal hysterectomy, for uterus 250 g or less	G2	2016
58262	Vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s)	G2	2016
58543	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g	G2	2016
58544	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s).	G2	2016
58553	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g;	G2	2016
58554	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s).	G2	2016
58573	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s).	G2	2016
63020	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, cervical.	G2	2015
63030	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, lumbar.	G2	2015
63042	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; lumbar.	G2	2015
63044	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; each additional lumbar interspace (list separately in addition to code for primary procedure).	N1	2015
63045	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [*e.g.,* spinal or lateral recess stenosis]), single vertebral segment; cervical.	G2	2015
63046	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [*e.g.,* spinal or lateral recess stenosis]), single vertebral segment; thoracic.	G2	2016
63047	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [*e.g.,* spinal or lateral recess stenosis]), single vertebral segment; lumbar.	G2	2015
63055	Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (*e.g.,* herniated intervertebral disc), single segment; thoracic.	G2	2016
63056	Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (*e.g.,* herniated intervertebral disc), single segment; lumbar (including transfacet, or lateral extraforaminal approach) (*e.g.,* far lateral herniated intervertebral disc).	G2	2015

2. Covered Ancillary Services

Consistent with the established ASC payment system policy, we are proposing to update the ASC list of covered ancillary services to reflect the payment status for the services under the CY 2019 OPPS (72 FR 42497). 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 2019. For example, if a covered ancillary service was separately paid under the ASC payment system in CY 2018, but is proposed for packaged status under the CY 2019 OPPS, to maintain consistency with the OPPS, we would also propose to package the ancillary service under the ASC payment system for CY 2019. We are proposing to continue this reconciliation of packaged status for subsequent calendar years. Comment indicator ''CH'', which is discussed in section XII.F. of this proposed rule, is used in Addendum BB to this proposed rule (which is available via the internet on the CMS website) to indicate covered ancillary services for which we are proposing a change in the ASC payment indicator to reflect a proposed change in the OPPS treatment of the service for CY 2019.

All ASC covered ancillary services and their proposed payment indicators for CY 2019 are included in Addendum BB to this proposed rule (which is available via the internet on the CMS website).

D. Proposed ASC Payment for Covered Surgical Procedures and Covered Ancillary Services

1. Proposed 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 that the packaged device payment amount is the same as under the OPPS, and only the service portion of the rate is subject to the ASC standard ratesetting methodology. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79732 through 79753), we updated the CY 2016 ASC payment rates for ASC covered surgical procedures with payment indicators of ''A2'', ''G2'', and ''J8'' using CY 2015 data, consistent with the CY 2017 OPPS update. We also updated payment rates for device-intensive procedures to incorporate the CY 2017 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 MPFS nonfacility PE RVU-based amount (we refer readers to the CY 2018 MPFS proposed and final rules) or the amount calculated using the ASC standard rate setting methodology for the procedure. In the CY 2017 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 2017 rate for each of the office-based procedures, calculated according to the ASC standard rate setting methodology, to the MPFS nonfacility PE RVU-based amount to determine which was lower and, therefore, would be the CY 2017 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 codes under the OPPS. Under the OPPS, a conditionally packaged code (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 address this concern, for the device removal procedures that are conditionally packaged in the OPPS (status indicator ''Q2''), we assigned the current ASC payment indicators associated with these procedures and continued to provide separate payment since CY 2014.

b. Proposed Update to ASC Covered Surgical Procedure Payment Rates for CY 2019

We are proposing to update ASC payment rates for CY 2019 and subsequent years using the established rate calculation methodologies under § 416.171 and using our definition of device-intensive procedures, as discussed in section XII.C.1.b. of this proposed rule. Because the proposed OPPS relative payment weights are based on geometric mean costs, the ASC system would use geometric means to determine proposed relative payment weights under the ASC standard methodology. We are proposing to continue to use the amount calculated under the ASC standard ratesetting methodology for procedures assigned payment indicators ''A2'' and ''G2''.

We are proposing 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 this proposed rule. Therefore, we are proposing 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 2019 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 2019

MPFS nonfacility PE RVU-based amount or the proposed CY 2018 ASC payment amount calculated according to the ASC standard ratesetting methodology.

As we did for CYs 2014 through 2018, for CY 2019, we are proposing 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.

2. Proposed Payment for Covered Ancillary Services

a. Background

Our payment policies under the ASC payment system for covered ancillary services 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 codes that are conditionally packaged in the OPPS (status indicators ''Q1'' and ''Q2''). Under the OPPS, a conditionally packaged code 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 always packaged (payment indictor ''N1'') under the ASC payment system (except for device removal codes, as discussed in section IV. of this 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. We generally pay for separately payable radiology services at the lower of the MPFS 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.

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 (42 CFR 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; 42 CFR 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 MPFS 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 MPFS 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. Proposed Payment for Covered Ancillary Services for CY 2019

For CY 2019 and subsequent years, we are proposing 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 2019 OPPS and ASC

payment rates and subsequent year payment rates. We also are proposing to continue to set the CY 2019 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 2019 and subsequent year payment rates.

Covered ancillary services and their proposed payment indicators for CY 2019 are listed in Addendum BB to this 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 MPFS proposed rates, the proposed payment indicators and rates set forth in this proposed rule are based on a comparison using the proposed MPFS rates effective January 1, 2019. For a discussion of the MPFS rates, we refer readers to the CY 2019 MPFS proposed rule that is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

3. Proposed CY 2019 ASC Packaging Policy for Non-Opioid Pain Management Treatments

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 expressed a variety of views on packaging under the OPPS. In the CY 2018 OPPS/ASC final rule with comment period, we summarized the comments received in response to our request (82 FR 59255). The 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. We 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, the President's Commission on Combating Drug Addiction and the Opioid Crisis (the Commission) recently recommended that CMS examine payment policies for certain drugs that function as a supply, specifically non-opioid pain management treatments. The Commission was established in 2017 to study ways to combat and treat drug abuse, addiction, and the opioid crisis. The Commission's report [47] 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 post-surgical pain. . . .'' [48] 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.'' [49] HHS also presented an Opioid Strategy in April 2017 [50] that aims, in part, to support cutting-edge research and advance the practice of pain management. On October 26, 2017, the opioid crisis was first declared a national public health emergency under Federal law [51] and this determination was renewed on April 20, 2018.[52]

In response to stakeholder comments on the CY 2018 OPPS/ASC proposed rule and in light of the recommendations regarding payment policies for certain drugs, we recently 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 HOPD and the ASC setting. Currently, as noted above, drugs that function as a supply are packaged under the OPPS and the ASC payment system, regardless of the costs of the drugs. 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 specific drugs that function as a supply over a 5-year time period (2013 through 2017) to determine whether this packaging policy has 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. 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 a supply, including Exparel (HCPCS code C9290). 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 the FDA for administration into the postsurgical site to provide postsurgical analgesia.[53] Exparel had pass-through payment status from 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. Exparel is currently the only non-opioid pain management drug that is packaged as a drug that functions as a supply when used in a surgical procedure under the OPPS and the ASC payment system.

From 2013 through 2017, there was an overall increase in the OPPS Medicare

[47] 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.*

[48] Ibid, at page 57, Recommendation 19.

[49] Ibid.

[50] Available at: *https://www.hhs.gov/about/leadership/secretary/speeches/2017-speeches/secretary-price-announces-hhs-strategy-for-fighting-opioid-crisis/index.html.*

[51] Available at: *https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html.*

[52] Available at: *https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx.*

[53] Available at: *https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/022496s000lbl.pdf.*

utilization of Exparel of approximately 229 percent (from 2.3 million units to 7.7 million units) during this 5-year time period. The total number of claims reporting Exparel increased by 222 percent (from 10,609 claims to 34,183 claims) over this time period. This increase in utilization continued, even after the 3-year drug pass-through payment period ended for this product in 2014, with 18 percent overall growth in the total number of units used from 2015 through 2017 (from 6.5 million units to 7.7 million units). The number of claims reporting Exparel increased by 21 percent during this time period (from 28,166 claims to 34,183 claims).

Thus, we have not found evidence to support the notion that the OPPS packaging policy has had an unintended consequence of discouraging the use of non-opioid treatment for postsurgical pain management in the hospital outpatient department. Therefore, based on this data analysis, we do not believe that changes are necessary under the OPPS for the packaged drug policy for drugs that function as a surgical supply when used in a surgical procedure in this setting at this time.

In terms of Exparel in particular, we have received several requests to pay separately for the drug rather than packaging payment for it as a surgical supply. In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66874 and 66875), in response to comments from stakeholders requesting separate payment for Exparel, we 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. We also stated that 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. In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59345), 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. In addition, we have reviewed recently available literature with respect to Exparel, including a briefing document [54] submitted for the 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.'' [55] On April 6, 2018, the FDA approved Exparel's new indication for use as an interscalene brachial plexus nerve block to produce postsurgical regional analgesia.[56] Based on our review of currently available OPPS Medicare claims data and public information from the manufacturer of the drug, we do not believe that the OPPS packaging policy has discouraged the use of Exparel for either of the drug's indications. Accordingly, we continue to believe it is appropriate to package payment for Exparel as we do with other postsurgical pain management drugs when it is furnished in a hospital outpatient department. However, as noted in section II.A.3.b. of this proposed rule, we are seeking comments on whether separate payment would nonetheless further incentivize appropriate use of Exparel in the hospital outpatient setting and peer-reviewed evidence that such increased utilization would lead to a decrease in opioid use and addiction among Medicare beneficiaries.

Although we found increases in utilization for Exparel when it is paid under the OPPS, we did notice different effects on Exparel utilization when examining the effects of our packaging policy under the ASC payment system. In particular, during the same 5-year period of 2013 through 2017, the total number of units of Exparel used in the ASC setting decreased by 25 percent (from 98,160 total units to 73,595 total units) and the total number of claims reporting Exparel decreased by 16 percent (from 527 claims to 441 claims). In the ASC setting, after the pass-through payment status ended for Exparel at the end of 2014, the total number of units of Exparel used decreased by 70 percent (from 244,757 units to 73,595 units) between 2015 and 2017. The total number of claims reporting Exparel also decreased during this time period by 62 percent (from 1,190 claims to 441 claims). However, there was an increase of 238 percent (from 98,160 total units to 331,348 total units) in the total number of units of Exparel used in the ASC setting during the time period of 2013–2014 when the drug received pass-through payments, which indicates that the payment rate of ASP+6 percent for Exparel may have impact on its usage in the ASC setting. The total number of claims reporting Exparel also increased during this time period from 527 total claims to 1,540 total claims, an increase of 192 percent.

While several variables may contribute to this difference between utilization and claims reporting in 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, therefore, ASCs may be less likely to choose to furnish non-opioid postsurgical pain management treatments, which are typically more expensive than opioids, as a result. 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.

In light of the results of our evaluation of packaging policies under the OPPS and the ASC payment system, which showed decreased utilization for certain drugs that function as a supply in the ASC setting in comparison to the hospital outpatient department setting, as well as the Commission's recommendation to examine payment policies for non-opioid pain management drugs that function as a supply, we believe a change in how we pay for non-opioid pain management drugs that function as surgical supplies may be warranted. In particular, we believe it may be 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, we are proposing 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 for CY 2019.

We have stated previously (82 FR 59250) that our packaging policies are designed to support our strategic goal of using larger payment bundles in the OPPS to maximize hospitals' incentives to provide care in the most efficient

[54] 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.*

[55] Ibid, page 9.

[56] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/022496s009lbledt.pdf.*

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 this proposal is a departure from our current ASC packaging policy for drugs (specifically, non-opioid pain management drugs) that function as a supply when used in a surgical procedure, we believe that this proposed change would incentivize the use of non-opioid postsurgical pain management drugs and is an appropriate response 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. However, we are also interested in peer-reviewed evidence that demonstrates that use of non-opioid alternatives, such as Exparel, in the outpatient setting actually do lead to a decrease in prescription opioid use and addiction and are seeking comments containing the types of evidence that demonstrate whether and how such non-opioid alternatives affect prescription opioid use during or after an outpatient visit or procedure.

As noted, for CY 2019, we are proposing to pay separately at average sales price (ASP) plus 6 percent for non-opioid pain management drugs that function as a supply when used in a surgical procedure when the procedure is performed in the ASC setting. As described in section V.A.1. of this proposed rule, section 1847A of the Act establishes the 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) (82 FR 59337). As noted in section V.B.2.b. of this proposed rule, since CY 2013, our policy has been 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) (82 FR 59350).

We are not proposing a change to the packaging policy under the OPPS for CY 2019. However, we are proposing to pay separately at ASP+6 percent for non-opioid pain management drugs that function as a supply when used in a surgical procedure when the procedure is performed in the ASC setting for CY 2019. Because the ASC payment rate also includes packaged payment for non-opioid pain management drugs, we intend to remove the packaged costs attributable to non-opioid pain management drugs—at this time, only Exparel qualifies—from the applicable OPPS rates prior to establishing the ASC rates in order to prevent potential overpayment of these procedures when separate payment is provided in the ASC setting.

Of the drugs that are currently packaged in the ASC setting, this policy would apply to Exparel. Exparel is the only non-opioid pain management drug that functions as a supply when used in a surgical procedure that is covered under Medicare Part B. While there are other non-opioid pain management drugs available that are also administered post-surgically, such as non-steroidal anti-inflammatory drugs (''NSAIDs''), Exparel is the currently the only drug used in the ASC setting that is both covered under Medicare Part B and policy packaged as a drug that functions as a supply in a surgical procedure. To the extent that other non-opioid drugs that function as surgical supplies come onto the U.S. market, we are proposing that this policy would apply to them as well in CY 2019. This proposal is also presented in section II.A.3.b. of this proposed rule for the OPPS. We are proposing a conforming change to the ASC regulation at 42 CFR 416.164(a)(4) to exclude non-opioid pain management drugs that function as a supply when used in a surgical procedure as an ASC service for which payment is packaged into the payment for a covered surgical procedure. We also are proposing a conforming change to 42 CFR 416.164 (b)(6) to include non-opioid pain management drugs that function as a supply when used in a surgical procedure as a covered ancillary service that is integral to a covered surgical procedure.

In addition, as noted in section II.A.3.b. of this proposed rule, we are seeking comment on whether the proposed policy would 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) as well as whether there are other non-opioid pain management alternatives that would have similar effects and may, therefore, warrant separate payment. For example, we are interested in identifying whether single post-surgical analgesic injections, such as Exparel, or other non-opioid drugs or devices that are used during an outpatient visit or procedure are associated with decreased opioid prescriptions and reduced cases of associated opioid addiction following such an outpatient visit or procedure. We are also requesting comments that provide evidence (such as published peer-reviewed literature), 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 separate payment under either or both the OPPS and the ASC payment system. The reduction or avoidance of prescription opioids would be the criteria we would seek to determine whether separate payment was warranted for CY 2019. Should evidence change over time, we would consider whether a reexamination of any policy adopted in the final rule would be necessary.

In addition, we also are inviting the public to submit ideas on regulatory, subregulatory, policy, practice, and procedural changes to help prevent opioid use disorder and improve access to treatment under the Medicare program. We are interested in identifying barriers that may inhibit access to non-opioid alternatives for pain treatment and management or access to opioid use disorder treatment, including those barriers related to payment methodologies or coverage. In addition, consistent with our ''Patients Over Paperwork'' Initiative, we also are interested in suggestions to improve existing requirements in order to more effectively address the opioid epidemic.

As noted above, and discussed in section II.A.3.b.of this proposed rule we are interested in comments regarding other non-opioid treatments for acute or chronic pain besides Exparel that might be affected by OPPS and ASC packaging policies including alternative, non-opioid pain treatments, such as devices or therapy services that are not currently separable payable. We are specifically interested in comments regarding whether CMS should consider separate payment for such items and services for which payment is currently packaged under the OPPS and ASC payment systems that are effective non-opioid alternatives as well as evidence that demonstrates such items and services lead to a decrease in prescription opioid use during or after an outpatient visit or procedure in order to determine whether separate payment may be warranted. We intend to examine the evidence submitted to determine whether to adopt a final policy that incentivizes use of non-opioid alternative items and services that have evidence to demonstrate an associated decrease in prescription opioid use and addiction following an outpatient visit

or procedure. Some examples of evidence that may be relevant could include an indication on the product's FDA label or studies published in peer-reviewed literature that such product aids in the management of acute or chronic pain and is an evidence-based non-opioid alternative for acute and/or chronic pain management. We would also be interested in evidence relating to products that have shown clinical improvement over other alternatives, such as a device that has been shown to provide a substantial clinical benefit over the standard of care for pain management. This could include, for example, spinal cord stimulators used to treat chronic pain such as the devices described by HCPCS codes C1822 (Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system), C1820 (Generator, neurostimulator (implantable), with rechargeable battery and charging system), and C1767 (Generator, neurostimulator (implantable), nonrechargeable) which are primarily assigned to APCs 5463–5464 (Levels 3 and 4 Neurostimulator and Related Procedures) with proposed CY 2019 payment rates of $18,718 and $27,662, respectively, that have received pass-through payment status as well as other similar devices.

Currently, all devices are packaged under the OPPS and ASC payment systems unless they have pass-through status, however, in light of the Commission's recommendation to review and modify ratesetting policies that discourage the use of non-opioid treatments for pain, we are interested in comments from stakeholders regarding whether, similar to the goals of the proposed payment policy for non-opioid pain management drugs that function as a supply when used in a surgical procedure, a policy of providing separate payment (rather than packaged payment) for these products, indefinitely or for a specified period of time would also incentivize the use of alternative non-opioid pain management treatments and improve access to care for non-opioid alternatives, particularly for innovative and low-volume items and services.

We are also interested in comments regarding whether we should provide separate payment for non-opioid pain management treatments or products using a mechanism such as an equitable payment adjustment under our 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. For example, we are considering whether an equitable payment adjustment in the form of an add-on payment for APCs that use a non-opioid pain management drug, device or service would be appropriate. To the extent that commenters provide evidence to support this approach being adopted, we would consider adopting a final policy, which could include regulatory changes that would allow for an exception to the packaging of certain non-passthrough devices which represent non-opioid alternatives for acute or chronic pain that have evidence to demonstrate that their use leads to a decrease in opioid prescriptions or addictions, in the final rule to effectuate such change.

Alternatively, we are interested in comments on whether a reorganization of the APC structure for procedures involving these products or establishing more granular APC groupings for specific procedure and device combinations to ensure that the payment rate for such services is aligned with the resources associated with procedures involving specific devices would better achieve our goal of incentivizing increased use of non-opioid alternatives, with the aim of reducing opioid use and subsequent addiction. For example, we would consider finalizing a policy to establish new APCs for procedures involving non-opioid pain management packaged items or services if such APC would better recognize the resources involved in furnishing such items and services and decrease or eliminate the need for prescription opioids. In addition, given the general desire to encourage provider efficiency through creating larger bundles of care and packaging items and services that are integral, ancillary, supportive, dependent, or adjunctive to a primary service, we are also seeking comment on how such alternative payment structures would continue to balance the goals of incentivizing provider efficiencies with encouraging the use of non-opioid alternatives to pain management.

Furthermore, since patients may receive opioid prescriptions following receipt of a non-opioid drug or implantation of a device, we are interested in identifying any cost implications for the patient and Medicare program caused by this potential change in policy. The implications of incentivizing non-opioid pain management drugs available for postsurgical acute pain relief during or after an outpatient visit or procedure are also of interest, including for non-opioid drugs. The goal is to encourage appropriate use of such non-opioid alternatives. This comment solicitation is also discussed in section II.A.3.b. of this proposed rule.

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 42 CFR 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 2019

We did not receive any requests for review to establish a new NTIOL class for CY 2019 by March 1, 2018, the due date published in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59416).

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 are not proposing to revise the payment adjustment amount for CY 2019.

F. Proposed 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 list of covered services 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 used 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 ''NP'' is used in the OPPS/ASC proposed rule to indicate new codes for the next calendar year for which the interim 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, as discussed in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60622). In the CY 2017 OPPS/ASC final rule with comment period, we responded to public comments and finalized the ASC treatment of all codes that were labeled with comment indicator ''NP'' in Addenda AA and BB to 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.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79748 through 79749), for CY 2017 and subsequent years, we finalized our policy to continue using the current comment indicators of ''NP'' and ''CH''.

2. Proposed ASC Payment and Comment Indicators

For CY 2019, there are 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 2018 and any new and existing Level II HCPCS codes with substantial revisions to the code descriptors for CY 2019 compared to the CY 2018 descriptors that are included in ASC Addenda AA and BB to this proposed rule are labeled with proposed comment indicator ''NP'' to indicate that these CPT and Level II HCPCS codes are open for comment as part of this proposed rule. Proposed comment indicator ''NP'' means 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 denotes that comments will be accepted on the proposed ASC payment indicator for the new code.

We will respond to public comments on ASC payment and comment indicators and finalize their ASC assignment in the CY 2019 OPPS/ASC final rule with comment period. We refer readers to Addenda DD1 and DD2 to this 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 2019 update.

G. Calculation of the Proposed ASC Payment Rates and the Proposed 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; 42 CFR 416.171(e)).

We note that we consider the term ''expenditures'' in the context of the budget neutrality requirement under section 1833(i)(2)(D)(ii) of the Act to mean expenditures from the Medicare Part B Trust Fund. We do not consider expenditures to include beneficiary coinsurance and copayments. This distinction was important for the CY 2008 ASC budget neutrality model that considered payments across the OPPS, ASC, and MPFS payment systems. However, because coinsurance is almost

always 20 percent for ASC services, this interpretation of expenditures has minimal impact for subsequent budget neutrality adjustments calculated within the revised ASC payment system.

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66857 through 66858), we set out a step-by-step illustration of the final budget neutrality adjustment calculation based on the methodology finalized in the August 2, 2007 final rule (72 FR 42521 through 42531) and as applied to updated data available for the CY 2008 OPPS/ASC final rule with comment period. The application of that methodology to the data available for the CY 2008 OPPS/ASC final rule with comment period resulted in a budget neutrality adjustment of 0.65.

For CY 2008, we adopted the OPPS relative payment weights as the ASC relative payment weights for most services and, consistent with the final policy, we calculated the CY 2008 ASC payment rates by multiplying the ASC relative payment weights by the final CY 2008 ASC conversion factor of $41.401. For covered office-based surgical procedures, covered ancillary radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents, as discussed in section XII.D.2. of this 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.

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. In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66937), we finalized a 1-year transition policy that we applied in CY 2015 for all ASCs that experienced any decrease in their actual wage index exclusively due to the implementation of the new OMB delineations. This transition does not apply in CY 2019.

Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses. 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. The attachment to OMB Bulletin No. 15–01 provides detailed information on the update to statistical areas since February 28, 2013. The updates provided in OMB Bulletin No. 15–01 are based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2012 and July 1, 2013. The complete list of statistical areas incorporating these changes is provided in the attachment to OMB Bulletin No. 15–01. According to OMB, ''[t]his bulletin establishes revised delineations for the Nation's Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas. The bulletin also provides delineations of Metropolitan Divisions as well as delineations of New England City and Town Areas.'' (A copy of this bulletin may be obtained at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2015/15-01.pdf.*)

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.

In OMB Bulletin No. 17–01, OMB announced that one Micropolitan Statistical Area now qualifies as a Metropolitan Statistical Area. The new urban CBSA is as follows:

- Twin Falls, Idaho (CBSA 46300). This CBSA is comprised of the principal city of Twin Falls, Idaho in Jerome County, Idaho and Twin Falls County, Idaho.

The OMB bulletin is available at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf.* We note that we did not have sufficient time to include this change in the computation of the proposed FY 2019 IPPS wage index. This new CBSA may affect the budget neutrality factors and wage indexes, depending on the impact of the overall payments of ASCs located in this new CBSA. We are providing below an estimate of this new area's wage index based on the average hourly wages for new CBSA 46300 and the national average hourly wages from the wage data for the proposed FY 2019 wage index (described in section III.B. of the preamble of the FY 2019 IPPS/LTCH PPS proposed rule). Currently, provider 130002 is the only hospital located in Twin Falls County, Idaho, and there are no hospitals located in Jerome County, Idaho. Thus, the proposed wage index for CBSA 46300 is calculated using the average hourly wage data for one provider (provider 130002).

	Estimated unadjusted wage index for new CBSA 46300	Estimated occupational mix adjusted wage index for new CBSA 46300
Proposed National Average Hourly Wage	42.990625267	42.948428861
Estimated CBSA Average Hourly Wage	35.833564813	38.127590025
Estimated Wage Index	0.8335	0.8878

Other than the previously described wage index, for CY 2019, the proposed CY 2019 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 No. 15–01).

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. Proposed Calculation of the ASC Payment Rates

a. Updating the ASC Relative Payment Weights for CY 2019 and Future Years

We update the ASC relative payment weights each year using the national OPPS relative payment weights (and MPFS 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 are proposing to scale the CY 2019 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 2017, we are proposing to compare the total payment using the CY 2018 ASC relative payment weights with the total payment using the CY 2019 ASC relative payment weights to take into account the changes in the OPPS relative payment weights between CY 2018 and CY 2019. We are proposing to use the ratio of CY 2018 to CY 2019 total payments (the weight scalar) to scale the ASC relative payment weights for CY 2019. The proposed CY 2019 ASC weight scalar is 0.8854 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 this proposed rule, we had available 98 percent of CY 2017 ASC claims data.

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 2017 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 this 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 2019, we calculated the proposed adjustment for the ASC payment system by using the most recent CY 2017 claims data available and estimating the difference in total payment that would be created by introducing the proposed CY 2019 ASC wage indexes. Specifically, holding CY 2017 ASC utilization, service-mix, and the proposed CY 2019 national payment rates after application of the weight scalar constant, we calculated the total adjusted payment using the CY 2018 ASC wage indexes (which would fully reflect the new OMB delineations) and the total adjusted payment using the

proposed CY 2019 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 2018 ASC wage indexes to the total adjusted payment calculated with the proposed CY 2019 ASC wage indexes and applied the resulting ratio of 1.0003 (the proposed CY 2019 ASC wage index budget neutrality adjustment) to the CY 2018 ASC conversion factor to calculate the proposed CY 2019 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 42 CFR 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 2018 OPPS/ASC rulemaking (82 FR 33668 through 33670; 59422 through 59424), we solicited and discussed comments regarding our current policy, codified at 42 CFR 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 2018 OPPS/ASC final rule with comment period, we noted that in 2008 facilities paid under the ASC payment system received approximately 65 percent of the payment that hospitals paid under the OPPS received for an average service. The differential between ASC facility payment and OPPS provider payment has continued to increase since 2008, and by 2017, facilities paid under the ASC payment system received approximately 56 percent of the payment that hospitals paid under the OPPS received for an average service. At the same time, indicators of ASC payment adequacy, such as capacity and supply of providers and providers' access to capital, suggest that Medicare beneficiaries have adequate access to ASC services.[57]

The Administration recognizes the value that ASCs may bring to the Medicare Program that results in the delivery of efficient, high-quality care to beneficiaries at a lower cost. The Administration is promoting greater price transparency across all of Medicare's payment systems. Both beneficiaries and the Medicare Program benefit from reduced expenditures when a beneficiary's clinical needs allow for a procedure to be performed in lower cost settings, such as ASCs relative to hospital outpatient departments.[58]

As articulated in the FY 2019 President's Budget, the Administration supports payment reforms that base payment on patient characteristics rather than the site of care. To that end, we are exploring ways to align payments with the costs of care and to incentivize use of the most efficient and clinically appropriate sites of care including hospital outpatient departments, ASCs, and physician offices, to the extent feasible, in future rulemaking. In the near term, however, there is concern by some stakeholders that the differential between payment updates for HOPDs and ASCs is resulting in inefficient and unnecessary shifts of care to the hospital outpatient setting and away from ASCs. We are concerned about the potential unintended consequences of using the CPI–U to update payments for ASCs, such as consolidation of ASCs or fewer physician-owned ASCs, which may contribute to higher prices; stagnation in number of ASC facilities and number of multispecialty ASC facilities; and payments being misaligned with the cost of treatment for complex patients.

We recognize commenters' belief that ASCs may incur some of the same costs that hospitals incur, which may be better reflected in the hospital market basket update than the CPI–U. Nevertheless, we recognize also that ASCs are among the only health care facilities in Medicare that do not submit cost information and therefore their rates are not updated based on a related market basket. We do not believe that the ASC cost structure is identical to the hospital cost structure for a few reasons (these differences are illustrative and not exhaustive). First, the majority of ASCs are single specialty (61 percent based on 2016 data), whereas hospitals provide a wider variety of services, and also provide inpatient care and room and board. Second, the vast majority of ASCs are for-profit and located in urban areas, whereas hospital ownership is varied and hospitals are located in more geographically diverse locations. Third, compliance with certain laws, such as the Emergency Medical Treatment and Labor Act (EMTALA), apply to hospitals and do not apply to ASCs. These differences illustrate why there is reason to believe there is a measure of misalignment between the HOPD and ASC cost structure, and should be considered when assessing the suitability of using the hospital market basket as a better proxy for ASC costs than the CPI–U.

According to commenters on last year's proposed rule, only 8.5 percent of the CPI–U inputs are related to health care, and even those inputs are based on a consumer's experience purchasing health care items, rather than a provider's experience purchasing the items necessary to furnish a health care service, and do not measure whether a facility's costs increase, such as the cost of purchasing supplies and equipment or personnel labor costs.

We also acknowledge commenters' concern that the disparity in payments between the OPPS and the ASC payment system may reduce the migration of services from the HOPD setting to the less costly ASC setting. For example, one study looked at the impact of the difference in facility fees paid to ASCs versus hospital outpatient departments on ASC growth using a fixed effects model.[59] The study found results indicating that, as ASC payments increase, patients are more likely to undergo outpatient procedures in an ASC than they are in a hospital. Another study found that the opening of an ASC in a hospital service area resulted in a decline in hospital-based outpatient surgery without increasing mortality or admission.[60] In markets where facilities opened, procedure growth at ASCs was greater than the decline in outpatient surgery use at their respective hospitals.

If a migration of services from the hospital setting to ASCs occurred, it may potentially yield savings to the Medicare program and beneficiaries if the savings from the migration of services net of any increases in total volume of services does not exceed the cost of a higher rate update factor. ASC

[57] MedPAC. Report to the Congress: March 2018.

[58] *Medicare Beneficiaries Could Save Billions if CMS Reduces Hospital Outpatient Department Payment Rates for Ambulatory Surgical Center-Approved Procedures to Ambulatory Surgical Center Payment Rates,* Department of Health and Human Services, Office of Inspector General, April 2014.

[59] Munnich EL, Parente ST. Returns to Specialization: Evidence from the Outpatient Surgery Market. Journal of Health Economics. Volume 57. January 2018.

[60] Hollenbeck BK, Dunn RL, et. al. Ambulatory Surgery Centers and Their Intended Effects on Outpatient Surgery. HSR: Health Services Research. 50:5. October 2015.

payment rates would still generally be significantly less than under the OPPS.

To the extent that it is clinically appropriate for a beneficiary to receive services in a lower cost setting, we believe it would be appropriate to continue to develop payment incentives and remove payment disincentives to facilitate this choice. While there are several factors that contribute to the divergence in payment between the two systems (which were identified in the comment solicitation on ASC payment reform in the CY 2018 OPPS/ASC rulemaking), such as different distribution of costs between hospitals and ASCs and different ratesetting methodologies between the OPPS and the ASC payment system, we believe that an alternative update factor could stabilize the differential between the OPPS payment and the ASC payment, to the extent that the CPI–U has been lower than the hospital market basket, and encourage the migration of services to lower cost settings as clinically appropriate (82 FR 59422 through 59424). In addition, we note that there are many services that can safely be performed in either the hospital setting or the ASC setting and a common rate update factor recognizes that the two provider types often compete for the same patients though patient acuity is likely higher in hospitals.

Therefore, we believe providing ASCs with the same rate update mechanism as hospitals could encourage the migration of 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. However, because physicians have a financial interest in ASCs, higher payments could also lead to greater utilization of services.[61] At the same time, we are cognizant of concerns that Medicare does not currently collect cost data from ASCs, which makes it difficult to assess payment adequacy in the same way that it is assessed for hospitals, to validate alignment between ASC and hospital cost structure, or to establish an ASC-specific market basket. Accordingly, until we have information on the ASC cost structure, we would like to balance our desire to promote migration of services away from the HOPD to ASCs where clinically appropriate with our desire to minimize increases in beneficiary out-of-pocket costs. Therefore, as described in more specific detail below, we are proposing to apply a hospital market basket update to ASCs for an interim period of 5 years but are seeking comments on ASC costs to assess whether the hospital market basket is an appropriate proxy for ASC costs. We note that the hospital market basket is collected under OMB Control No. 0938–0050 and the information collected through hospital cost reports is used, in part, to inform the calculation of the hospital market basket.

The hospital market basket update would be derived using the same hospital inpatient market basket percentage increase that we are proposing to use to derive the OPD fee increase factor as described in section II.B. of this proposed rule and is adjusted for multifactor productivity. We are proposing this payment update methodology for a 5-year period, during which we would assess whether there is a migration 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 (for example, an unnecessary increase in the overall volume of services or beneficiaries' out-of-pocket costs). We believe that 5 years would be an appropriate number of years to assess changes in the migration of services, as it should provide us enough time to confirm that trends in the data are consistent over time. We welcome comment on whether implementing the hospital market basket update for a different number of years might be more appropriate.

We are interested in commenter feedback on additional ways we can evaluate the impacts of this payment change over the 5-year period. For example, we welcome input on how we should delineate between changes in the volume of a particular service due to the higher update, versus changes in the volume of a service due to changes in enrollment, patient acuity, or utilization, and what would be an appropriate interval to measure such migration of services. 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. As previously mentioned, in response to the comment solicitation in the CY 2018 OPPS/ASC proposed rule, stakeholders indicated a willingness to work with CMS to collect cost information in the least burdensome manner (82 FR 59422 through 59424).

Therefore, for CY 2019 through 2023, in response to stakeholder concerns described in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59420 through 59421) that ASCs may incur some of the same costs that hospitals incur and that are better reflected in the hospital market basket update than the CPI–U, and including the concern that the payment differentials between the different settings of care due to the use of the CPI–U may stagnate the migration of services from hospitals to the ASC setting, even though those services can be safely performed in ASCs, we are proposing to update ASC payment rates using the hospital market basket and to revise our regulations under 42 CFR 416.171(a)(2), which address the annual update to the ASC conversion factor, to reflect this proposal. In addition, we are requesting comments and evidence to assess whether the hospital market basket is an appropriate proxy for ASC costs. Under this proposal, for CY 2019, we would use the proposed FY 2019 hospital market basket update as published in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20381). This proposed update to ASC payment rates would be derived using the same hospital inpatient market basket percentage increase that we are proposing to use to derive the OPD fee increase factor as described in section II.B. of this proposed rule. We also are seeking comments on an alternative proposal to maintain CPI–U while collecting evidence to justify a different payent pdate, or adopting the new proposed payhment update based on the hospital market basket permanently. We are requesting comments on what type of evidence should be used to justify a different payment update and how CMS should go about collecting that information in the least burdensome way possible.

Section 1833(t)(3)(G)(v) of the Act applies an additional adjustment of 0.75 for CY 2019 to hospitals. We note that such adjustment was authorized by the Affordable Care Act and that, while the Affordable Care Act authorized a productivity adjustment for ASCs (as it did for hospitals), it expressly did not authorize the ''additional adjustment'' that was mandated for hospitals. The additional adjustment is separate and distinct from the productivity adjustment that already applies to both hospitals and ASCs and there does not appear to be a correlation between the productivity adjustment and the additional adjustment. Further, application of the additional adjustment may be contrary to the goals we have

[61] Munnich EL, Parente ST. Returns to Specialization: Evidence from the Outpatient Surgery Market. Journal of Health Economics. Volume 57. January 2018.

articulated that led us to propose to apply the hospital market basket to the ASC payment system in the first place; that is, we believe that proposing to apply the hospital market basket to ASC rates may encourage the migration of services from the hospital setting to the ASC setting. However, if we were to propose to apply the additional adjustment, the ASC rate update would be 1.25 percent, instead of the proposed 2.0 percent. The 1.25 percent is lower than applying the CPI–U rate update factor, which would have been 1.3 percent for CY 2019. This lower update would appear contrary to the goals set forth earlier in this section. However, we are seeking comment on whether applying this additional adjustment may nonetheless be appropriate.

While we expect this proposal would increase spending, by both the government and beneficiaries, relative to the current update factor over the 5-year period, as previously stated, we believe that the proposal could encourage the migration of services that are currently performed in the hospital outpatient setting to the ASC setting, which could result in savings to beneficiaries and the Medicare program. We believe that it is important to maximize patient choice to obtain services at a lower cost to the extent feasible. We believe also that without cost data from ASCs to examine their cost structure and adequacy of payment, we lack key data that may help inform the development of payment policies that are based on patients' clinical needs rather than the site of care.

If, after review of all comments and all available evidence, we choose to finalize this proposal, we will continue to monitor site-of-service shifts for the duration of this policy to determine if services move safely to lower cost settings and to explore collecting additional data that may help inform further development of the ASC payment system. We are proposing to continue to use the adjusted hospital market basket update through CY 2023 (for 5 years total). We intend to reassess whether application of the hospital market basket update to ASC rates has provided more patient choice to obtain services at a lower cost beginning with the CY 2024 rulemaking period, or sooner if appropriate. Section 3401(k) of the Affordable Care Act amended section 1833(i)(2)(D) of the Act by adding a new clause (v), which requires that any annual update under the ASC payment system for the year, after application of clause (iv), shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, effective with the calendar year beginning January 1, 2011. The statute 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) (the ''MFP adjustment''). Clause (iv) of section 1833(i)(2)(D) of the Act authorizes the Secretary to provide for a reduction in any annual update for failure to report on quality measures. Clause (v) of section 1833(i)(2)(D) of the Act states that application of the MFP adjustment to the ASC payment system may result in the update to the ASC payment system being less than zero for a year and may result in payment rates under the ASC payment system for a year being less than such payment rates for the preceding year.

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74516), we finalized a policy that ASCs begin submitting data on quality measures for services beginning on October 1, 2012 for the CY 2014 payment determination under the ASC Quality Reporting (ASCQR) Program. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499 through 68500), we finalized a methodology to calculate 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 the CY 2014 payment determination and subsequent years. The application of the 2.0 percentage point reduction to the annual update factor, which we are proposing to be the hospital market basket update, may result in the update to the ASC payment system being less than zero for a year for ASCs that fail to meet the ASCQR Program requirements. We amended §§ 416.160(a)(1) and 416.171 to reflect these policies.

In prior years, in accordance with section 1833(i)(2)(C)(i) of the Act, before applying the MFP adjustment, the Secretary first determined the ''percentage increase'' in the CPI–U, which we interpreted cannot be a negative percentage. Thus, in the instance where the percentage change in the CPI–U for a year was negative, we would hold the CPI–U update factor for the ASC payment system to zero (75 FR 72062). Consistent with past practice, in the instance where the percentage change in the hospital market basket for a year is negative, we are proposing to hold the hospital market basket update factor for the ASC payment system to zero. For the CY 2014 payment determination and subsequent years, under section 1833(i)(2)(D)(iv) of the Act, we would reduce the annual update by 2.0 percentage points for an ASC that fails to submit quality information under the policies established by the Secretary in accordance with section 1833(i)(7) of the Act.

Section 1833(i)(2)(D)(v) of the Act, as added by section 3401(k) of the Affordable Care Act, requires that the Secretary reduce the annual update factor, after application of any quality reporting reduction, by the MFP adjustment, and states that application of the MFP adjustment to the annual update factor after application of any quality reporting reduction may result in the update being less than zero for a year. If the application of the MFP adjustment to the annual update factor after application of any quality reporting reduction would result in an MFP-adjusted update factor that is less than zero, the resulting update to the ASC payment rates would be negative and payments would decrease relative to the prior year. We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72062 through 72064) for examples of how the MFP adjustment is applied to the ASC payment system.

For this proposed rule, as published in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20381), based on IHS Global Inc.'s (IGI's) 2017 fourth quarter forecast with historical data through the third quarter of 2017, the hospital market basket update for CY 2019 is projected to be 2.8 percent.

We finalized the methodology for calculating the MFP adjustment in the CY 2011 MPFS final rule with comment period (75 FR 73394 through 73396) and revised it in the CY 2012 MPFS 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). For this proposed rule, as published in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20382) based on IGI's 2017 fourth quarter forecast, the proposed MFP adjustment for CY 2019 is projected to be 0.8 percent.

We note that the update factor for CY 2019 under the current policy, which is to increase the payment amounts by the percentage increase in the CPI–U, U.S. city average, as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved, is currently projected to be 2.1 percent (based on IGI's first quarter 2018 forecast). If we were to derive the MFP adjustment that aligns with this

payment update under current policy (ending with the midpoint of the year involved), the MFP adjustment is projected to be 0.8 percent, which would lead to a proposed update amount of 1.3 percent.

For CY 2019, we are proposing to utilize the hospital market basket update of 2.8 percent minus the MFP adjustment of 0.8 percentage point, resulting in an MFP-adjusted hospital market basket update factor of 2.0 percent for ASCs meeting the quality reporting requirements. Therefore, we are proposing to apply a 2.0 percent MFP-adjusted hospital market basket update factor to the CY 2018 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the CY 2019 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 are proposing to utilize the hospital market basket update of 2.8 percent by 2.0 percentage points for ASCs that do not meet the quality reporting requirements and then subtract the 0.8 percentage point MFP adjustment. Therefore, we are proposing to apply a 0.0 percent MFP-adjusted hospital market basket update factor to the CY 2018 ASC conversion factor for ASCs not meeting the quality reporting requirements. We also are proposing 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 2019 ASC update for the final rule with comment period.

For CY 2019, we are proposing to adjust the CY 2018 ASC conversion factor ($45.575) by the proposed wage index budget neutrality factor of 1.0003 in addition to the MFP-adjusted hospital market basket update factor of 2.0 percent discussed above, which results in a proposed CY 2019 ASC conversion factor of $46.500 for ASCs meeting the quality reporting requirements. For ASCs not meeting the quality reporting requirements, we proposed to adjust the CY 2018 ASC conversion factor ($45.575) by the proposed wage index budget neutrality factor of 1.0003 in addition to the quality reporting/MFP-adjusted hospital market basket update factor of 0.0 percent discussed above, which results in a proposed CY 2019 ASC conversion factor of $45.589.

3. Display of Proposed CY 2019 ASC Payment Rates

Addenda AA and BB to this proposed rule (which are available on the CMS website) display the proposed updated ASC payment rates for CY 2019 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 proposed rates, the proposed payment indicators and rates set forth in this proposed rule are based on a comparison using the proposed MPFS rates that would be effective January 1, 2019. For a discussion of the MPFS rates, we refer readers to the CY 2019 MPFS proposed rule.

The proposed payment rates included in these addenda 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 2019 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 2018. 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 ''Proposed CY 2019 Payment Weight'' are the proposed relative payment weights for each of the listed services for CY 2019. 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.

To derive the proposed CY 2019 payment rate displayed in the ''Proposed CY 2019 Payment Rate'' column, each ASC payment weight in the ''Proposed CY 2019 Payment Weight'' column was multiplied by the proposed CY 2019 conversion factor of $46.500. The proposed 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 (as discussed in section XII.G.2.b. of this proposed rule). In Addendum BB, there are no relative payment weights displayed in the ''Proposed CY 2019 Payment Weight'' column for items and services with predetermined national payment amounts, such as separately payable drugs and biologicals. The ''Proposed CY 2019 Payment'' column displays the proposed CY 2019 national unadjusted ASC payment rates for all items and services. The proposed CY 2019 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 April 2018.

Addendum EE provides the HCPCS codes and short descriptors for surgical procedures that are proposed to be excluded from payment in ASCs for CY 2019.

XIII. 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). In addition to the Hospital IQR and Hospital OQR Programs, CMS has implemented quality reporting programs as well as value-based purchasing programs for other care settings.

We refer readers to section I.A.2. of this proposed rule where we discuss our new 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 2018 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; and 81 FR 79753 through 79797; 82 FR 59424 through 59445). We have also codified certain requirements under the Hospital OQR Program at 42 CFR 419.46.

4. Meaningful Measures Initiative

In this proposed rule, we are proposing a number of new policies for the Hospital OQR Program. We developed these proposals after conducting an overall review of the program under our new Meaningful Measures Initiative, which is discussed in more detail in section I.A.2. of this proposed rule. The proposals reflect our efforts to ensure that the Hospital OQR Program measure set continues to promote improved health outcomes for our beneficiaries while minimizing costs, which can consist of several different types of costs including, but not limited to: (1) Facility information collection burden and related cost and burden associated with the submitting/reporting of quality measures to CMS; (2) the facility cost associated with complying with other quality programmatic requirements; (3) the facility cost associated with participating in multiple quality programs, and tracking multiple similar or duplicative measures within or across those programs; (4) the CMS cost associated with the program oversight of the measure, including measure maintenance and public display; and (5) the facility cost associated with compliance with other federal and/or State regulations (if applicable). They also reflect our efforts to improve the usefulness of the data that we publicly report in the Hospital OQR Program. Our goal is to improve the usefulness and usability of CMS quality program data by streamlining how facilities are reporting and accessing data, while maintaining or improving consumer understanding of the data publicly reported on a *Compare* website. We believe this framework will allow hospitals and patients to continue to obtain meaningful information about HOPD performance and incentivize quality improvement while also streamlining the measure sets to reduce duplicative measures and program complexity so that the costs to hospitals associated with participating in this program do not outweigh the benefits of improving beneficiary care.

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 are not proposing any changes to these policies.

2. Accounting for Social Risk Factors in the Hospital OQR Program

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59425 through 59427), we discussed the importance of improving beneficiary outcomes including reducing health disparities. We also discussed our commitment to ensuring that medically complex patients, as well as those with social risk factors, receive excellent care. We discussed how studies show that social risk factors, such as being near or below the poverty level as determined by HHS, belonging to a racial or ethnic minority group, or living with a disability, can be associated with poor health outcomes and how some of this disparity is related to the quality of health care.[62] Among our core objectives, we aim to improve health outcomes, attain health equity for all beneficiaries, and ensure that complex patients as well as those with social risk factors receive excellent care. Within this context, reports by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the National Academy of Medicine have examined the influence of social risk factors in CMS value-based purchasing programs.[63] As we noted in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59425), ASPE's report to Congress found that, in the context of value-based purchasing programs, dual eligibility was the most powerful predictor of poor health care outcomes among those social risk factors that they examined and tested. In addition, as we noted in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59425), the National Quality Forum (NQF) undertook a 2-year trial period in which certain new measures and measures undergoing maintenance review have been assessed to determine if risk adjustment for social risk factors is appropriate for these measures.[64] The trial period ended in April 2017 and a final report is available at: *http://www.qualityforum.org/SES_Trial_Period.aspx*. The trial concluded that ''measures with a conceptual basis for adjustment generally did not demonstrate an empirical relationship'' between social risk factors and the outcomes measured. This discrepancy may be explained in part by the methods used for adjustment and the limited availability of robust data on social risk factors. NQF has extended the socioeconomic status (SES) trial,[65]

[62] See, for example United States Department of Health and Human Services. ''Healthy People 2020: Disparities. 2014.'' Available at: *http://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities;* or National Academies of Sciences, Engineering, and Medicine. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: National Academies of Sciences, Engineering, and Medicine 2016.

[63] Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE), ''Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs.'' December 2016. Available at: *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[64] National Quality Forum. Final Report-Disparities Project. September 2017. Available at: *http://www.qualityforum.org/SES_Trial_Period.aspx.*

[65] National Quality Forum. Health Equity Program: Social Risk Initiative 2.0. 2017. Available

allowing further examination of social risk factors in outcome measures.

In the FY 2018 and CY 2018 proposed rules for our quality reporting and value-based purchasing programs, we solicited feedback on which social risk factors provide the most valuable information to stakeholders and the methodology for illuminating differences in outcomes rates among patient groups within a hospital or facility that would also allow for a comparison of those differences, or disparities, across facilities. Feedback we received through our quality reporting programs included encouraging CMS to explore whether factors that could be used to stratify or risk adjust the measures (beyond dual eligibility); considering the full range of differences in patients' backgrounds that might affect outcomes; exploring risk adjustment approaches; and offering careful consideration of what type of information display would be most useful to the public. We also sought public comment on confidential reporting and future public reporting of some of our measures stratified by patient dual eligibility. In general, commenters noted that stratified measures could serve as tools for hospitals to identify gaps in outcomes for different groups of patients, improve the quality of health care for all patients, and empower beneficiaries and other consumers to make informed decisions about health care. Commenters encouraged us to stratify measures by other social risk factors such as age, income, and educational attainment. With regard to value-based purchasing programs, commenters also cautioned to balance fair and equitable payment while avoiding payment penalties that mask health disparities or discourage the provision of care to more medically complex patients. Commenters also noted that value-based purchasing program measure selection, domain weighting, performance scoring, and payment methodology must account for social risk.

As a next step, CMS is considering options to reduce health disparities among patient groups within and across health care settings by increasing the transparency of disparities as shown by quality measures. We also are considering how this work applies to other CMS quality programs in the future. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38403 through 38409) for more details, where we discuss the potential stratification of certain Hospital IQR Program outcome measures. Furthermore, we continue to consider options to address equity and disparities in our value-based purchasing programs.

We plan to continue working with ASPE, the public, and other key stakeholders on this important issue to identify policy solutions that achieve the goals of attaining health equity for all beneficiaries and minimizing unintended consequences.

3. 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). Thus, quality measures adopted in a previous year's rulemaking are retained in the Hospital OQR Program for use in subsequent years unless otherwise specified. We refer readers to that final rule with comment period for more information. We are not proposing any changes to our retention policy; however, we are proposing to codify this policy at proposed 42 CFR 419.46(h)(1).

4. Removal of Quality Measures From the Hospital OQR Program Measure Set

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60315), 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.[66] We are not proposing any changes to this policy; however, we are proposing to codify this policy at 42 CFR 419.46(h)(3). We refer readers to section XIII.B.4.a. of this proposed rule for more details.

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 raise patient safety concerns.[67] We are not proposing any changes to our policy to immediately remove measures as a result of patient safety concerns; however, we are proposing to codify that policy at 42 CFR 419.46(h)(2).

(2) Consideration Factors for Removing Measures

In the CY 2013 OPPS/ASC final rule with comment period, we finalized a set of factors[68] for determining whether to remove measures from the Hospital OQR Program (77 FR 68472 through 68473). These factors are:

- Factor 1. Measure performance among hospitals 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 such as patient harm.

In addition, we refer readers to the CY 2015 OPPS/ASC final rule with comment period where we finalized the criteria for determining when a measure is ''topped-out'' (79 FR 66769). In that final rule with comment period, we finalized two criteria for determining when a measure is ''topped out'' under the Hospital OQR Program: (1) When there is statistically indistinguishable performance at the 75th and 90th percentiles of national facility performance; and (2) when the measure's truncated coefficient of variation (TCOV) is less than or equal to 0.10 (79 FR 66942).

The benefits of removing a measure from the Hospital OQR Program are

at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86357.*

[66] 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.

[67] 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.

[68] 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.

assessed on a case-by-case basis (79 FR 66941 through 66942). We note that, under this case-by-case approach, a measure will not be removed solely on the basis of meeting any specific factor. We note that in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66967), a similar measure removal policy was finalized for the ASCQR Program. In this proposed rule, we are proposing to: (1) Update measure removal Factor 7; (2) add a new removal Factor 8; and (3) codify our measure removal policies and factors at 42 CFR 419.46(h) effective upon finalization of the CY 2019 OPPS/ASC final rule and for subsequent years. We also are providing clarification of our ''topped-out'' criteria.

(3) Proposed Update to Measure Removal Factor 7

As shown above, Factor 7 under the Hospital OQR Program states, ''collection or public reporting of a measure leads to negative unintended consequences *such as* patient harm.'' In contrast, under the ASCQR Program, Factor 7 reads as follows, ''collection or public reporting of a measure leads to negative unintended consequences *other than* patient harm'' (79 FR 66967). We believe the wording in the ASCQR Program is more appropriate because measures causing patient harm would be removed from the program immediately, outside of rulemaking, in accordance with our previously finalized policy to immediately remove measures as a result of patient safety concerns (74 FR 60634 and discussed above). Therefore, in this proposed rule, we are proposing to change measure removal Factor 7 in the Hospital OQR Program to ''collection or public reporting of a measure leads to negative unintended consequences other than patient harm'' such that it aligns with measure removal Factor 7 in the ASCQR Program.

(4) Proposed New Measure Removal Factor 8

We are proposing to adopt an additional factor to consider when evaluating measures for removal from the Hospital OQR Program measure set:

- Factor 8. The costs associated with a measure outweigh the benefit of its continued use in the program.

As we discuss in section I.A.2. of this proposed rule with respect to our new Meaningful Measures Initiative, we are engaging in efforts to ensure that the Hospital OQR Program measure set continues to promote improved health outcomes for beneficiaries while minimizing the overall costs associated with the program. We believe these costs are multifaceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining the program. We have identified several different types of costs, including, but not limited to: (1) Facility information collection burden and related costs and burden associated with the submission/reporting of quality measures to CMS; (2) the facility cost associated with complying with other programmatic requirements; (3) the facility cost associated with participating in multiple quality programs and tracking multiple similar or duplicative measures within or across those programs; (4) the CMS cost associated with the program oversight of the measure including measure maintenance and public display; and (5) the facility cost associated with compliance with other Federal and State regulations (if applicable). For example, it may be needlessly costly and/or of limited benefit to retain or maintain a measure which our analyses show no longer meaningfully supports program objectives (for example, informing beneficiary choice or payment scoring). It may also be costly for health care providers to track confidential feedback, preview reports, and publicly reported information on a measure where we use the measure in more than one program. CMS may also have to expend unnecessary resources to maintain the specifications for the measure, as well as the tools needed to collect, validate, analyze, and publicly report the measure data. Furthermore, beneficiaries may find it confusing to see public reporting on the same measure in different programs.

In weighing the costs against the benefits, we evaluate the benefits of the measure, but, we assess the benefits through the framework of our Meaningful Measures Initiative, as we discussed in section I.A.2. of this proposed rule. One key aspect of patient benefits is assessing the improved beneficiary health outcomes if a measure is retained in our measure set. We believe that these benefits are multifaceted, and are illustrated through the Meaningful Measures framework's 6 domains and 19 areas. For example, we assessed the Healthcare Worker Influenza Vaccination and patient Influenza Vaccination measures categorized in the Quality Priority ''Promote Effective Prevention and Treatment of Chronic Disease'' in the meaningful measure area of ''Preventive Care'' across multiple CMS programs, and considered: patient outcomes, such as mortality and hospitalizations associated with influenza; CMS measure performance in a program; and other available and reported influenza process measures, such as population influenza vaccination coverage.

When these costs outweigh the evidence supporting the benefits to patients with the continued use of a measure in the Hospital OQR Program, we believe it may be appropriate to remove the measure from the program. Although we recognize that one of the main goals of the Hospital OQR Program is to improve beneficiary outcomes by incentivizing health care facilities to focus on specific care issues and making public data related to those issues, we also recognize that those goals can have limited utility where, for example, the publicly reported data (including percentage payment adjustment data) is of limited use because it cannot be easily interpreted by beneficiaries, and used to inform their choice of facility. In these cases, removing the measure from the Hospital OQR Program may better accommodate the costs of program administration and compliance without sacrificing improved health outcomes and beneficiary choice.

We are proposing that we would remove measures based on this factor on a case-by-case basis. We might, for example, decide to retain a measure that is burdensome for health care facilities to report if we conclude that the benefit to beneficiaries justifies the reporting burden. Our goal is to move the program forward in the least burdensome manner possible, while maintaining a parsimonious set of meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients. We are inviting public comment on our proposal to adopt an additional measure removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program, beginning with the effective date of the CY 2019 OPPS/ASC final rule with comment period and for subsequent years.

We refer readers to section XIII.B.4.b. of this proposed rule, where we are proposing to remove two measures based on this proposed measure removal factor. We note that we have also proposed this same removal factor for the ASCQR Program in section XIV.B.3.b. of this proposed rule, as well as for other quality reporting and value-based purchasing programs for FY 2019 including: the Hospital Value-Based Purchasing (VBP) Program (83 FR 20409), the Hospital IQR Program (83 FR 20472); the PPS-exempt Cancer Hospital Quality Reporting (PCHQR) Program (83 FR 20501 through 20502); the Long-Term Care Hospital Quality

Reporting Program (LTCH QRP) (83 FR 20512); the Hospice Quality Reporting Program (HQRP) (83 FR 20956); the Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP) (83 FR 21000); the Skilled Nursing Facility Quality Reporting Program (SNF QRP) (83 FR 21082); and the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program (83 FR 21118).

If our proposals to update one and add one new removal factor are finalized as proposed, the new removal factors list would be:

- Factor 1. Measure performance among hospitals 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.
- Factor 8. The costs associated with a measure outweigh the benefit of its continued use in the program.

(5) Proposed Codification at 42 CFR 419.46(h)(2) and (3)

We are proposing to codify our measure removal policies, including proposals made in this rule, in proposed 42 CFR 419.46(h)(2) and (3).

(6) Clarification of Removal Factor 1: ''Topped-Out'' Measures

As noted above, we refer readers to the CY 2015 OPPS/ASC final rule with comment period where we finalized the criteria for determining when a measure is ''topped-out'' (79 FR 66769). In that final rule with comment period, we finalized two criteria for determining when a measure is ''topped out'' under the Hospital OQR Program: (1) When there is statistically indistinguishable performance at the 75th and 90th percentiles of national facility performance; and (2) when the measure's truncated coefficient of variation (TCOV) is less than or equal to 0.10 (79 FR 66942).

In this proposed rule, we are clarifying our process for calculating the truncated coefficient of variation (TCOV), particularly for two of the measures (OP–11 and OP–14) proposed for removal from the Hospital OQR Program. In accordance with our finalized methodology (79 FR 66942), we determine the truncated coefficient of variation (TCOV) by calculating the truncated standard deviation (SD) divided by the truncated mean. As discussed above, our finalized removal criteria state that to be considered ''topped-out,'' a measure must have a truncated TCOV of less than 0.10. We utilize the TCOV because it is generally a good measure of variability and provides a relative methodology for comparing different types of measures.

Unlike the majority of the measures, for which a higher rate (indicating a higher proportion of a desired event) is the preferred outcome, some measures—in particular, OP–11 and OP–14—assess the rate of rare, undesired events for which a lower rate is preferred. For example, OP–11 assesses the use of both a contrast and non-contrast CT Thorax study at the same time, which is not recommended, as no clinical guidelines or peer-reviewed literature supports such CT Thorax ''combined studies.'' However, when determining the TCOV for a measure assessing rare, undesired events, the mean–or average rate of event occurrence–is very low, and the result is a TCOV that increases rapidly and approaches infinity as the proportion of rare events declines.[69] We note that the SD, the variability statistic, is the same in magnitude for measures assessing rare and nonrare events.

In this proposed rule, we are proposing to remove two measures that assess the rate of rare, undesired events for which a lower rate is preferred—OP–11 and OP–14—and refer readers to section XIII.B.4.b. of this proposed rule, where these proposals are discussed in detail. Because by design these measures have maintained very low rates of rare, undesired events (indicating the preferred outcomes), we utilized the mean of *non-adverse* events in our calculation of the TCOV. For example, for OP–11, to calculate the TCOV, we divide the SD by the average rate of patients *not* receiving both contrast and non-contrast abdominal CT (1.0 minus the rate of patients receiving both), rather than the rate of those receiving both types of CT. Utilizing this methodology results in a TCOV that is comparable to that calculated for other measures and allows us to assess rare-event measures by still generally using our previously finalized topped-out criteria.

[69] Rose-Hulman Institute of Technology. Denominator approaching zero. Available at: *https://www.rose-hulman.edu/media/89584/lclimitsguide.pdf.*

b. Proposed Removal of Quality Measures from the Hospital OQR Program Measure Set

In this proposed rule, we are proposing to remove a total of 10 measures from the Hospital OQR Program measure set across the CY 2020 and CY 2021 payment determinations. Specifically, beginning with the CY 2020 payment determination, we are proposing to remove (1) OP–27: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431); and beginning with the CY 2021 payment determination, we are proposing to remove—(2) OP–5: Median Time to ECG (NQF #0289); (3) OP 31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536); (4) OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658); (5) OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use (NQF #0659); (6) OP–9: Mammography Follow-up Rates (no NQF number); (7) OP–11: Thorax Computed Tomography (CT)—Use of Contrast Material (NQF #0513); (8) OP–12: The Ability for Providers with HIT (Health Information Technology) to Receive Laboratory Data Electronically Directly into Their Qualified/Certified EHR System as Discrete Searchable Data (NQF endorsement removed); (9) OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT (no NQF number); and (10) OP–17: Tracking Clinical Results between Visits (NQF endorsement removed). We are proposing to remove these measures under the following removal factors: proposed measure removal Factor 8—the costs associated with a measure outweigh the benefit of its continued use in the program; measure removal Factor 3—a measure does not align with current clinical guidelines or practice; measure removal Factor 1—measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped-out'' measures); and measure removal Factor 2—performance or improvement on a measure does not result in better patient outcomes. These

proposed measure removals are discussed in detail below.

(1) Proposed Measure Removal for the CY 2020 Payment Determination and Subsequent Years—Proposed Removal of OP–27: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431)

For the CY 2020 payment determination and subsequent years, we are proposing to remove one NHSN measure under proposed measure removal Factor 8, the costs associated with this measure outweigh the benefit of its continued use in the program.

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75099), where we adopted OP–27: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431), beginning with the CY 2016 payment determination and for subsequent years. This process-of-care measure, also a National Healthcare Safety Network (NHSN) measure, assesses the percentage of healthcare personnel who have been immunized for influenza during the flu season. We initially adopted this measure based on our recognition that influenza immunization is an important public health issue and vital component to preventing healthcare associated infections. We believe that the measure addresses this public health concern by assessing influenza vaccination in the HOPD among health care personnel (HCP), who can serve as vectors for influenza transmission.

In this proposed rule, we are proposing to remove OP–27, beginning with the CY 2020 payment determination under our proposed measure removal Factor 8 because we have concluded that the costs associated with this measure outweigh the benefit of its continued use in the program.

The information collection burden for the Influenza Vaccination Coverage Among Healthcare Personnel measure is less than for measures that require chart-abstraction of patient data because influenza vaccination among healthcare personnel can be calculated through review of records maintained in administrative systems and because facilities have fewer healthcare personnel than patients. As such, OP–27 does not require review of as many records. However, this measure does still pose information collection burden on facilities due to the requirement to identify personnel who have been vaccinated against influenza and for those not vaccinated, the reason why.

Furthermore, as we stated in section XIII.B.4.a. of this proposed rule, costs are multi-faceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining the program. For example, it may be costly for health care providers to maintain general administrative knowledge to report these measures. In addition, CMS must expend resources in maintaining information collection systems, analyzing reported data, and providing public reporting of the collected information.

In our analysis of the Hospital OQR Program measure set, we recognized that some facilities face challenges with respect to the administrative requirements of the NHSN in their reporting of the Influenza Vaccination Coverage Among Healthcare Personnel measure. These administrative requirements (which are unique to NHSN) include annually completing NHSN system user authentication. Enrolling in NHSN is a five-step process that the Centers for Disease Control and Prevention (CDC) estimates takes an average of 263 minutes per facility.[70]

Furthermore, submission via NHSN requires the system security administrator of participating facilities to re-consent electronically, ensure that contact information is kept current, ensure that the hospital has an active facility administrator account, keep Secure Access Management Service (SAMS) credentials active by logging in approximately every 2 months and changing their password, create a monthly reporting plan, and ensure the facility's CCN information is up-to-date. Unlike acute care hospital which participate in other quality programs, such as the Hospital IQR and HAC Reduction Programs, HOPDs are only required to participate in NHSN to submit data for this one measure. In our assessment, we also considered that the vast majority (99.7 percent) of Hospital OQR Program eligible hospitals already report this measure in the Hospital IQR Program for workers providing any services to inpatient care. The Hospital IQR Program measure includes the vast majority of all hospital personnel, since many workers in outpatient departments provide services to both inpatient and outpatient departments (adopted at 76 FR 51631 through 51633). These workers include most emergency department clinicians, specialists such as pharmacists and imaging professionals, and custodians and other support staff working across the hospital.

We continue to believe that the OP–27: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) measure provides the benefit of protecting patients against influenza. However, we believe that these benefits are offset by other efforts to reduce influenza infection among patients, such as numerous healthcare employer requirements for health care personnel to be vaccinated against influenza.[71] We also expect that a portion of MIPS-eligible clinicians nationwide will report on the Preventive Care and Screening: Influenza Immunization measure through the Quality Payment Program (QPP).[72] Although MIPS-eligible clinicians may voluntarily select measures from a list of options, HOPD providers that are MIPS-eligible will have the opportunity to continue collecting information for the measure. We remain responsive to the public health concern of influenza infection within the Medicare FFS population by collecting data on rates of influenza immunization among patients.[73] Thus, the public health concern of influenza immunization is addressed via these other efforts to track influenza vaccination. The availability of this measure in another CMS program demonstrates CMS' continued commitment to this measure area. In addition, as we discuss in section XIII.B.4.a of this proposed rule, where we are proposing to adopt measure removal Factor 8, beneficiaries may find it confusing to see public reporting on the same measure in different programs.

We wish to minimize the level of cost of our programs for participating facilities, as discussed under the Meaningful Measures Initiative, described in section I.A.2. of this proposed rule. In our assessment of the Hospital OQR Program measure set, we prioritized measures that align with this Initiative's framework as the most important to the Hospital OQR Program's population. Our assessment concluded that while the OP–27 measure continues to provide benefits, these benefits are diminished by other factors and are outweighed by the costs and burdens of reporting this chart-abstracted measure.

[70] CDC, National Healthcare Safety Network (NHSN). Five-Step Enrollment for Acute Care Hospitals/Facilities. Available at: *https://www.cdc.gov/nhsn/acute-care-hospital/enroll.html* (the estimates for time to complete are 2 hours 45 minutes for step 1, 10 minutes for step 2, 16 minutes for step 3a, 35 minutes for step 3b, 32 minutes for step 4, and 5 minutes for step 5; totaling 263 minutes).

[71] CDC, Influenza Vaccination Information for Health Care Workers. Available at: *https://www.cdc.gov/flu/healthcareworkers.htm.*

[72] QPP 2017 Measures Selection: Influenza. Retrieved from: *https://qpp.cms.gov/mips/quality-measures.*

[73] Ibid.

For these reasons, we are proposing to remove OP–27: NHSN Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) from the Hospital OQR Program beginning with the CY 2020 payment determination and for subsequent years. We note that if proposed measure removal Factor 8 is not finalized, removal of this measure would also not be finalized. We note that this measure is also proposed for removal from the ASCQR Program in section XIV.B.3.c. of this proposed rule and the IPFQR Program in the FY 2019 IPF PPS proposed rule (83 FR 21104).

(2) Proposed Measure Removals for the CY 2021 Payment Determination and Subsequent Years

For the CY 2021 payment determination and subsequent years, we are proposing to remove: Four measures under proposed measure removal Factor 8; one measure under measure removal Factor 3; two measures under removal Factor 1; and two measures under measure removal Factor 2.

(a) Proposed Measure Removals Under Proposed Removal Factor 8: OP–5, OP–29, OP–30, and OP–31

In this proposed rule, we are proposing to remove four measures under our proposed measure removal Factor 8 for the CY 2021 payment determination and subsequent years: OP–5, OP–29, OP–30, and OP–31. We note that if proposed measure removal Factor 8 is not finalized, removal of these measures would also not be finalized. The proposals are discussed in more detail below. We note that in crafting our proposals, we considered removing these measures beginning with the CY 2020 payment determination, but we decided on proposing to delay removal until the CY 2021 payment determination to be sensitive to facilities' planning and operational procedures given that data collection for this measure begins during CY 2018 for the CY 2020 payment determination.

- Proposed Removal of OP–5: Median Time to ECG (NQF #0289)

We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66865) where we adopted OP–5: Median Time to ECG (NQF #0289) beginning with the CY 2009 payment determination.[74] This chart-abstracted measure assesses the median number of minutes before outpatients with heart attack (or chest pain that suggests a possible heart attack) received an electrocardiograph (ECG) test to help diagnose heart attack.

We are proposing to remove the OP–5 measure beginning with the CY 2021 payment determination under our proposed measure removal Factor 8, the costs associated with the measure outweigh the benefit of its continued use in the program. As noted above, OP–5 is a chart-abstracted measure, which can be potentially more challenging for facilities to report than claims-based or structural measures. Chart-abstraction requires facilities to select a sample population, access historical records from several clinical data quarters past, and interpret that patient data. This process is typically more time and resource-consuming than for other measure types. As described in section I.A.2. of this proposed rule, our Meaningful Measures Initiative is intended to reduce costs and minimize burden, and we believe that removing this chart-abstracted measure from the Hospital OQR Program would reduce program complexity.

However, we do not believe the use of chart-abstracted measure data alone is sufficient justification for removal of a measure under proposed measure removal Factor 8. The costs of collection and submission of chart-abstracted measure data is burdensome for facilities, especially when taking into consideration that, although this measure is not topped-out, we have come to the conclusion that the benefit of this measure is limited. Based on our analysis of data submitted by 1,995 hospitals from Quarter 3 in 2016 through Quarter 2 in 2017 the variation in average measure performance between hospitals is minimal, with a difference in median time to ECG of less than 2 minutes between the 75th and 90th percentile hospitals. Furthermore, the difference between the 25th and 75th percentile, distinguishing between high and low performers, is only 5.5 minutes, further indicating that variations are not sufficiently large to inform beneficiary decision-making to justify the costs of collecting the data. These data are demonstrated in the table below.

DIFFERENCES IN PERFORMANCE FOR OP–5: MEDIAN WAIT TIME TO ECG

Period	Number of hospitals	25th Percentile	75th Percentile	90th Percentile
2016 Q3—2017 Q2	1,995	11.0 minutes	5.5 minutes	3.8 minutes.

We believe that the minimal variation in hospital performance does not help beneficiaries to make informed care decisions, since distinguishing meaningful differences in hospital performance on this measure is difficult. As such, the measure benefit is limited, and no longer meaningfully supports program objectives of informing beneficiary choice.

Thus, we believe that costs and burdens to both facilities and CMS such as program oversight, measure maintenance, and public display, associated with keeping this measure in the program outweigh the limited benefit associated with the measure's continued use. Therefore, we are proposing to remove OP–5: Median Time to ECG from the Hospital OQR Program beginning with the CY 2021 payment determination and for subsequent years.

- Proposed Removal of OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75099 through 75100) where we adopted OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0659) beginning with the CY 2016 payment determination. This chart-abstracted process measure assesses the ''[p]ercentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of a prior colonic polyp in previous colonoscopy findings, who had a follow-up interval of 3 or more years since their last colonoscopy documented in the colonoscopy report'' (78 FR 75099). This measure aims to assess whether average risk patients

[74] This measure was formerly called ''ED–AMI–4—Median Time to Electrocardiogram (ECG)'' in the cited **Federal Register**.

with normal colonoscopies receive a recommendation to receive a repeat colonoscopy in an interval that is less than the recommended amount of 10 years.

In this proposed rule, we are proposing to remove OP–29: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients beginning with the CY 2021 payment determination and for subsequent years under our proposed measure removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program. We adopted OP–29: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75099 through 75100) noting that performing colonoscopy too frequently increases patients' exposure to procedural harm. However, we now believe that the costs of this measure outweigh the benefit of its continued use in the program.

Chart-abstraction requires facilities to select a sample population, access historical records from several current and historic clinical data quarters, and interpret that patient data. This process is typically more time and resource-consuming than for other measure types. In addition to submission of manually chart-abstracted data, we take all burden and costs into account when evaluating a measure. Removing OP–29 would reduce the burden and cost to facilities associated with collection of information and reporting on their performance associated with the measure.

However, we do not believe the use of chart-abstracted measure data alone is sufficient justification for removal of a measure under proposed measure removal Factor 8. The costs of collection and submission of chart-abstracted measure data is burdensome for facilities especially when taking into consideration the availability of other CMS quality measures that are relevant in the clinical condition and highly correlated in performance across measures. Another colonoscopy-related measure required in the Hospital OQR Program, OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (NQF# 2539), measures all-cause, unplanned hospital visits (admissions, observation stays, and emergency department visits) within 7 days of an outpatient colonoscopy procedure (79 FR 66949). This claims-based outcomes measure does not require chart-abstraction, and similarly contributes data on quality of care related to colonoscopy procedures, although the measure does not specifically track processes such as follow-up intervals. When we adopted OP–32, we believed this measure would reduce adverse patient outcomes associated with preparation for colonoscopy, the procedure itself, and follow-up care by capturing and making more visible to facilities and patients all unplanned hospital visits following the procedure (79 FR 66949). Furthermore, the potential benefits of keeping OP–29 in the program are mitigated by the existence of the same measure (Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients) [75] for gastroenterologists in the Merit-Based Incentive Payment System (MIPS) for the 2019 performance period in the QPP (82 FR 30292). Thus, we believe the issue of preventing harm to patients from colonoscopy procedures that are performed too frequently is adequately addressed through MIPS in the QPP, because we expect a portion of MIPS-eligible clinicians reporting on the measure nationwide to provide meaningful data to CMS. We note that although MIPS-eligible clinicians may voluntarily select measures from a list of options, HOPD providers that are MIPS-eligible will have the opportunity to continue collecting information for the measure without being penalized if they determine there is value for various quality improvement efforts.[76] The availability of this measure in another CMS program demonstrates CMS' continued commitment to this measure area.

Furthermore, we seek to align our quality reporting work with the Patients Over Paperwork and the Meaningful Measures Initiatives described in section I.A.2. of this proposed rule. The purpose of this effort is to hold providers accountable for only the measures that are most important to patients and clinicians and those that are focused on patient outcomes in particular, because outcome measures evaluate the actual results of care. As described in section I.A.2. of this proposed rule, our Meaningful Measures Initiative is intended to reduce costs and minimize burden, and we believe that removing this chart-abstracted measure from the Hospital OQR Program would reduce program complexity. In addition, as we discuss in section XIV.B.3.b. of this proposed rule, where we are proposing to adopt measure removal Factor 8, beneficiaries may find it confusing to see public reporting on the same measure in different programs.

Therefore, due to the combination of factors of the costs of collecting data for this chart-abstracted measure, the preference for an outcomes measure in the Hospital OQR Program that provides valuable data for the same procedure, and the existence of the same measure in another CMS program, we believe that the burdens and costs associated with this measure outweigh the limited benefit to beneficiaries. As a result, we are proposing to remove OP–29: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients beginning with the CY 2021 payment determination and for subsequent years. We note that we are also proposing to remove a similar measure in the ASCQR Program in section XIV.B.3.c. of this proposed rule.

- Proposed Removal of OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use

We refer readers to CY 2014 OPPS/ASC final rule with comment period (78 FR 75102) where we adopted OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use (NQF #0659) beginning with the CY 2016 payment determination. This chart-abstracted process measure assesses the percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of a prior colonic polyp in previous colonoscopy findings, who had a follow-up interval of 3 or more years since their last colonoscopy documented in the colonoscopy report.

In this proposed rule, we are proposing to remove OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use beginning with the CY 2021 payment determination and for subsequent years under our proposed measure removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program.

We adopted OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use in the CY 2014 OPPS/ASC final rule

[75] QPP Measure Selection: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients. Available at: *https://qpp.cms.gov/mips/quality-measures*.

[76] CMS finalized that services furnished by an eligible clinician that are payable under the ASC, HHA, Hospice, or HOPD methodology will not be subject to the MIPS payments adjustments, but eligible clinicians payable under those methodologies may have the option to still voluntarily report on applicable measures and the data reported will not be used to determine future eligibility (82 FR 53586).

with comment period (78 FR 75102) noting that colonoscopy screening for high risk patients is recommended based on risk factors and one such factor is a history of adenomatous polyps. The frequency of colonoscopy screening varies depending on the size and amount of polyps found, with the general recommendation of a 3-year follow-up. We stated that this measure is appropriate for the measurement of quality of care furnished by hospital outpatient departments because colonoscopy screening is commonly performed in these settings (78 FR 75102). However, we now believe that the costs of this measure outweigh the benefit of its continued use in the program.

Chart-abstraction requires facilities to select a sample population, access historical records from several clinical data quarters past, and interpret that patient data. This process is typically more time and resource-consuming than for other measure types. In addition to submission of manually chart-abstracted data, we take all burden and costs into account when evaluating a measure. Removing OP–30 would reduce the burden and cost to facilities associated with collection of information and reviewing their data and performance associated with the measure.

However, we do not believe the use of chart-abstracted measure data alone is sufficient justification for removal of a measure under proposed measure removal Factor 8. The costs of collection and submission of chart-abstracted measure data is burdensome for facilities especially when taking into consideration the availability of other CMS quality measures. Another colonoscopy-related measure required in the Hospital OQR Program, OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (NQF# 2539) measures all-cause, unplanned hospital visits (admissions, observation stays, and emergency department visits) within 7 days of an outpatient colonoscopy procedure (79 FR 66949). This claims-based outcome measure does not require chart-abstraction, and similarly contributes data on quality of care related to colonoscopy procedures, although the measure does not specifically track processes such as follow-up intervals. When we adopted OP–32, we believed this measure would reduce adverse patient outcomes associated with preparation for colonoscopy, the procedure itself, and follow-up care by capturing and making more visible to facilities and patients all unplanned hospital visits following the procedure (79 FR 66949). Furthermore, the potential benefits of keeping OP–30 in the program are mitigated by the existence of the same measure for gastroenterologists in the Merit-Based Incentive Payment System (MIPS) for the 2019 performance period in the QPP (82 FR 30292). Thus, we believe the issue of preventing harm to patients from colonoscopy procedures that are performed too frequently is adequately addressed through MIPS in the QPP because we expect a portion of MIPS-eligible clinicians reporting on the measure nationwide to provide meaningful data to CMS. Although MIPS-eligible clinicians may voluntarily select measures from a list of options, HOPD providers that are MIPS-eligible will have the opportunity to continue collecting information for the measure without being penalized if they determine there is value for various quality improvement efforts.[77] The availability of this measure in another CMS program demonstrates CMS' continued commitment to this measure area.

Furthermore, we seek to align our quality reporting work with the Patients Over Paperwork and the Meaningful Measures Initiatives described in section I.A.2. of this proposed rule. The purpose of this effort is to hold providers accountable for only the measures that are most important to patients and clinicians and those that are focused on patient outcomes in particular, because outcome measures evaluate the actual results of care. As described in section I.A.2. of this proposed rule, our Meaningful Measures Initiative is intended to reduce costs and minimize burden, and we believe that removing this chart-abstracted measure from the Hospital OQR Program would reduce program complexity. In addition, as we discuss in section XIII.B.4.a. of this proposed rule, where we are proposing to adopt measure removal Factor 8, beneficiaries may find it confusing to see public reporting on the same measure in different programs.

Therefore, due to the combination of factors of the costs of collecting data for this chart-abstracted measure, the preference for an outcomes measure in OQR that provides valuable data for the same procedure, and the existence of the same measure in the MIPS program, we believe that the burdens and costs associated with manual chart abstraction outweigh the limited benefit to beneficiaries of receiving this information. As a result, we are proposing to remove OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use beginning with the CY 2021 payment determination and for subsequent years. We note that we are also proposing to remove a similar measure in the ASCQR Program in section XIV.B.3.c. of this proposed rule.

- Proposed Removal of OP–31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75103) where we adopted OP–31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536) beginning with the CY 2016 payment determination and subsequent years. This measure assesses the rate of patients 18 years and older (with a diagnosis of uncomplicated cataract) in a sample who had improvement in visual function achieved within 90 days following cataract surgery based on completing both a pre-operative and post-operative visual function survey.

Since the adoption of this measure, we came to believe that it can be operationally difficult for facilities to collect and report the measure (79 FR 66947). Specifically, we were concerned that the results of the survey used to assess the pre-operative and post-operative visual function of the patient may not be shared across clinicians and facilities, making it difficult for facilities to have knowledge of the visual function of the patient before and after surgery (79 FR 66947). We were also concerned about the surveys used to assess visual function; the measure allows for the use of any validated survey and results may be inconsistent should clinicians use different surveys (79 FR 66947). Therefore, on December 31, 2013, we issued guidance stating that we would delay data collection for OP–31 for 3 months (data collection would commence with April 1, 2014 encounters) for the CY 2016 payment determination (*https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772854917*). We issued additional guidance on April 2, 2014, stating that we would further delay the implementation of OP–31 for an additional 9 months, until January 1, 2015 for the CY 2016 payment

[77] CMS finalized that services furnished by an eligible clinician that are payable under the ASC, HHA, Hospice, or HOPD methodology will not be subject to the MIPS payments adjustments, but eligible clinicians payable under those methodologies may have the option to still voluntarily report on applicable measures and the data reported will not be used to determine future eligibility (82 FR 53586).

determination, due to continued concerns (*https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228773786593*). As a result of these concerns, in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66948), we finalized our proposal to allow voluntary data collection and reporting of this measure beginning with the CY 2017 payment determination and for subsequent years.

In this proposed rule, we are proposing to remove OP–31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery beginning with the CY 2021 and for subsequent years under our proposed measure removal Factor 8, the costs associated with the measure outweigh the benefit of its continued use in the program. We originally adopted OP–31 because we believe facilities should be a partner in care with physicians and other clinicians using their facility and that this measure would provide an opportunity to do so (79 FR 66947). However, in light of the history of complications and upon reviewing this measure within our Meaningful Measures framework, we have concluded that it is overly burdensome for facilities to report this measure due to the difficulty of tracking care that occurs outside of the HOPD setting. In order to report on this measure to CMS, a facility would need to obtain the visual function assessment results from the appropriate ophthalmologist and ensure that the assessment utilized is validated for the population for which it is being used. If the assessment is not able to be used or is not available, the facility would then need to administer the survey directly and ensure that the same visual function assessment tool is utilized preoperatively and postoperatively. There is no simple, preexisting means for information sharing between ophthalmologists and facilities, so a facility would need to obtain assessment results from each individual patient's ophthalmologist both preoperatively and postoperatively. The high administrative costs of the technical tracking of this information presents an undue cost, and also burden associated with submission and reporting of OP–31 to CMS, especially for small facilities with limited staffing capacity.

Furthermore, this measure currently provides limited benefits. Since making the measure voluntary, only 59[78] facilities have reported this measure to CMS, compared to approximately 4,798 total facilities for all other measures, resulting in only 1.2 percent of facilities reporting. Consequently, we have been unable to uniformly offer pertinent information to beneficiaries on how the measure assesses facility performance. This reinforces comments made in the CY 2015 OPPS/ASC final rule with comment period in which commenters expressed concern that the incomplete display of data associated with voluntary reporting is confusing and not meaningful to beneficiaries and other consumers (79 FR 66947). The data are also hard to validate. Furthermore, commenters feared that the display of data from some hospitals, but not others, would lead some patients to conclude that some hospitals are more committed to improving cataract surgery. As described in section I.A.2. of this proposed rule, we strive to ensure that beneficiaries are empowered to make decisions about their health care using information from data-driven insights. Because of the lack of sufficient data, this measure may be difficult for beneficiaries to interpret or use to aid in their choice of where to obtain care; thus, the benefits of this measure are limited.

Thus, we believe the high technical and administrative costs of this measure, coupled with the high technical and administrative burden, outweigh the limited benefit associated with the measure's continued use in the Hospital OQR Program. As discussed in section I.A.2. of this proposed rule, above, our Meaningful Measures Initiative is intended to reduce costs and minimize burden. We believe that removing this measure from the Hospital OQR Program will reduce program burden, costs, and complexity. Therefore, we are proposing to remove OP–31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery beginning with the CY 2021 payment determination and for subsequent years. We note that we are also proposing to remove a similar measure under the ASCQR Program in section XIV.B.3.c. of this proposed rule.

(b) Proposed Measure Removal Under Removal Factor 3: OP–9: Mammography Follow-Up Rates

We refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68766) where we adopted OP–9: Mammography Follow-up Rates beginning with the CY 2010 payment determination. This claims-based measure assesses the percentage of patients with mammography screening studies that are followed by a diagnostic mammography, ultrasound, or MRI of the breast in an outpatient or office setting within 45 days. We are proposing to remove this measure under measure removal Factor 3, a measure does not align with current clinical guidelines or practice.

An examination of the measure specifications[79] shows that recent changes in clinical practice are not incorporated into the measure calculation. Since development of this measure in 2008, advancements in imaging technology and clinical practice for mammography warrant updating the measure's specifications to align with current clinical practice guidelines and peer-reviewed literature. Specifically, findings from the annual Literature Reviews and Environmental Scans conducted by the measure developer suggest that there is additional clinical benefit in performing adjuvant DBT concomitant with full-field digital mammography (FFDM) or conventional mammography (currently included in the measure denominator), especially in women with dense breast tissue.[80] [81] [82] In addition, in 2016, the American College of Radiology (ACR) updated its Breast Cancer Screening Appropriateness Criteria® to include DBT.[83] The ACR notes that DBT can better detect potential false-positive findings without the need for recall. Furthermore, the cancer detection rate is increased with use of DBT compared with traditional mammography alone.[84] A 2014 study published in the Journal of the American College of Radiology assessed the utilization of DBT among physician members of the Society of

[78] OQR Hospital Compare. Available at: *https://data.medicare.gov/Hospital-Compare/Timely-and-Effective-Care-Hospital/yv7e-xc69.*

[79] Hospital Outpatient Quality Reporting Specifications Manual. Version 11.0a. Available at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FSpecsManualTemplate&cid=1228776146046.*

[80] Bernardi, D., Macaskill, P., Pellegrini, M., Valentini, M., Fanto, C., Ostillio, L., Houssami, N. (2016). Breast cancer screening with tomosynthesis (3D mammography) with acquired or synthetic 2D mammography compared with 2D mammography alone (STORM–2): A population-based prospective study. Lancet Oncol, 17(8), 1105–1113. doi: 10.1016/s1470–2045(16)30101–2.

[81] Bian, T., Lin, Q., Cui, C., Li, L., Qi, C., Fei, J., & Su, X. (2016). Digital Breast Tomosynthesis: A New Diagnostic Method for Mass-Like Lesions in Dense Breasts. Breast J, 22(5), 535–540. doi: 10.1111/tbj.12622.

[82] Pozz, A., Corte, A.D., Lakis, M. A., & Jeong, H. (2016). Digital Breast Tomosynthesis in Addition to Conventional 2DMammography Reduces Recall Rates and is Cost Effective. Asian Pac J Cancer Prev, 17(7), 3521–3526.

[83] Mainiero MB, Bailey L, D'Orsi C, Green ED, Holbrook AI, Lee SJ, Lourenco AP, Moy L, Sepulveda KA, Slanetz PJ, Trikha S, Yepes MM, Newell MS, Expert Panel on Breast Imaging. ACR Appropriateness Criteria® breast cancer screening. Reston (VA): American College of Radiology (ACR); 2016. 7 p.

[84] Ibid.

Breast Imaging and found that 30 percent of respondents reported using DBT concurrent with traditional mammography.[85] With the update of the ACR clinical practice guidelines (that is, the Breast Cancer Screening Appropriateness Criteria®) to include DBT, use of this technology is expected to increase.

As currently specified, the measure does not adequately capture this shift in clinical practice. Thus, we believe this measure as specified does not align with current clinical guidelines or practice, and we are proposing to remove OP–9: Mammography Follow-up Rates from the program for the CY 2021 payment determination and subsequent years. We intend to investigate respecification of this measure and consider it for adoption to the program through future rulemaking. Specifically, we will consider ways to capture a broader, more comprehensive spectrum of mammography services including adding diagnostic digital breast tomosynthesis (DBT). We note that, in crafting our proposal, we considered removing this measure beginning with the CY 2020 payment determination, but decided on proposing to delay removal until the CY 2021 payment determination and subsequent years to be sensitive to facilities' planning and operational procedures given that data collection for this measure begins during CY 2018 for the CY 2020 payment determination.

(c) Proposed Measure Removals Under Removal Factor 1: OP–11 and OP–14

In this proposed rule, for the CY 2021 payment determination and subsequent years, we are proposing to remove OP–11 and OP–14 under removal Factor 1, measure performance among providers is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made. The Hospital OQR Program previously finalized two criteria for determining when a measure is ''topped-out'': (1) When there is statistically indistinguishable performance at the 75th and 90th percentiles of national facility performance; and (2) when the measure's truncated coefficient of variation is less than or equal to 0.10 (79 FR 66968 through 66969). We refer readers to section XIII.B.4.a.(6) of this proposed rule, above, where we clarify and discuss how we calculate the TCOV for measures that assess the rate of rare, undesired events for which a lower rate is preferred such as OP–11 and OP–14.

For each of these measures, we believe that removal from the Hospital OQR Program measure set is appropriate as there is little room for improvement. In addition, as discussed in section I.A.2. of this proposed rule above, our Meaningful Measures Initiative is intended to reduce costs and minimize burden. We believe that removing these measures from the Hospital OQR Program will reduce program burden, costs, and complexity. As such, we believe the burden associated with reporting these measures outweighs the benefits of keeping them in the Hospital OQR Program.

Each measure is discussed in more detail below. We also note that in crafting our proposals, we considered removing these measures beginning with the CY 2020 payment determination, but decided on proposing to delay removal until the CY 2021 payment determination and subsequent years to be sensitive to providers' planning and operational procedures given that data collection for the measures begins during CY 2018 for the CY 2020 payment determination.

- Proposed Removal of OP–11: Thorax CT Use of Contrast Material

We refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68766) where we adopted OP–11: Thorax CT Use of Contrast Material (NQF #0513) beginning with the CY 2010 payment determination. This claims-based measure assesses the percentage of thorax studies that are performed with and without contrast out of all thorax studies performed.

Based on our analysis of Hospital OQR Program measure data, we have determined that this measure meets our measure removal Factor 1. These analyses are captured in the table below.

OP–11—Thorax CT Use of Contrast Material Topped-Out Analysis

Encounters	Number of hospitals	75th Percentile	90th Percentile	Truncated COV
CY 2012	867	96.9	98.4	0.081
CY 2013	869	97.1	98.5	0.074
CY 2014	796	97.2	98.4	0.065
CY 2015	711	97.4	98.5	0.054

As displayed in the table above, there is a statistically indistinguishable difference in hospital performance between the 75th and 90th percentiles, and the truncated coefficient of variation has been below 0.10 since 2012.

- Proposed Removal of OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT

We refer readers to the CY 2010 OPPS/ASC final rule with comment period (75 FR 72082) where we adopted OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT beginning with the CY 2012 payment determination and for subsequent years. This claims-based measure assesses the extent to which patients with a headache who have a brain CT also have a sinus CT performed on the same date at the same facility.

Based on our analysis of Hospital OQR Program measure data, we have determined that this measure meets our measure removal Factor 1. These analyses are captured in the table below.

OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT Topped-Out Analysis

Encounters	Number of hospitals	75th percentile	90th percentile	Truncated COV
CY 2012	1,478	97.8	98.3	0.012

[85] Hardesty LA, Kreidler SM, Glueck DH. Digital breast tomosynthesis utilization in the United States: A survey of physician members of the Society of Breast Imaging. Journal of the American College of Radiology. 2014. 11(6): 594–599.

OP–14: SIMULTANEOUS USE OF BRAIN COMPUTED TOMOGRAPHY (CT) AND SINUS CT TOPPED-OUT ANALYSIS—Continued

Encounters	Number of hospitals	75th percentile	90th percentile	Truncated COV
CY 2013	1,939	97.7	98.2	0.010
CY 2014	2,023	97.6	98.2	0.011
CY 2015	1,101	98.5	98.8	0.007

As displayed in the table above, there is a statistically indistinguishable difference in hospital performance between the 75th and 90th percentiles, and the truncated coefficient of variation has been below 0.10 since 2012.

Therefore, we are inviting public comment on our proposals to remove: (1) OP–11: Thorax CT Use of Contrast Material, and (2) OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT measure for the CY 2021 payment determination and subsequent years as discussed above.

(d) Proposed Removals Under Measure Removal Factor 2: OP–12 and OP–17

In this proposed rule, for the CY 2021 payment determination and subsequent years, we are proposing to remove two measures under our measure removal Factor 2, performance or improvement on a measure does not result in better patient outcomes: OP–12 and OP–17. The proposals are discussed in more detail below. As discussed in section I.A.2. of this proposed rule above, our Meaningful Measures Initiative is intended to reduce costs and minimize burden. We believe that removing these measures from the Hospital OQR Program will reduce program burden, costs, and complexity. In addition, we note that in crafting our proposals, we considered removing these measures beginning with the CY 2020 payment determination, but decided on proposing to delay removal until the CY 2021 payment determination to be sensitive to facilities' planning and operational procedures given that data collection for this measure begins during CY 2018 for the CY 2020 payment determination.

• Proposed Removal of OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into Their Qualified/Certified EHR System as Discrete Searchable Data

We refer readers to CY 2011 OPPS/ASC final rule with comment period (75 FR 72076) where we adopted OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into Their Qualified/Certified EHR System as Discrete Searchable Data beginning with the CY 2012 payment determination. This web-based measure assesses the extent to which a provider uses an Office of the National Coordinator for Health Information Technology (ONC) certified electronic health record (EHR) system that incorporates an electronic data interchange with one or more laboratories allowing for direct electronic transmission of laboratory data in the EHR as discrete searchable data elements. In this proposed rule, we are proposing to remove OP–12 beginning with the CY 2021 payment determination and for subsequent years under our measure removal Factor 2, performance or improvement on a measure does not result in better patient outcomes.

OP–12 is a process measure that tracks the transmittal of data, but does not directly assess quality or patient outcomes. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72075), commenters expressed concern that the measure only assesses HIT functionality and does not assess the quality of care provided. As discussed in section I.A.2. of this proposed rule, one of the goals of our Meaningful Measures Initiative is to reduce burden associated with payment policy, quality measures, documentation requirements, conditions of participation, and health information technology. As also discussed in section I.A.2. of this proposed rule, one of the goals of our Meaningful Measures Initiative is to utilize measures that are ''outcome-based where possible.'' We do not believe OP–12 adds to these goals. In fact, we believe that provider performance in the measure is not an indicator for patient outcomes and continued collection provides little benefit.

Therefore, we are proposing to remove OP–12 from the Hospital OQR Program beginning with the CY 2021 payment determination and for subsequent years.

• Proposed Removal of OP–17: Tracking Clinical Results Between Visits

We refer readers to CY 2011 OPPS/ASC final rule with comment period (75 FR 72085) where we adopted OP–17: Tracking Clinical Results between Visits beginning with the CY 2013 payment determination. This web-based measure assesses the extent to which a provider uses a certified/qualified EHR system to track pending laboratory tests, diagnostic studies (including common preventive screenings), or patient referrals. In this proposed rule, we are proposing to remove OP–17 beginning with the CY 2021 payment determination and for subsequent years under our measure removal Factor 2, performance or improvement on a measure does not result in better patient outcomes.

OP–17 is a process measure that tabulates only the ability for transmittal of data, but does not directly assess quality or patient outcomes. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72075), commenters expressed concern that the measure only assesses HIT functionality and does not assess the quality of care provided. As discussed in section I.A.2. of this proposed rule, one of the goals of our Meaningful Measures Initiative is to reduce burden associated with payment policy, quality measures, documentation requirements, conditions of participation, and health information technology. As also discussed in section I.A.2. of this proposed rule, one of the goals of our Meaningful Measures Initiative is to utilize measures that ''outcome-based where possible.'' We do not believe OP–17 supports this goal. In fact, we believe that provider performance in the measure does not improve patient outcomes and continued collection provides little benefit. Therefore, we are proposing to remove OP–17 from the Hospital OQR Program beginning with the CY 2021 payment determination and for subsequent years.

5. Summary of Proposed Hospital OQR Program Measure Sets for the CY 2020 and CY 2021 Payment Determinations

In this proposed rule, we are not proposing any new measures for the Hospital OQR Program. We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59434 through 59435) for the previously finalized measure set for the CY 2020 payment determination and subsequent years. The tables below summarize the

proposed Hospital OQR Program measure sets for the CY 2020 and 2021 payment determinations and subsequent years (including previously adopted measures and excluding measures proposed for removal in this proposed rule).

PROPOSED HOSPITAL OQR PROGRAM MEASURE SET FOR THE CY 2020 PAYMENT DETERMINATION

NQF No.	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
0289	OP–5: Median Time to ECG †
0514	OP–8: MRI Lumbar Spine for Low Back Pain
None	OP–9: Mammography Follow-up Rates
None	OP–10: Abdomen CT—Use of Contrast Material
0513	OP–11: Thorax CT—Use of Contrast Material
None	OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data
0669	OP–13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery
None	OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT)
0491	OP–17: Tracking Clinical Results between Visits †
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 *
0659	OP–30: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use *
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
1822	OP–33: External Beam Radiotherapy for Bone Metastases
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.

* OP–26: Procedure categories and corresponding HCPCS codes are located at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1196289981244.*

** We note that measure name was revised to reflect NQF title.

*** Measure voluntarily collected as set forth in section XIII.D.3.b. of 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 section XIII.B.5. of the CY 2018 OPPS/ASC final rule with comment period (82 FR 59432 through 59433).

PROPOSED HOSPITAL OQR PROGRAM MEASURE SET FOR THE CY 2021 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

NQF No.	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.
2539	OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy.
1822	OP–33: External Beam Radiotherapy for Bone Metastases.
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.

º OP–26: Procedure categories and corresponding HCPCS codes are located at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1196289981244.*

* We note that measure name was revised to reflect NQF title.

** Measure voluntarily collected as set forth in section XIII.D.3.b. of 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 section XIII.B.5. of the CY 2018 OPPS/ASC final rule with comment period (82 FR 59432 through 59433).

6. Hospital OQR Program Measures and Topics for Future Consideration

In this proposed rule, we are requesting public comment on future measure topics for the Hospital OQR Program. We seek to develop a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality improvement in the hospital outpatient setting. The current measure set for the Hospital OQR Program includes measures that assess process of care, imaging efficiency patterns, care transitions, 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 help us further our goal of achieving better health care and improved health for Medicare beneficiaries who receive health care in hospital outpatient settings, while aligning quality measures across the Medicare program to the extent possible.

We are moving towards greater use of outcome measures and away from use of clinical process measures across our Medicare quality reporting and value-based purchasing programs. We are inviting public comments on possible measure topics for future consideration in the Hospital OQR Program. We are specifically requesting comment on any outcome measures that would be useful to add to as well as any process measures that should be eliminated from the Hospital OQR Program.

7. 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.* In this proposed rule, we are proposing to change the frequency of the Hospital OQR Program Specifications Manual release beginning with CY 2019 and for subsequent years and we refer readers to section XIII.D.2. of this proposed rule for more details.

8. 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 this proposed rule, we are not proposing 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). In that final rule with comment period, we codified these procedural requirements at 42 CFR 419.46(a). In this proposed rule, we are not proposing any changes to our requirements for the QualityNet account and security administrator.

2. Requirements Regarding Participation Status

In this proposed rule, we are proposing to update our requirements related to the Notice of Participation (NOP) form.

a. Background

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75108 through 75109) and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70519) for requirements for participation and withdrawal from the Hospital OQR Program. We also codified these procedural requirements at 42 CFR 419.46(a) and 42 CFR 419.46(b).

b. Proposal to Remove the Notice of Participation (NOP) Form Requirement

We finalized in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75108 through 75109) that participation in the Hospital OQR Program requires that hospitals must: (1) Register on the QualityNet website before beginning to report data; (2) identify and register a QualityNet security administrator; and (3) complete and submit an online participation form, the Notice of Participation (NOP) form, available at the QualityNet website if this form has not been previously completed, if a hospital has previously withdrawn, or if the hospital acquires a new CMS Certification Number (CCN). In addition, in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75108 through 75109), we finalized the requirement that that hospitals must submit the NOP according to the below deadlines. These requirements are also codified at 42 CFR 419.46(a).

- If a hospital has a Medicare acceptance date before January 1 of the year prior to the affected annual payment update, the hospital must complete and submit to CMS a completed Hospital OQR Notice of Participation Form by July 31 of the calendar year prior to the affected annual payment update.
- If a hospital has a Medicare acceptance date on or after January 1 of the year prior to the affected annual payment update, the hospital must submit a completed participation form no later than 180 days from the date identified as its Medicare acceptance date. In this proposed rule, beginning with the CY 2018 reporting period/CY 2020 payment determination, we are proposing to remove submission of the NOP form as a requirement for the Hospital OQR Program. After reevaluating program requirements, we have concluded that this form does not provide CMS with any unique information, and as such, we believe it is unnecessarily burdensome for hospitals to complete and submit. In place of the NOP form, we are proposing that submission of any Hospital OQR Program data would indicate a hospital's status as a participant in the program. This includes submitting just one data element. That is, hospitals would no longer be required to submit the NOP form as was previously required. Instead, hospitals would need to do the following to be a participant in the Hospital OQR Program: (1) Register on the QualityNet website before beginning to report data; (2) identify and register a QualityNet security administrator; and (3) submit data. We are also proposing to update 42 CFR 419.46(a) to reflect these changes.

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 also codified our 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 finalized deadlines for the CY 2020 payment

determination and subsequent years are illustrated in the table below.

CY 2020 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Patient encounter quarter	Clinical data submission deadline
Q2 2018 (April 1–June 30)	11/1/2018
Q3 2018 (July 1–September 30)	2/1/2019
Q4 2018 (October 1–December 31)	5/1/2019
Q1 2019 (January 1–March 31)	8/1/2019

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). In this proposed rule, we are not proposing any changes to these policies.

2. Proposal To Change Frequency of Hospital Outpatient Quality Reporting Specifications Manual Release Beginning With CY 2019 and for Subsequent Years

In this proposed rule, we are proposing to change the frequency of the Hospital Outpatient Quality Reporting Specifications Manual release beginning with CY 2019 and for subsequent years. In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68766 through 68767), we established a subregulatory process for making updates to the measures we have adopted for the Hospital OQR Program. As stated in CY 2014 OPPS/ASC final rule with comment period (78 FR 75091), we believe that a measure can be updated through this subregulatory process provided it is a nonsubstantive change. We expect to continue to make the determination of what constitutes a substantive versus a nonsubstantive change on a case-by-case basis. Examples of nonsubstantive changes to measures might include updated diagnosis or procedure codes, medication updates for categories of medications, broadening of age ranges, and exclusions for a measure (such as the addition of a hospice exclusion to the 30-day mortality measures). We believe that nonsubstantive changes may include updates to measures based upon changes to guidelines upon which the measures are based.

For a history of our policies regarding maintenance of technical specifications for quality measures, we refer readers to the CY 2010 OPPS/ASC final rule with comment period (74 FR 60631), the CY 2011 OPPS/ASC final rule with comment period (75 FR 72069), and the CY 2013 OPPS/ASC final rule with comment period (77 FR 68469 through 68470). We note that we will continue to use rulemaking to adopt substantive updates to measures we have adopted for the Hospital OQR Program. We believe that this policy adequately balances our need to incorporate nonsubstantive updates to Hospital OQR Program measures in the most expeditious manner possible, while preserving the public's ability to comment on updates that so fundamentally change an endorsed measure that it is no longer the same measure that we originally adopted. We also note that the NQF process incorporates an opportunity for public comment and engagement in the measure maintenance process.

As stated in CY 2014 OPPS/ASC final rule with comment period (78 FR 75091), under current policy, technical specifications for the Hospital OQR Program measures are listed in the Hospital Outpatient Quality Reporting Specifications Manual, which is posted on the CMS QualityNet website at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FSpecsManualTemplate&cid=1228772438492.* We maintain the technical specifications for the measures by updating this Hospital Outpatient Quality Reporting Specifications Manual and including detailed instructions and calculation algorithms. In some cases where the specifications are available elsewhere, we may include links to websites hosting technical specifications. These resources are for hospitals to use when collecting and submitting data on required measures. We revise the Hospital Outpatient Quality Reporting Specifications Manual so that it clearly identifies the updates and provide links to where additional information on the updates can be found. We provide sufficient lead time for facilities to implement the changes where changes to the data collection systems would be necessary. We generally release the Hospital Outpatient Quality Reporting Specifications Manual every 6 months and release addenda as necessary. This release schedule provides at least 3 months of advance notice for nonsubstantive changes such as changes to ICD–10, CPT, NUBC, and HCPCS codes, and at least 6 months of advance notice for changes to data elements that would require significant systems changes (78 FR 75091).

However, we believe that unnecessarily releasing two manuals a year has the potential to cause confusion for Hospital OQR Program participants. Therefore, in this proposed rule, we are proposing to update the frequency with which we release Hospital Outpatient Quality Reporting Specifications Manuals, such that instead of every 6 months, we would release Specifications Manuals every 6 to 12 months beginning with CY 2019 and for subsequent years. Under this proposal, we would release a Hospital Outpatient Quality Reporting Specifications Manual one to two times per calendar year, depending on the need for an updated release and consideration of our policy to provide at least 6 months' notice for substantive changes.

3. Requirements for Chart-Abstracted Measures Where Patient-Level Data Are Submitted Directly to CMS for the CY 2020 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 are not proposing any changes to our policies regarding the submission of chart-abstracted measure data where patient-level data are submitted directly to CMS.

We note that, in section XIII.B.4.b. of this proposed rule, we are proposing to remove OP–5: Median Time to ECG for the CY 2021 payment determination and subsequent years. If that proposal is finalized as proposed, only the following previously finalized Hospital OQR Program chart-abstracted measures will require patient-level data to be submitted for the CY 2021 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).

4. Claims-Based Measure Data Requirements for the CY 2020 Payment Determination and Subsequent Years

In this proposed rule, we are proposing to extend the reporting

period [86] for OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy.

a. General

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75111 through 75112) for a discussion of the general claims-based measure data submission requirements for the CY 2015 payment determination and subsequent years.

We are not proposing changes to our general requirements for claims-based measure data, but refer readers to the section below for our proposal specific to OP–32.

We note that, in section XIII.B.4.b. of this proposed rule, we are proposing to remove OP–9: Mammography Follow-up Rates, OP–11: Thorax CT Use of Contrast Material, and OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT for the CY 2021 payment determination and subsequent years. If these removals are finalized as proposed, only the following previously finalized Hospital OQR Program claims-based measures will be required for the CY 2021 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).

b. Proposed Extension of the Reporting Period for OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66949), we finalized the adoption of OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy into the Hospital OQR Program for the CY 2018 payment determination and subsequent years, with public display to begin on or after December 1, 2017. This measure is calculated with data obtained from paid Medicare FFS claims (79 FR 66950). For this reason, facilities are not required to submit any additional information. In that final rule with comment period, we also finalized the reporting period for measure calculation as claims data from 2 calendar years prior to the payment determination year. Specifically, for the CY 2018 payment determination, we stated we would use paid Medicare FFS claims from January 1, 2016 to December 31, 2016 to calculate measure results (79 FR 66955). We finalized a 1-year reporting period, as it adequately balanced competing interests of measure reliability and timeliness for payment determination purposes, and explained that we would continue to assess this during the dry run (79 FR 66955).

We noted we would complete a dry run of the measure in 2015 using 3 or 4 years of data, and, from the results of this dry run, we would review the appropriate volume cutoff for facilities to ensure statistical reliability in reporting the measure score (79 FR 66953). Our analyses of the 2015 dry run using data from July 2011 through June 2014 showed that a reporting period of one year had moderate to high reliability for measure calculation. Specifically, using data from July 2013 through June 2014, we calculated facility-level reliability estimates as the ratio of true variance to observed variance.[87] Consistent with the original measure specifications as described in the 2014 technical report,[88] this calculation was performed combining the measure results for HOPDs and ASCs. We found that for a facility with median case size, the reliability estimate was high (over 0.90), but the minimum reliability estimate for facilities with 30 cases (the minimum case size chosen for public reporting) was only moderate (that is, between 0.40 and 0.60).[89]

However, after the 2015 dry run, CMS calculated the HOPD and ASC scores separately to compare similar types of providers to each other. During subsequent analysis of the 1-year period July 2013 through June 2014, we confirmed that a 1-year reporting period with separate calculations for HOPDs and ASCs was sufficient, but did result in lower reliability and decreased precision compared to these measures calculated from longer reporting periods (2 or 3 years). Based on analyses conducted using data from July 2013 through June 2014 (1-year reporting period) and 2017 measure specifications,[90] we found that the median facility-level reliability was 0.74 for ASCs and 0.51 for HOPDs. Using a 2-year reporting period (data from July 2012—June 2014), we found that median facility-level reliability was 0.81 for ASCs and 0.67 for HOPDs. When the reporting period was extended to 3 years (using data from July 2011 through June 2014), we found that median facility-level reliability was higher for both ASCs and HOPDs: 0.87 for ASCs and 0.75 for HOPDs. These results indicate that a larger portion of the included facilities have scores measured with higher reliability when 3 years of data are used rather than 1 year of data.

Using 3 years of data, compared to just 1 year, is estimated to increase the number of HOPDs with eligible cases for OP–32 by 5 percent, adding approximately 235 additional facilities to the measure calculation. Facilities reporting the measure would increase their sample sizes and, in turn, increase the precision and reliability of their measure scores. Thus, we believe extending the reporting period to 3 years from 1 year for purposes of increasing reliability would be beneficial for providing better information to beneficiaries regarding the quality of care associated with low-risk outpatient colonoscopy procedures. In crafting our proposal, we considered extending the reporting period to 2 years beginning with the CY 2020 payment determinations and subsequent years, but decided on proposing 3 years instead, because a higher level of reliability is achieved with a 3-year reporting period compared to 2 years.

Therefore, we are proposing to change the reporting period for OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy from 1 year to 3 years beginning with the CY 2020 payment determination (which would use claims data from January 1, 2016 through December 31, 2018) and for subsequent years. Under this proposal, the annual reporting requirements for facilities would not change, because this is a claims-based measure. However, with a 3-year reporting period, the most current year

[86] We note that we previously referred to these reporting periods as ''collection periods'' (for example, 82 FR 59440); we now use the term ''reporting period'' 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.

[87] Snijders TA, Bosker RJ. *Multilevel Analysis: An introduction to basic and advanced multilevel modeling.* SAGE Publications. 2000. London.

[88] Additional methodology details and information obtained from public comments for measure development are available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html* under ''Hospital Outpatient Colonoscopy.''

[89] Landis JR, Koch GG. The Measurement of Observer Agreement for Categorical Data. *Biometrics.* 1977;33(1):159–174.

[90] Current and past measure specifications are available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228775214597.*

of data would be supplemented by the addition of 2 prior years. For example, for the CY 2020 payment determination, we would use a reporting period of CY 2018 data plus 2 prior years of data (CYs 2016 and 2017). We note that since implementation of this measure began with the CY 2018 payment determination, we have already used paid Medicare fee-for-service claims from January 1, 2016 to December 31, 2016 to calculate measure scores, which have been previously previewed by facilities and publicly displayed. In crafting our proposal, we also considered timeliness related to payment determinations and public display. Because we would utilize data already collected to supplement current data, our proposal to use 3 years of data would not disrupt payment determinations or public display. We refer readers to the table below for example reporting periods and public display dates corresponding to the CY 2020, CY 2021, and CY 2022 payment determinations:

	CY 2020 payment determination	CY 2021 payment determination	CY 2022 payment determination
Public display	January 2020	January 2021	January 2022.
Reporting period	January 1, 2016–December 31, 2018.	January 1, 2017–December 31, 2019.	January 1, 2018–December 31, 2020.

5. 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 2020 Payment Determination and Subsequent Years

We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79792 through 79794) for a discussion of the previously finalized requirements related to survey administration and vendors for the OAS CAHPS Survey-based measures. In addition, we refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59432 through 59433), where we finalized a policy to delay implementation of the OP–37a–e OAS CAHPS Survey-based measures beginning with the CY 2020 payment determination (2018 reporting period) until further action in future rulemaking. We are not proposing any changes to the previously finalized requirements related to survey administration and vendors for the OAS CAHPS Survey-based measures.

6. Data Submission Requirements for Previously Finalized Measures for Data Submitted via a Web-Based Tool for the CY 2020 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. We are not proposing any changes to our policies regarding the submission of measure data submitted via a web-based tool.

We note that, in section XIII.B.4.b. of this proposed rule, we are proposing to remove of OP–27: Influenza Vaccination Coverage Among Healthcare Personnel beginning with the CY 2020 payment determination and for subsequent years. If this removal is finalized as proposed, for the CY 2020 payment determination, the following web-based quality measures would be required:

- OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data (via CMS' QualityNet website);
- OP–17: Tracking Clinical Results between Visits (NQF #0491) (via CMS' QualityNet website);
- OP–22: Left Without Being Seen (NQF #0499) (via CMS' QualityNet website);
- OP–29: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658) (via CMS' QualityNet website);
- OP–30: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use (NQF #0659) (via CMS' QualityNet website);
- OP–31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536) (via CMS' QualityNet website); and
- OP–33: External Beam Radiotherapy (EBRT) for Bone Metastases (NQF #1822) (via CMS' QualityNet website).

Furthermore, we note that in section XIII.B.4.b. of this proposed rule, for the CY 2021 payment determination and subsequent years, we are proposing to remove: OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into Their Qualified/Certified EHR System as Discrete Searchable Data; OP–17: Tracking Clinical Results between Visits; OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients; OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use; and OP–31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery beginning with the CY 2021 payment determination and for subsequent years. If these removals are finalized as proposed, only the following web-based quality measures would require data to be submitted via a web-based tool for the CY 2021 payment determination and subsequent years:

- OP–22: Left Without Being Seen (NQF #0499) (via CMS' QualityNet website); and
- OP–33: External Beam Radiotherapy (EBRT) for Bone Metastases (NQF #1822) (via CMS' QualityNet website).

7. Population and Sampling Data Requirements for the CY 2020 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. In this proposed rule, we are not proposing any changes to our population and sampling requirements for chart-abstracted measures.

8. 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 are not proposing any changes to these policies in this proposed rule.

9. Extraordinary Circumstances Exception (ECE) Process for the CY 2020 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 are not proposing any changes to our ECE policy in this proposed rule.

10. Hospital OQR Program Reconsideration and Appeals Procedures for the CY 2020 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 are not proposing any changes to our reconsideration and appeals procedures in this proposed rule.

E. Proposed Payment Reduction for Hospitals That Fail To Meet the Hospital OQR Program Requirements for the CY 2019 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 this 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 this proposed rule.

2. Proposed Reporting Ratio Application and Associated Adjustment Policy for CY 2019

We are proposing 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 2019 annual payment update factor. For the CY 2019 OPPS, the proposed reporting ratio is 0.980, calculated by dividing the proposed reduced conversion factor of 77.955 by the proposed full conversion factor of 79.546. We are proposing to continue to apply the reporting ratio to all services calculated using the OPPS conversion factor. For the CY 2019 OPPS, we are proposing 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 are proposing to continue to exclude services paid under New Technology APCs. We are proposing 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 are also proposing 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 are proposing 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.

XIV. Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

A. Background

1. Overview

We refer readers to section XIII.A.1. of this proposed rule for a general overview of our quality reporting programs and to section I.A.2. of this proposed rule for a discussion of our new Meaningful Measures Initiative.

2. Statutory History of the ASCQR Program

We refer readers to section XIV.K.1. of 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-agreed-upon quality measures. We have worked with relevant stakeholders to define measures of quality in almost every healthcare setting and currently measure some aspect of care for almost all Medicare beneficiaries. These measures assess structural aspects of care, clinical processes, patient experiences with care, and outcomes. We have implemented quality measure reporting programs for multiple settings of care. To measure the quality of ASC services and to make such information publicly available, we implemented the ASCQR Program. We refer readers to section XV.A.3. of the CY 2014 OPPS/ASC final rule with comment period (78 FR 75122), section XIV. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66966 through 66987), section XIV. of the CY 2016 OPPS/ASC final rule with comment period (80 FR 70526 through 70538), section XIV. of the CY 2017 OPPS/ASC final rule with comment period (81 FR 79797 through 79826) and section XIV. of the CY 2018 OPPS/ASC final rule with comment period (82 FR 59445 through 59476) for an overview of the regulatory history of the ASCQR Program.

4. Meaningful Measures Initiative

In this proposed rule, we are proposing a number of new policies for the ASCQR Program. We developed these proposals after conducting an overall review of the Program under our new Meaningful Measures Initiative, which is discussed in more detail in section I.A.2. of this proposed rule. The proposals reflect our efforts to ensure that the ASCQR Program measure set continues to promote improved health outcomes for our beneficiaries while minimizing costs, which can consist of several different types of costs, including, but not limited to: (1) Facility information collection burden and related cost and burden associated with the submitting/reporting of quality measures to CMS; (2) the facility cost associated with complying with other quality programmatic requirements; (3) the facility cost associated with participating in multiple quality programs, and tracking multiple similar or duplicative measures within or across those programs; (4) the CMS cost associated with the program oversight of the measure, including measure maintenance and public display; and (5) the facility cost associated with compliance with other federal and/or State regulations (if applicable). They also reflect our efforts to improve the usefulness of the data that we publicly report in the ASCQR Program. Our goal is to improve the usefulness and usability of CMS quality program data by streamlining how facilities are reporting and accessing data, while maintaining or improving consumer understanding of the data publicly reported on a *Compare* website. We believe this framework will allow ASCs and patients to continue to obtain meaningful information about ASC performance and incentivize quality improvement while also streamlining the measure sets to reduce duplicative measures and program complexity so that the costs to ASCs associated with participating in this program do not outweigh the benefits of improving beneficiary care.

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 are not proposing any changes to these policies.

2. Accounting for Social Risk Factors in the ASCQR Program

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59445 through 59447), we discussed the importance of improving beneficiary outcomes including reducing health disparities. We also discussed our commitment to ensuring that medically complex patients, as well as those with social risk factors, receive excellent care. We discussed how studies show that social risk factors, such as being near or below the poverty level as determined by HHS, belonging to a racial or ethnic minority group, or living with a disability, can be associated with poor health outcomes and how some of this disparity is related to the quality of health care.[91] Among our core objectives, we aim to improve health outcomes, attain health equity for all beneficiaries, and ensure that complex patients as well as those with social risk factors receive excellent care. Within this context, reports by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the National Academy of Medicine have examined the influence of social risk factors in CMS value-based purchasing programs.[92] As we noted in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59445 through 59447), ASPE's report to Congress found that, in the context of value-based purchasing programs, dual eligibility was the most powerful predictor of poor health care outcomes among those social risk factors that they examined and tested. In addition, as we noted in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59446), the National Quality Forum (NQF) undertook a 2-year trial period in which certain new measures and measures undergoing maintenance review have been assessed to determine if risk adjustment for social risk factors is appropriate for these measures.[93] The trial period ended in April 2017 and a final report is available at: *http://www.qualityforum.org/SES_Trial_Period.aspx.* The trial concluded that ''measures with a conceptual basis for adjustment generally did not demonstrate an empirical relationship'' between social risk factors and the outcomes measured. This discrepancy may be explained in part by the methods used for adjustment and the limited availability of robust data on social risk factors. NQF is now undertaking an extension of the socioeconomic status (SES) trial,[94] allowing further examination of social risk factors in outcome measures.

In the FY 2018 and CY 2018 proposed rules for our quality reporting and value-based purchasing programs, we solicited feedback on which social risk factors provide the most valuable information to stakeholders and the methodology for illuminating differences in outcomes rates among patient groups within a hospital or facility that would also allow for a comparison of those differences, or disparities, across facilities. Feedback we received through our quality reporting programs included encouraging CMS to explore whether factors that could be used to stratify or risk adjust the measures (beyond dual eligibility); considering the full range of differences in patients' backgrounds that might affect outcomes; exploring risk adjustment approaches; and offering careful consideration of what type of information display would be most useful to the public. We also sought public comment on confidential reporting and future public reporting of some of our measures stratified by patient dual eligibility. In general, commenters noted that stratified measures could serve as tools for facilities to identify gaps in outcomes for different groups of patients, improve the quality of health care for all patients, and empower beneficiaries and other consumers to make informed decisions about health care. Commenters encouraged us to stratify measures by other social risk factors such as age, income, and educational attainment. With regard to value-based purchasing programs, commenters also cautioned to balance fair and equitable payment while avoiding payment penalties that mask health disparities or discourage the provision of care to more medically complex patients. Commenters also noted that value-based payment program measure selection, domain weighting, performance scoring, and payment methodology must account for social risk.

As a next step, CMS is considering options to reduce health disparities among patient groups within and across healthcare settings by increasing the transparency of disparities as shown by quality measures. We also are considering how this work applies to other CMS quality programs in the future. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38403 through 38409) for more details, where we discuss the potential stratification of certain Hospital Inpatient Quality Reporting Program outcome measures. Furthermore, we continue to consider options to address equity and disparities in our value-based purchasing programs.

We plan to continue working with ASPE, the public, and other key stakeholders on this important issue to identify policy solutions that achieve the goals of attaining health equity for all beneficiaries and minimizing unintended consequences.

3. Policies for Retention and Removal of Quality Measures From the ASCQR Program

a. Retention of Previously Adopted ASCQR Program Measures

We previously adopted 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). In this proposed rule, we are not proposing any changes to this policy.

b. Removal Factors for ASCQR Program Measures

(1) Current Policy

We refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66967 through 66969) and 42 CFR 416.320 for a detailed discussion of the process for removing adopted measures from the ASCQR Program. In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66967 through 66969), we finalized the ASCQR Program measure removal factors[95] for determining whether to

[91] See, for example, United States Department of Health and Human Services. ''Healthy People 2020: Disparities. 2014.'' Available at: *http://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities;* or National Academies of Sciences, Engineering, and Medicine. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: National Academies of Sciences, Engineering, and Medicine 2016.

[92] Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE), ''Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs.'' December 2016. Available at: *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[93] National Quality Forum. Final Report-Disparities Project. September 2017. Available at: *http://www.qualityforum.org/SES_Trial_Period.aspx.*

[94] National Quality Forum. Health Equity Program: Social Risk Initiative 2.0. 2017. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86357.*

[95] We note that we previously referred to these factors as ''criteria'' (for example, 82 FR 59474 through 59475); we now use the term ''factors'' in order to align the ASCQR Program terminology with the terminology we use in other CMS quality

remove ASCQR Program measures as follows:

- 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. Availability of alternative measures with a stronger relationship to 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.

In that final rule with comment period, we stated that the benefits of removing a measure from the ASCQR Program will be assessed on a case-by-case basis (79 FR 66969). Under this case-by-case approach, a measure will not be removed solely on the basis of meeting any specific factor. We note that in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68472 through 68473), similar measure removal factors were finalized for the Hospital OQR Program.

In this proposed rule, we are proposing to: (1) Remove one factor; (2) add two new measure removal factors, and (3) update 42 CFR 416.320(c) to better reflect our measure removal policies. We are also making one clarification to measure removal Factor 1. These items are discussed in detail below.

(2) Proposal To Remove Factor 2

We received comments in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66967) remarking the duplicative nature of the ASCQR Program's measure removal Factor 2, availability of alternative measures with a stronger relationship to patient outcomes, with measure removal Factor 6, the availability of a measure that is more strongly associated with desired patient outcomes for the particular topic. In that final rule with comment period, we stated that ''criterion (2) applies when there is more than one alternative measure with a stronger relationship to patient outcomes that is available, and criterion (6) applies where there is only one measure that is strongly and specifically associated with desired patient outcomes for the particular topic that is available'' (79 FR 66967). Since reevaluating those comments, we have now come to agree that ASCQR measure removal Factor 2 is repetitive with Factor 6. Therefore, we are proposing to remove Factor 2, ''availability of alternative measures with a stronger relationship to patient outcomes,'' beginning with the effective date of the CY 2019 OPPS/ASC final rule with comment period.

(3) Proposals To Add Two New Measure Removal Factors

(a) Proposed Measure Removal Factor 2: Performance or Improvement on a Measure Does Not Result in Better Patient Outcomes

We would like the ASCQR Program measure removal factors to be fully aligned with the Hospital OQR Program to provide consistency across these two outpatient setting quality reporting programs. We believe it is important to evaluate the appropriateness of measures across programs using similar standards. In evaluating the two programs' removal factors, we became aware that the Hospital OQR Program includes one factor not currently in the ASCQR Program. The Hospital OQR Program's second measure removal factor specifies ''performance or improvement on a measure does not result in better patient outcomes'' (75 FR 50185).

Therefore, in this proposed rule, we are proposing to add ''performance or improvement on a measure does not result in better patient outcomes'' as the new removal Factor 2 for the ASCQR Program (replacing the previously adopted factor proposed for removal above). We believe that this factor is applicable in evaluating the ASCQR Program quality measures for removal because we have found it useful for evaluating measures in the Hospital OQR Program, which also evaluates the outpatient setting. We also note that this proposed factor is already included in the Hospital IQR (80 FR 49641 through 49642), the PCHQR (82 FR 38411), the LTCH QRP (77 FR 53614 through 53615), and the IPFQR (82 FR 38463) Programs. Therefore, we are proposing to add a new removal factor to the ASCQR Program: ''performance or improvement on a measure does not result in better patient outcomes'' beginning with the effective date of the CY 2019 OPPS/ASC final rule with comment period.

(b) Proposed New Measure Removal Factor 8

We are proposing to adopt an additional factor to consider when evaluating measures for removal from the ASCQR Program measure set:

- Factor 8. The costs associated with a measure outweigh the benefit of its continued use in the program.

As we discuss in section I.A.2. of this proposed rule with respect to our new Meaningful Measures Initiative, we are engaging in efforts to ensure that the ASCQR Program measure set continues to promote improved health outcomes for beneficiaries while minimizing the overall costs associated with the program. We believe these costs are multifaceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining the program. We have identified several different types of costs, including, but not limited to: (1) Facility information collection burden and related costs and burden associated with the submission/reporting of quality measures to CMS; (2) the facility cost associated with complying with other programmatic requirements; (3) the facility cost associated with participating in multiple quality programs, and tracking multiple similar or duplicative measures within or across those programs; (4) the CMS cost associated with the program oversight of the measure including measure maintenance and public display; and (5) the facility cost associated with compliance with other federal and/or State regulations (if applicable). For example, it may be needlessly costly and/or of limited benefit to retain or maintain a measure which our analyses show no longer meaningfully supports program objectives (for example, informing beneficiary choice or payment scoring). It may also be costly for ASCs to track confidential feedback, preview reports, and publicly reported information on a measure where we use the measure in more than one program. CMS may also have to expend unnecessary resources to maintain the specifications for the measure, as well as the tools needed to collect, validate, analyze, and publicly report the measure data. Furthermore, beneficiaries may find it confusing to see public reporting on the same measure in different programs.

In weighing the costs against the benefits, we evaluate the benefits of the

reporting and pay for performance (value-based purchasing) programs.

measure as a whole, but in particular, we assess the benefits through the framework of our Meaningful Measures Initiative, as we discussed in section I.A.2. of this proposed rule. One key aspect of patient benefits is assessing the improved beneficiary health outcomes if a measure is retained in our measure set. We believe that these benefits are multifaceted, and are illustrated through the Meaningful Measures framework's 6 domains and 19 areas. For example, we assessed the Healthcare Worker Influenza Vaccination and patient Influenza Vaccination measures categorized in the Quality Priority ''Promote Effective Prevention and Treatment of Chronic Disease'' in the meaningful measure area of ''Preventive Care'' across multiple CMS programs, and considered: Patient outcomes, such as mortality and hospitalizations associated with influenza; CMS measure performance in a program; and other available and reported influenza process measures, such as population influenza vaccination coverage.

When these costs outweigh the evidence supporting the benefits to patients with the continued use of a measure in the ASCQR Program, we believe it may be appropriate to remove the measure from the Program. Although we recognize that one of the main goals of the ASCQR Program is to improve beneficiary outcomes by incentivizing health care facilities to focus on specific care issues and making public data related to those issues, we also recognize that those goals can have limited utility where, for example, the publicly reported data (including percentage payment adjustment data) is of limited use because it cannot be easily interpreted by beneficiaries and used to inform their choice of facility. In these cases, removing the measure from the ASCQR Program may better accommodate the costs of program administration and compliance without sacrificing improved health outcomes and beneficiary choice.

We are proposing that we would remove measures based on this factor on a case-by-case basis. We might, for example, decide to retain a measure that is burdensome for ASCs to report if we conclude that the benefit to beneficiaries justifies the reporting burden. Our goal is to move the program forward in the least burdensome manner possible, while maintaining a parsimonious set of meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients.

We are inviting public comment on our proposal to adopt an additional measure removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program, beginning with the effective date of the CY 2019 OPPS/ASC final rule with comment period and for subsequent years.

We refer readers to section XIV.B.3.c. of this proposed rule, where we are proposing to remove four measures based on this proposed measure removal factor. We note that we have also proposed this same removal factor for the Hospital OQR Program in section XIII.B.4.a.(4) of this proposed rule, as well as for other quality reporting and value-based purchasing programs for FY 2019 including: the Hospital VBP Program (83 FR 20409), the Hospital IQR Program (83 FR 20472); the PCHQR Program (83 FR 20501 through 20502); the LTCH QRP (83 FR 20512); the HQRP (83 FR 20956); the IRF QRP (83 FR 21000); the SNF QRP (83 FR 21082); and the IPFQR Program (83 FR 21118).

If our proposals to remove one and add two new removal factors are finalized as proposed, the new removal factors list would be:

- 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.
- Factor 8. The costs associated with a measure outweigh the benefit of its continued use in the program.

(4) Proposed Revisions to 42 CFR 416.320(c)

We are proposing to revise 42 CFR 416.320(c) to better reflect our considerations for removing measures policy in light of the above proposals.

(5) Clarification for Removal Factor 1: ''Topped-Out'' Measures

We refer readers to the CY 2015 OPPS/ASC final rule with comment period where we finalized the criteria for determining when a measure is ''topped-out'' (79 FR 66968). In that final rule with comment period, we finalized two criteria for determining when a measure is ''topped-out'' under the ASCQR Program: (1) When there is statistically indistinguishable performance at the 75th and 90th percentiles of national facility performance; and (2) when the measure's truncated coefficient of variation (TCOV) is less than or equal to 0.10 (79 FR 66968 through 66969).

We are not proposing any changes to this policy; however, we are clarifying our process for calculating the truncated coefficient of variation (TCOV) for four of the measures (ASC–1, ASC–2, ASC–3, and ASC–4) proposed for removal from the ASCQR Program. Utilizing our finalized methodology (79 FR 66968), we determine the truncated coefficient of variation (TCOV) by calculating the truncated standard deviation (SD) divided by the truncated mean. As discussed above, our finalized removal criteria state that to be considered ''topped-out'', a measure must have a TCOV of less than 0.10. We utilize the TCOV because it is generally a good measure of variability and provides a relative methodology for comparing different types of measures.

Unlike the majority of our measures, for which a higher rate (indicating a higher proportion of a desired event) is the preferred outcome, some measures—in particular, ASC–1, ASC–2, ASC–3, and ASC–4—assess the rate of rare, undesired events for which a lower rate is preferred. For example, ASC–1 assesses the occurrence of patient burns, a patient safety issue. However, when determining the TCOV for a measure assessing rare, undesired events, the mean, or average rate of event occurrence, is very low and the result is a TCOV that increases rapidly and approaches infinity as the proportion of rare events declines.[96] We note that the SD, the variability statistic, is the same in magnitude for measures assessing rare and non-rare events.

In this proposed rule, we are proposing to remove a number of measures that assess the rate of rare, undesired events for which a lower rate is preferred—ASC–1, ASC–2, ASC–3, and ASC–4—and refer readers to section

[96] Rose-Hulman Institute of Technology. Denominator approaching zero. Retrieved from: *https://www.rose-hulman.edu/media/89584/lclimitsguide.pdf.*

XIV.B.3.c. of this proposed rule where these proposed measure removals are discussed in detail. Because by design these measures have maintained very low rates (indicating the preferred outcome), we utilized the mean of *non-adverse* events in our calculation of the TCOV. For example, for ASC–1, to calculate the TCOV we divide the SD by the average rate of patients *not* receiving burns (1 minus the rate of patients receiving burns) rather than the rate of patients receiving burns. Utilizing this methodology results in a TCOV that is comparable to that calculated for other measures and allows us to assess rare-event measures by still generally using our previously finalized topped-out criteria.

c. Proposed Removal of Quality Measures From the ASCQR Program Measure Set

In this proposed rule, we are proposing to remove a total of 8 measures from the ASCQR Program measure set across the CY 2020 and CY 2021 payment determinations. Specifically, beginning with the CY 2020 payment determination, we are proposing to remove: (1) ASC–8: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431); and beginning with the CY 2021 payment determination, we are proposing to remove: (2) ASC–1: Patient Burn (NQF #0263); (3) ASC–2: Patient Fall (NQF #0266); (4) ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (NQF #0267); (5) ASC–4: All-Cause Hospital Transfer/Admission (NQF #0265); (6) ASC–9: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658); (7) ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use (NQF #0659); and (8) ASC–11: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536). We are proposing to remove these measures under the following measure removal factors: 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); and proposed Factor 8—the costs associated with a measure outweigh the benefit of its continued use in the program.

These proposed measure removals are discussed in detail below.

(1) Proposed Measure Removal for the CY 2020 Payment Determination and Subsequent Years—Proposed Removal of ASC–8: Influenza Vaccination Coverage Among Healthcare Personnel

For the CY 2020 payment determination and subsequent years, we are proposing to remove one NHSN measure under proposed measure removal Factor 8, the costs associated with this measure outweigh the benefit of its continued use in the program.

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74510), where we adopted ASC–8: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431), beginning with the CY 2016 payment determination and for subsequent years. This process of care measure, also a National Healthcare Safety Network (NHSN) measure, assesses the percentage of healthcare personnel who have been immunized for influenza during the flu season. We initially adopted this measure based on our recognition that influenza immunization is an important public health issue and vital component to preventing healthcare associated infections. We believe that the measure addresses this public health concern by assessing influenza vaccination in the ASC among healthcare personnel (HCP), who can serve as vectors for influenza transmission.

In this proposed rule, we are proposing to remove ASC–8: Influenza Vaccination Coverage Among Healthcare Personnel beginning with the CY 2020 payment determination under proposed measure removal Factor 8, because we have concluded that the costs associated with this measure outweigh the benefit of its continued use in the program.

The information collection burden for the Influenza Vaccination Coverage Among Healthcare Personnel measure is less than for measures that require chart abstraction of patient data because influenza vaccination among health care personnel can be calculated through review of records maintained in administrative systems and because facilities have fewer health care personnel than patients. As such, ASC–8 does not require review of as many records. However, this measure does still pose information collection burden on facilities due to the requirement to identify personnel who have been vaccinated against influenza and for those not vaccinated, the reason why.

Furthermore, as we stated in section XIV.B.3.b. of this proposed rule, costs are multifaceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining the program. For example, it may be costly for health care providers to maintain general administrative knowledge to report these measures. In addition, CMS must expend resources in maintaining information collection systems, analyzing reported data, and providing public reporting of the collected information.

In our analysis of the ASCQR Program measure set, we recognized that some ASCs face challenges with respect to the administrative requirements of the NHSN in their reporting of the Influenza Vaccination Coverage Among Healthcare Personnel measure. These administrative requirements (which are unique to NHSN) include annually completing NHSN system user authentication. Enrolling in NHSN is a five-step process that the CDC estimates takes an average of 263 minutes per ASC.[97] Furthermore, submission via NHSN requires the system security administrator of participating facilities to reconsent electronically, ensure that contact information is kept current, ensure that the ASC has an active facility administrator account, keep Secure Access Management Service (SAMS) credentials active by logging in approximately every 2 months and changing their password, create a monthly reporting plan, and ensure the ASC's CCN information is up-to-date.

Unlike acute care hospitals which participate in other quality programs, such as the Hospital IQR and HAC Reduction Programs, ASCs are only required to participate in NHSN to submit data for this one measure. This may unduly disadvantage smaller ASCs, specifically those that are not part of larger hospital systems, because these ASCs do not have NHSN access for other quality reporting or value-based payment programs. It is our goal to ensure that the ASCQR Program is equitable to all ASCs and this measure may disproportionately affect small, independent ASCs. Especially for these small, independent ASCs, the incremental costs of this measure, as compared to other measures in the ASCQR Program measure set, are significant because of the requirements imposed by NHSN participation.

We continue to believe that the Influenza Vaccination Coverage Among Healthcare Personnel measure provides the benefit of protecting ASC patients

[97] Available at: *https://www.cdc.gov/nhsn/ambulatory-surgery/enroll.html* (the estimates for time to complete are 2 hours 45 minutes for step 1, 10 minutes for step 2, 16 minutes for step 3a, 35 minutes for step 3b, 32 minutes for step 4, and 5 minutes for step 5; totaling 263 minutes).

against influenza. However, we believe that these benefits are offset by other efforts to reduce influenza infection among ASC patients, such as numerous healthcare employer requirements for healthcare personnel to be vaccinated against influenza.[98] We also expect that a portion of MIPS-eligible clinicians nationwide will report on the Preventive Care and Screening: Influenza Immunization measure (NQF #0041) through the Quality Payment Program (QPP).[99] Although MIPS-eligible clinicians may voluntarily select measures from a list of options, ASC providers that are MIPS-eligible will have the opportunity to continue collecting information for the measure. CMS remains responsive to the public health concern of influenza infection within the Medicare FFS population by collecting data on rates of influenza immunization among patients.[100] Thus, the public health concern is addressed via these other efforts to track influenza vaccination. The availability of this measure in another CMS program demonstrates CMS' continued commitment to this measure area. In addition, as we discuss in section XIV.B.3.b. of this proposed rule, where we are proposing to adopt measure removal Factor 8, beneficiaries may find it confusing to see public reporting on the same measure in different programs.

We wish to minimize the level of cost of our programs for participating facilities, as discussed under the Meaningful Measures Initiative described in section I.A.2. of this proposed rule. In our assessment of the ASCQR Program measure set, we prioritized measures that align with this Framework as the most important to the ASC population. Our assessment concluded that while the Influenza Vaccination Coverage Among Healthcare Personnel measure continues to provide benefits, these benefits are diminished by other factors and are outweighed by the costs and burdens of reporting this measure.

For these reasons, we are proposing to remove ASC–8: Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) from the ASCQR Program beginning with the CY 2020 payment determination and for subsequent years because the costs associated with the measure outweigh the benefit of its continued use in the program. We note that if proposed measure removal Factor 8 is not finalized, removal of this measure would also not be finalized. We note that this measure is also being proposed for removal from the Hospital OQR Program in section XIII.B.4.b. of this proposed rule and the IPFQR Program in the FY 2019 IPF PPS proposed rule (83 FR 21119 through 21120).

(2) Proposed Measure Removals for the CY 2021 Payment Determination and Subsequent Years

For the CY 2021 payment determination and subsequent years, we are proposing to remove: (1) Four claims-based measures under measure removal Factor 1, ''topped-out'' status; (2) two chart-abstracted measures and one web-based tool measure under proposed measure removal Factor 8.

(a) Proposed Measure Removals Under Removal Factor 1: ASC–1, ASC–2, ASC–3, and ASC–4

In this proposed rule, beginning with the CY 2021 payment determination and subsequent years, we are proposing to remove ASC–1, ASC–2, ASC–3, and ASC–4 under measure removal Factor 1, measure performance among ASCs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made. The ASCQR Program previously finalized two criteria for determining when a measure is ''topped-out'': (1) When there is statistically indistinguishable performance at the 75th and 90th percentiles of national facility performance; and (2) when the measure's truncated coefficient of variation is less than or equal to 0.10 (79 FR 66968 through 66969). We refer readers to section XIV.B.3.b. of this proposed rule, above, where we clarify and discuss how we calculate the TCOV for measures that assess the rate of rare, undesired events for which a lower rate is preferred, such as ASC–1, ASC–2, ASC–3, and ASC–4.

For each of these measures, we believe that removal from the ASCQR Program measure set is appropriate as there is little room for improvement. In addition, removal would alleviate the maintenance costs and administrative burden to ASCs associated with retaining the measures. As such, we believe the burden associated with reporting these measures outweighs the benefits of keeping them in the program.

Each measure is discussed in more detail below. We also note that in crafting our proposals, we considered removing these measures beginning with the CY 2020 payment determination, but opted to delay removal until the CY 2021 payment determination to be sensitive to facilities' planning and operational procedures given that data collection for the measures begins during CY 2018 for the CY 2020 payment determination.

• Proposed Removal of ASC–1: Patient Burn

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74497 through 74498) where we adopted ASC–1: Patient Burn beginning with the CY 2014 payment determination (NQF #0263). This claims-based outcome measure assesses the percentage of ASC admissions experiencing a burn prior to discharge.

Based on our analysis of ASCQR Program measure data for CYs 2013 to 2017 encounters, the ASC–1 measure meets our measure removal Factor 1. These analyses are captured in the table below.

ASC–1—Patient Burn Topped-Out Analysis

Encounters	Number of ASCs	75th percentile	90th percentile	Truncated COV
Q1–Q4 2013	4,768	100.00	100.00	0.023
Q1–Q4 2014	4,794	100.00	100.00	0.015
Q1–Q4 2015	4,783	100.00	100.00	0.011
Q1–Q4 2016	4,788	100.00	100.00	0.010
Q1–Q4 2017	4,814	100.00	100.00	0.008

[98] CDC, Influenza Vaccination Information for Health Care Workers. Available at: *https://www.cdc.gov/flu/healthcareworkers.htm.*

[99] QPP 2017 Measures Selection: Influenza. Retrieved from: *https://qpp.cms.gov/mips/quality-measures.*

[100] Ibid.

As displayed in the analysis above, there is no distinguishable difference in ASC performance between the 75th and 90th percentiles, and the truncated coefficient of variation has been below 0.10 since 2013. We also note that NQF endorsement of this measure (NQF #0263) was removed on May 24, 2016.[101]

• Proposed Removal of ASC–2: Patient Fall

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74498) where we adopted ASC–2: Patient Fall beginning with the CY 2014 payment determination. This NQF-endorsed (NQF #0266), claims-based measure assesses the percentage of ASC admissions experiencing a fall in the ASC.

Based on our analysis of ASCQR Program measure data for CYs 2013 to 2017 encounters, the ASC–2 measure meets our measure removal Factor 1. These analyses are captured in the table below.

ASC–2—Patient Fall Topped-Out Analysis

Encounters	Number of ASCs	75th percentile	90th percentile	Truncated COV
Q1–Q4 2013	4,769	100.00	100.00	0.011
Q1–Q4 2014	4,793	100.00	100.00	0.007
Q1–Q4 2015	4,783	100.00	100.00	0.006
Q1–Q4 2016	4,787	100.00	100.00	0.003
Q1–Q4 2017	4,815	100.00	100.00	0.001

As displayed in the analysis above, there is no distinguishable difference in ASC performance between the 75th and 90th percentiles and the truncated coefficient of variation has been below 0.10 since 2013.

• Proposed Removal of ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74498 through 74499) where we adopted ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant beginning with the CY 2014 payment determination (NQF #0267). This claims-based outcome measure assesses the percentage of ASC admissions experiencing a wrong site, wrong side, wrong patient, wrong procedure, or wrong implant.

Based on our analysis of ASCQR Program measure data for CYs 2013 to 2017 encounters, the ASC–3 measure meets our measure removal Factor 1. These analyses are captured in the table below.

ASC–3—Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant Topped-Out Analysis

Encounters	Number of ASCs	75th percentile	90th percentile	Truncated COV
Q1–Q4 2013	4,769	100.00	100.00	0.000
Q1–Q4 2014	4,793	100.00	100.00	0.000
Q1–Q4 2015	4,781	100.00	100.00	0.000
Q1–Q4 2016	4,787	100.00	100.00	0.000
Q1–Q4 2017	4,815	100.00	100.00	0.000

As displayed in the analysis above, there is no distinguishable difference in ASC performance between the 75th and 90th percentiles and the truncated coefficient of variation has been below 0.10 since 2013. We also note that NQF endorsement of this measure (NQF #0267) was removed on May 24, 2016.[102]

• Proposed Removal of ASC–4: All-Cause Hospital Transfer/Admission

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74499) where we adopted ASC–4: All-Cause Hospital Transfer/Admission beginning with the CY 2014 payment determination (NQF #0265). This claims-based outcome measure assesses the rate of ASC admissions requiring a hospital transfer or hospital admission upon discharge from the ASC.

Based on our analysis of ASCQR Program measure data for CYs 2013 to 2017 encounters, the ASC–4 measure meets our measure removal Factor 1. These analyses are captured in the table below.

ASC–4—All Cause Hospital Transfer/Admission Topped-Out Analysis

Encounters	Number of ASCs	75th percentile	90th percentile	Truncated COV
Q1–Q4 2013	4,768	100.00	100.00	0.059
Q1–Q4 2014	4,793	100.00	100.00	0.050
Q1–Q4 2015	4,781	100.00	100.00	0.041
Q1–Q4 2016	4,787	100.00	100.00	0.040
Q1–Q4 2017	4,814	100.00	100.00	0.037

[101] National Quality Forum. Available at: *http://www.qualityforum.org/QPS/0263.*

[102] National Quality Forum. Available at: *http://www.qualityforum.org/QPS/0267.*

As displayed in the analysis above, there is no distinguishable difference in ASC performance between the 75th and 90th percentiles and the truncated coefficient of variation has been below 0.10 since 2013. We also note that NQF endorsement of this measure (NQF #0265) was removed on February 4, 2016.[103]

Therefore, we are inviting public comment on our proposals to remove: (1) ASC–1: Patient Burn; (2) ASC–2: Patient Fall; (3) ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; and (4) ASC–4: All-Cause Hospital Transfer/Admission beginning with the CY 2021 payment determination and for subsequent years as discussed above.

(b) Proposed Measure Removals Under Removal Factor 8: ASC–9, ASC–10, and ASC–11

In this proposed rule, we are proposing to remove three measures (ASC–9, ASC–10, and ASC–11) under proposed measure removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program, for the CY 2021 payment determination and subsequent years. We note that if proposed measure removal Factor 8 is not finalized, removal of these measures would also not be finalized.

The proposals are discussed in more detail below. We note that in crafting our proposals, we considered removing these measures beginning with the CY 2020 payment determination, but opted to delay removal until the CY 2021 payment determination to be sensitive to facilities' planning and operational procedures given that data collection for these measures begins during CY 2018 for the CY 2020 payment determination.

• Proposed Removal of ASC–9: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75127 through 75128) where we adopted ASC–9: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0659) beginning with the CY 2016 payment determination. This chart-abstracted process measure assesses the ''[p]ercentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of a prior colonic polyp in previous colonoscopy findings, who had a follow-up interval of 3 or more years since their last colonoscopy documented in the colonoscopy report'' (78 FR 75128). This measure aims to assess whether average risk patients with normal colonoscopies receive a recommendation to receive a repeat colonoscopy in an interval that is less than the recommended amount of 10 years.

In this proposed rule, we are proposing to remove ASC–9: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients beginning with the CY 2021 payment determination and for subsequent years under our proposed measure removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program. We adopted ASC–9: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75127 through 75128) noting that performing colonoscopy too frequently increases patients' exposure to procedural harm. However, we now believe that the costs of this measure outweigh the benefit of its continued use in the program.

Chart-abstraction requires facilities to select a sample population, access historical records from several current and historic clinical data quarters, and interpret that patient data. This process is typically more time and resource-consuming than for other measure types. In addition to submission of manually chart-abstracted data, we take all burden and costs into account when evaluating a measure. Removing ASC–9 would reduce the burden and cost to facilities associated with collection of information and reviewing their data and performance associated with the measure.

However, we do not believe the use of chart-abstracted measure data alone is sufficient justification for removal of a measure under proposed measure removal Factor 8. The costs of collection and submission of chart-abstracted measure data is burdensome for facilities, especially when taking into consideration the availability of other CMS quality measures that are relevant in the clinical condition and highly correlated in performance across measures. Another colonoscopy-related measure required in the ASCQR Program, ASC–12: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (NQF #2539) measures all-cause, unplanned hospital visits (admissions, observation stays, and emergency department visits) within 7 days of an outpatient colonoscopy procedure (79 FR 66970). This claims-based outcome measure does not require chart-abstraction, and similarly contributes data on quality of care related to colonoscopy procedures, although the measure does not specifically track processes such as follow-up intervals. When we adopted ASC–12, we believed this measure would reduce adverse patient outcomes associated with preparation for colonoscopy, the procedure itself, and follow-up care by capturing and making more visible to facilities and patients all unplanned hospital visits following the procedure (79 FR 66970).

Furthermore, the potential benefits of keeping ASC–9 in the program are mitigated by the existence of the same measure (Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients)[104] for gastroenterologists in the Merit-Based Incentive Payment System (MIPS) for the 2019 performance period in the QPP (82 FR 30292). Thus, we believe the issue of preventing harm to patients from colonoscopy procedures that are performed too frequently is adequately addressed through MIPS in the QPP, because we expect a portion of MIPS-eligible clinicians reporting on the measure nationwide to provide meaningful data to CMS. Although MIPS-eligible clinicians may voluntarily select measures from a list of options, ASC providers that are MIPS-eligible will have the opportunity to continue collecting information for the measure without being penalized if they determine there is value for various quality improvement efforts.[105] The availability of this measure in another CMS program demonstrates CMS' continued commitment to this measure area.

Furthermore, we seek to align our quality reporting work with the Patients Over Paperwork and the Meaningful Measures Initiatives described in section I.A.2. of this proposed rule. The purpose of this effort is to hold providers accountable for only the measures that are most important to patients and clinicians and those that are focused on patient outcomes in particular, because outcome measures

[103] National Quality Forum. Available at: *http://www.qualityforum.org/QPS/0265.*

[104] QPP Measure Selection: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients. Retrieved from: *https://qpp.cms.gov/mips/quality-measures.*

[105] CMS finalized that services furnished by an eligible clinician that are payable under the ASC, HHA, Hospice, or HOPD methodology will not be subject to the MIPS payments adjustments, but eligible clinicians payable under those methodologies may have the option to still voluntarily report on applicable measures and the data reported will not be used to determine future eligibility (82 FR 53586).

evaluate the actual results of care. As described in section I.A.2. of this proposed rule, our Meaningful Measures Initiative is intended to reduce costs and minimize burden, and we believe that removing this chart-abstracted measure from the ASCQR Program would reduce program complexity. In addition, as we discuss in section XIV.B.3.b. of this proposed rule, where we are proposing to adopt measure removal Factor 8, beneficiaries may find it confusing to see public reporting on the same measure in different programs.

Therefore, due to the combination of factors of the costs of collecting data for this chart-abstracted measure, the preference for an outcomes measure in the ASCQR Program that provides valuable data for the same procedure, and the existence of the same measure in another CMS program, we believe that the burdens and costs associated with this measure outweigh the limited benefit to beneficiaries. As a result, we are proposing to remove ASC–9: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients beginning with the CY 2021 payment determination and for subsequent years. We note that we are also proposing to remove a similar measure in the Hospital OQR Program in section XIII.B.4.b. of this proposed rule.

• Proposed Removal of ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use

We refer readers to CY 2014 OPPS/ASC final rule with comment period (78 FR 75128) where we adopted ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use (NQF #0659) beginning with the CY 2016 payment determination. This chart-abstracted process measure assesses the percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of a prior colonic polyp in previous colonoscopy findings, who had a follow-up interval of 3 or more years since their last colonoscopy documented in the colonoscopy report.

In this proposed rule, we are proposing to remove ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use beginning with the CY 2021 payment determination and for subsequent years under our proposed measure removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program.

We adopted ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75128) noting that colonoscopy screening for high risk patients is recommended based on risk factors, and one such factor is a history of adenomatous polyps. The frequency of colonoscopy screening varies depending on the size and amount of polyps found, with the general recommendation of a 3-year follow-up. We stated that this measure is appropriate for the measurement of quality of care furnished by ASCs, because colonoscopy screening is commonly performed in these settings (78 FR 75128). However, we now believe that the costs of this measure outweigh the benefit of its continued use in the program.

Chart-abstraction requires facilities to select a sample population, access historical records from several clinical data quarters past, and interpret that patient data. This process is typically more time and resource-consuming than for other measure types. In addition to submission of manually chart-abstracted data, we take all burden and costs into account when evaluating a measure. Removing ASC–10 would reduce the burden and cost to facilities associated with collection of information and reporting on their performance associated with the measure.

However, we do not believe the use of chart-abstracted measure data alone is sufficient justification for removal of a measure under proposed measure removal Factor 8. The costs of collection and submission of chart-abstracted measure data is burdensome for facilities especially when taking into consideration the availability of other CMS quality measures. Another colonoscopy-related measure required in the ASCQR Program, ASC–12: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (NQF #2539) measures all-cause, unplanned hospital visits (admissions, observation stays, and emergency department visits) within 7 days of an outpatient colonoscopy procedure (79 FR 66970). This claims-based outcome measure does not require chart-abstraction, and similarly contributes data on quality of care related to colonoscopy procedures, although the measure does not specifically track processes such as follow-up intervals. When we adopted ASC–12, we believed this measure would reduce adverse patient outcomes associated with preparation for colonoscopy, the procedure itself, and follow-up care by capturing and making more visible to facilities and patients all unplanned hospital visits following the procedure (79 FR 66970). Furthermore, the potential benefits of keeping ASC–10 in the ASCQR Program are mitigated by the existence of the same measure (Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients) [106] for gastroenterologists in the Merit-Based Incentive Payment System (MIPS) for the 2019 performance period in the QPP (82 FR 30292). Thus, we believe the issue of preventing harm to patients from colonoscopy procedures that are performed too frequently is adequately addressed through MIPS in the QPP, because we expect a portion of MIPS-eligible clinicians reporting on the measure nationwide to provide meaningful data to CMS. Although MIPS-eligible clinicians may voluntarily select measures from a list of options, ASC providers that are MIPS-eligible will have the opportunity to continue collecting information for the measure without being penalized if they determine there is value for various quality improvement efforts.[107] The availability of this measure in another CMS program demonstrates CMS' continued commitment to this measure area.

Furthermore, we seek to align our quality reporting work with the Patients Over Paperwork and the Meaningful Measures Initiatives described in section I.A.2. of this proposed rule. The purpose of this effort is to hold providers accountable for only the measures that are most important to patients and clinicians and that are focused on patient outcomes in particular, because outcome measures evaluate the actual results of care. As described in section I.A.2. of this proposed rule, our Meaningful Measures Initiative is intended to reduce costs and minimize burden, and we believe that removing this chart-abstracted measure from the ASCQR Program would reduce program complexity. In addition, as we discuss in section

[106] QPP Measure Selection: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients. Retrieved from: *https://qpp.cms.gov/mips/quality-measures.*

[107] CMS finalized that services furnished by an eligible clinician that are payable under the ASC, HHA, Hospice, or HOPD methodology will not be subject to the MIPS payments adjustments, but eligible clinicians payable under those methodologies may have the option to still voluntarily report on applicable measures and the data reported will not be used to determine future eligibility (82 FR 53586).

XIV.B.3.b. of this proposed rule, where we are proposing to adopt measure removal Factor 8, beneficiaries may find it confusing to see public reporting on the same measure in different programs.

Therefore, due to the combination of factors of the costs of collecting data for this chart-abstracted measure, the preference for an outcomes measure in the ASCQR Program that provides valuable data for the same procedure, and the existence of the same measure in the MIPS program, we believe that the burdens and costs associated with manual chart abstraction outweigh the limited benefit to beneficiaries of receiving this information. As a result, we are proposing to remove ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use beginning with the CY 2021 payment determination and for subsequent years. We note that we are also proposing to remove a similar measure in the Hospital OQR Program in section XIII.B.4.b. of this proposed rule.

• Proposed Removal of ASC–11: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75129) where we adopted ASC–11: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536) beginning with the CY 2016 payment determination. This measure assesses the rate of patients 18 years and older (with a diagnosis of uncomplicated cataract) in a sample who had improvement in visual function achieved within 90 days following cataract surgery based on completing both a preoperative and postoperative visual function survey.

Since the adoption of this measure, we came to believe that it can be operationally difficult for ASCs to collect and report the measure (79 FR 66984). Specifically, we were concerned that the results of the survey used to assess the preoperative and post-operative visual function of the patient may not be shared across clinicians and facilities, making it difficult for ASCs to have knowledge of the visual function of the patient before and after surgery (79 FR 66984). We were also concerned about the surveys used to assess visual function; the measure allows for the use of any validated survey and results may be inconsistent should clinicians use different surveys (79 FR 66984). Therefore, on December 31, 2013, we issued guidance stating that we would delay data collection for ASC–11 for 3 months (data collection would commence with April 1, 2014 encounters) for the CY 2016 payment determination (*https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772879036*). We issued additional guidance on April 2, 2014, stating that we would further delay the implementation of ASC–11 for an additional 9 months, until January 1, 2015 for the CY 2016 payment determination, due to continued concerns (*https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228773811586*). As a result of these concerns, in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66984 through 66985), we finalized our proposal to allow voluntary data collection and reporting of this measure beginning with the CY 2017 payment determination and for subsequent years.

In this proposed rule, we are proposing to remove ASC–11: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery from the ASCQR Program beginning with the CY 2021 payment determination under proposed measure removal Factor 8, the costs associated with the measure outweigh the benefit of its continued use in the program. We originally adopted ASC–11 because we believe ASCs should be a partner in care with physicians and other clinicians using their facility and that this measure would provide an opportunity to do so (79 FR 66984). However, in light of the history of complications and upon reviewing this measure within our Meaningful Measures framework, we have concluded that it is overly burdensome for facilities to report this measure due to the difficulty of tracking care that occurs outside of the ASC setting.

In order to report on this measure to CMS, a facility would need to obtain the visual function assessment results from the appropriate ophthalmologist and ensure that the assessment utilized is validated for the population for which it is being used. If the assessment is not able to be used or is not available, the ASC facility would then need to administer the survey directly and ensure that the same visual function assessment tool is utilized preoperatively and postoperatively. There is no simple, preexisting means for information sharing between ophthalmologists and ASCs, so an ASC would need to obtain assessment results from each individual patient's ophthalmologist both preoperatively and postoperatively. The high administrative costs of the technical tracking of this information presents an undue cost, and also burden associated with submission and reporting of ASC–11 to CMS, especially for small ASCs with limited staffing capacity.

Furthermore, this measure currently provides limited benefits. Since making the measure voluntary, only 118 facilities have reported this measure to CMS, compared to approximately 5,121 total facilities for all other measures, resulting in only 2.3 percent of facilities reporting.[108] Consequently, we have been unable to uniformly offer pertinent information to beneficiaries on how the measure assesses ASC performance. This reinforces comments made in the CY 2015 OPPS/ASC final rule with comment period, in which commenters expressed concern that the voluntary reporting of this measure would result in incomplete data that may be confusing to beneficiaries and other consumers (79 FR 66984). As we state in section I.A.2. of this proposed rule, we strive to ensure that beneficiaries are empowered to make decisions about their healthcare using information from data-driven insights. Because of the lack of sufficient data, this measure may be difficult for beneficiaries to interpret or use to aid in their choice of where to obtain care; thus, the benefits of this measure are limited.

Therefore, we believe the high technical and administrative costs of this measure outweigh the limited benefit associated with its continued use in the ASCQR Program. As discussed in section I.A.2. of this proposed rule, above, our Meaningful Measures Initiative is intended to reduce costs and minimize burden. We believe that removing this measure from the ASCQR Program will reduce program burden, costs, and complexity. As a result, we are proposing to remove ASC–11 beginning with the CY 2021 payment determination and for subsequent years. We are also proposing to remove a similar measure under the Hospital OQR Program in section XIII.B.4.b. of this proposed rule.

4. Summary of ASCQR Program Quality Measure Sets Proposed for the CY 2020, CY 2021, and CY 2022 Payment Determinations

In this CY 2019 OPPS/ASC proposed rule, we are not proposing any new measures for the ASCQR Program. We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR

[108] ASCQR Compare Data. Available at: *https://data.medicare.gov/Hospital-Compare/Ambulatory-Surgical-Quality-Measures-Facility/4jcv-atw7/data.*

59470) for the previously finalized ASCQR Program measure set for the CY 2020 payment determination and subsequent years. We note that we are proposing to change the reporting period for one previously adopted measure, ASC–12, and refer readers to section XIV.D.4.b. of this proposed rule for details.

The tables below summarize the proposed ASCQR Program measure sets for the CY 2020, 2021, and 2022 payment determinations (including previously adopted measures and measures proposed for removal in this proposed rule).

PROPOSED ASCQR PROGRAM MEASURE SET FOR THE CY 2020 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

ASC No.	NQF No.	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–10	0659	Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use.
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.**

† NQF endorsement was removed.

* Measure voluntarily collected effective beginning with the CY 2017 payment determination as set forth in section XIV.E.3.c. of 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 section XIV.B.4. of the CY 2018 OPPS/ASC final rule with comment period (82 FR 59450 through 59451).

PROPOSED ASCQR PROGRAM MEASURE SET FOR THE CY 2021 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

ASC No.	NQF No.	Measure name
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.*

* 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 section XIV.B.4. of the CY 2018 OPPS/ASC final rule with comment period (82 FR 59450 through 59451).

PROPOSED ASCQR PROGRAM MEASURE SET FOR THE CY 2022 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

ASC No.	NQF No.	Measure name
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	None	Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures.
ASC–18	None	Hospital Visits after Urology Ambulatory Surgical Center Procedures.

* 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 section XIV.B.4. of the CY 2018 OPPS/ASC final rule with comment period (82 FR 59450 through 59451).

5. ASCQR Program Measures and Topics for Future Consideration: Possible Future Validation of ASCQR Program Measures

We are requesting public comment on the possible future validation of ASCQR Program measures. There is currently no validation of ASCQR measure data, and we believe ASCs may benefit from the opportunity to better understand their data and examine potential discrepancies. We believe the ASCQR Program may similarly benefit from the opportunity to produce a more reliable estimate of whether an ASC's submitted data have been abstracted correctly and provide more statistically reliable estimates of the quality of care delivered in each selected ASC as well as at the national level. We believe the Hospital OQR Program validation policy could be a good model for the ASCQR Program and are requesting comment on the validation methodology and identifying one measure with which to start.

The Hospital OQR Program requires validation of its chart-abstracted measures. We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68484 through 68487) and the CY 2015 OPPS/ASC final rule with comment period (79 FR 66964 through 66965) for a discussion of finalized policies regarding Hospital OQR Program validation requirements, which are also codified at 42 CFR 419.46(e). Under the Hospital OQR Program, CMS selects a random sample of 450 hospitals and an additional 50 hospitals based on the following criteria: (1) The hospital failing of the validation requirement that applies to the previous year's payment determination; or (2) the hospital having an outlier value for a measure based on data that it submits. An ''outlier value'' is defined as a measure value that is greater than 5 standard deviations from the mean of the measure values for other hospitals, and indicates a poor score. Then, CMS or its contractor provides written requests to the randomly selected hospitals by requesting supporting medical record documentation used for purposes of data submission under the program. The hospital must submit the supporting medical record documentation within 45 days of the date written in the request. A hospital meets the validation requirement with respect to a calendar year if it achieves at least a 75 percent reliability score, as determined by CMS.

Specifically for the ASCQR Program, we are interested in the validation of chart-abstracted measures. We believe it would be beneficial to start with validation of just one measure, such as ASC–13: Normothermia Outcome, prior to expanding to more measures. ASC–13: Normothermia Outcome was finalized in the 2017 OPPS/ASC final rule with comment period (81 FR 79798 through 79801) and assesses the percentage of patients having surgical procedures under general or neuraxial anesthesia of 60 minutes or more in duration who are normothermic within 15 minutes of arrival in the post-anesthesia care unit. We also considered starting with ASC–14: Unplanned Anterior Vitrectomy instead, which was finalized in the 2017 OPPS/ASC final rule with comment period (81 FR 79801 through 79803) and assesses the percentage of cataract surgery patients who have an unplanned anterior vitrectomy. However, we believe ASC–13 would be the most feasible measure for validation because it assesses surgical cases and would have a larger population of cases from which to sample. ASC–14, which assesses rare, unplanned events that are less common, would have a smaller population of cases from which to sample.

Therefore, we are inviting public comment on the possible future validation of ASCQR Program measures. We specifically request comment on whether Hospital OQR Program's validation policies could be an appropriate model for the ASCQR Program, the possible ASC sample size, sampling methodology, number of cases to sample, validation score methodology, and reduced annual payment updates for facilities that do not pass validation requirements. We also are requesting comment on possibly starting with only one measure, specifically ASC–13, before expanding to more measures.

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 (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 the 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 this proposed rule, we are not proposing 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 this proposed rule, we are not proposing 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 42 CFR 416.310(c)(1)(i). In the CY 2018 OPPS/ASC final rule (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 42 CFR 416.310(c)(1)(i). In this proposed rule, we are not proposing 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 and 70534), we codified these requirements regarding participation status for the ASCQR Program at 42 CFR 416.305. In this proposed rule, we are not proposing 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 this proposed rule, we are not proposing any changes to these requirements. However, we note that in section XIV.B.3.c. of this proposed rule, beginning with the CY 2021 payment determination and for subsequent years, we are proposing to remove all four claims-based measures currently using QDCs:

- 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.

If the removal of these measures is finalized as proposed, no claims-based measures using QDCs would remain in the ASCQR Program. However, we are not proposing any changes to our requirements regarding data processing and collection periods for these types of measures. These requirements would apply to any future claims-based measures using QDCs adopted in the 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 this proposed rule, we are not proposing 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/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228773314768.*

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).

Currently, we only have one measure (ASC–8: Influenza Vaccination Coverage among Healthcare Personnel) that is submitted via a non-CMS online data submission tool. We note that we are proposing this measure for removal for the CY 2020 payment determination and subsequent years in section XIV.B.3.c. of this proposed rule. If the removal of ASC–8 is finalized as proposed, no measures submitted via a non-CMS online data submission tool would remain in the ASCQR Program. However, we are not proposing 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 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 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 as our CMS online data submission tool: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetHomepage&cid=1120143435383.* 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 42 CFR 416.310(c)(1)(i).

In this proposed rule, we are not proposing any changes to this policy. However, we note that in sections XIV.B.3.c. of this proposed rule, we are proposing to remove three measures collected via a CMS online data submission tool–ASC–9: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients, ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use, and ASC–11: Cataracts: Improvement in Patients' Visual Function within 90 Days Following

Cataract Surgery [109] beginning with the CY 2021 payment determination. If those measures are finalized for removal as proposed, only the following previously finalized measures will require data to be submitted via a CMS online data submission tool for the CY 2021 payment determination and subsequent years:

- ASC–13: Normothermia Outcome
- ASC–14: Unplanned Anterior Vitrectomy

4. Requirements for Non-QDC Based, Claims-Based Measure Data

In this proposed rule, we are not proposing any changes to our requirements for non-QDC based, claims-based measures. However, we are proposing to change the reporting period for the previously adopted measure, ASC–12: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy. This proposal is discussed in more detail further below.

a. General

We refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66985) and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70536) for our previously adopted policies regarding data processing and reporting periods for claims-based measures for the CY 2018 payment determination and subsequent years. In addition, in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70536), we codified these policies at 42 CFR 416.310(b). We are not proposing any changes to these policies. We note that the non-QDC, claims-based measures in the program are as follows:

- CY 2020 payment determination and subsequent years: ASC 12: Facility 7-Day Risk Standardized Hospital Visit Rate after Outpatient Colonoscopy (79 FR 66970 through 66978)
- CY 2022 payment determination and subsequent years:
  - •• ASC–17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures (82 FR 59455 through 59470)
  - •• ASC–18: Hospital Visits after Urology Ambulatory Surgical Center Procedures (82 FR 59455 through 59470)

[109] We note that the ASC–11 measure is voluntarily collected effective beginning with the CY 2017 payment determination, as set forth in section XIV.E.3.c. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66984 through 66985).

b. Proposed Extension of the Reporting Period for ASC–12: Facility Seven-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66970 through 66978), we finalized the adoption of ASC–12: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy into the ASCQR Program for the CY 2018 payment determination and subsequent years, with public display to begin on or after December 1, 2017. This measure is calculated with data obtained from paid Medicare FFS claims (79 FR 66978). For this reason, facilities are not required to submit any additional information. In that final rule with comment period, we also finalized the reporting period for measure calculation as claims data from two calendar years prior to the payment determination year. Specifically, for the CY 2018 payment determination, we stated we would use paid Medicare FFS claims from January 1, 2016 to December 31, 2016 to calculate measure results (79 FR 66985). We finalized a 1-year reporting period as it adequately balanced competing interests of measure reliability and timeliness for payment determination purposes, and explained that we would continue to assess this during the dry run (79 FR 66973).

We noted we would complete a dry run of the measure in 2015 using 3 or 4 years of data, and, from the results of this dry run, we would review the appropriate volume cutoff for facilities to ensure statistical reliability in reporting the measure score (79 FR 66974). Our analyses of the 2015 dry run using data from July 2011 through June 2014 showed that a reporting period of 1 year had moderate to high reliability for measure calculation. Specifically, using data from July 2013 through June 2014, we calculated facility-level reliability estimates as the ratio of true variance to observed variance.[110] Consistent with the original measure specifications as described in the 2014 technical report,[111] this calculation was performed combining the measure results for HOPDs and ASCs. We found that for a facility with median case size, the reliability estimate was high (over 0.90), but the minimum reliability estimate for facilities with 30 cases (the minimum case size chosen for public reporting) was only moderate (that is, between 0.40 and 0.60).[112]

However, after the 2015 dry run, CMS calculated the HOPD and ASC scores separately to compare similar types of facilities to each other. During subsequent analysis of the 1-year period of July 2013 through June 2014, we confirmed that a 1-year reporting period with separate calculations for HOPDs and ASCs was sufficient, but did result in lower reliability and decreased precision, compared to results calculated with longer reporting periods (2 or 3 years). Based on analyses conducted using data from July 2013 through June 2014 (1-year reporting period) and 2017 measure specifications,[113] we found that the median facility-level reliability was 0.74 for ASCs and 0.51 for HOPDs. Using a 2-year reporting period (data from July 2012—June 2014), we found that median facility-level reliability was 0.81 for ASCs and 0.67 for HOPDs. When the reporting period was extended to 3 years (using data from July 2011 through June 2014), we found that median facility-level reliability was higher for both ASCs and HOPDs: 0.87 for ASCs and 0.75 for HOPDs. These results indicate that a larger portion of the included facilities have scores measured with higher reliability when 3 years of data are used rather than 1 year of data.

Using 3 years of data, compared to just 1 year, is estimated to increase the number of ASCs with eligible cases for ASC–12 by 10 percent, adding approximately 235 additional ASCs to the measure calculation. ASCs reporting the measure would increase their sample sizes and, in turn, increase the precision and reliability of their measure scores. Thus, we believe extending the reporting period to 3 years from 1 year for purposes of increasing reliability would be beneficial for providing better information to beneficiaries regarding the quality of care associated with low-risk outpatient colonoscopy procedures. In crafting our proposal, we considered extending the reporting period to 2 years beginning with the CY 2020 payment determinations and subsequent years, but decided on proposing 3 years instead, because a higher level of reliability is achieved with a 3-year reporting period compared to 2 years.

[110] Snijders TA, Bosker RJ. *Multilevel Analysis: An introduction to basic and advanced multilevel modeling.* SAGE Publications. 2000. London.

[111] Additional methodology details and information obtained from public comments for measure development are available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html* under ''Hospital Outpatient Colonoscopy.''

[112] Landis JR, Koch GG. The Measurement of Observer Agreement for Categorical Data. *Biometrics.* 1977;33(1):159–174.

[113] Current and past measure specifications are available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228775214597.*

Therefore, we are proposing to change the reporting period for ASC–12: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy from 1 year to 3 years beginning with the CY 2020 payment determination (which would use claims data from January 1, 2016 through December 31, 2018) and for subsequent years. Under this proposal, the annual reporting requirements for ASCs would not change because this is a claims-based measure. However, with a 3-year reporting period, the most current year of data would be supplemented by the addition of 2 prior years. For example, for the CY 2020 payment determination, we would use a reporting period of CY 2018 data plus 2 prior years of data (CYs 2016 and 2017). We note that since implementation of this measure began with the CY 2018 payment determination, we have already used paid Medicare FFS claims from January 1, 2016 to December 31, 2016 to calculate the measure scores, which have been previously previewed by ASCs and publicly displayed. In crafting our proposal, we also considered timeliness related to payment determinations and public display. Because we would utilize data already collected to supplement current data, our proposal to use 3 years of data would not disrupt payment determinations or public display. We refer readers to the table below for example reporting periods and public display dates corresponding to the CY 2020, CY 2021, and CY 2022 payment determinations:

	CY 2020 Payment determination	CY 2021 Payment determination	CY 2022 Payment determination
Public display	January 2020	January 2021	January 2022.
Reporting period	January 1, 2016–December 31, 2018.	January 1, 2017–December 31, 2019.	January 1, 2018–December 31, 2020.

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 this proposed rule, we are not proposing 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 this proposed rule, we are not proposing 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 this proposed rule, we are not proposing 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 section XVI.D.1. of 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. Proposed 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 equal the product of the ASC conversion factor and the scaled relative payment weight for the APC to which the service is assigned. For CY 2019, the proposed 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 proposed annual update for the ASC payment system for an interim 5-year period (CY 2019 through CY 2023). As discussed in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72062), if the CPI–U update factor is a negative number, the CPI–U update factor would be held to zero. Consistent with past practice, in the event the percentage change in the hospital market basket for a year is negative, we are proposing to hold the hospital market basket update factor for the ASC payment system to zero. 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 proposal to update the ASC payment rates using the inpatient hospital market basket update for CYs 2019 through 2023, we refer readers to section XII.G. of this proposed rule.

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, certain 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 (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 section XII.D.2.b. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66933 through 66934), we finalized our proposal that payment for the new category of covered ancillary services (that is, certain diagnostic test codes within the medical range of CPT codes for which separate payment is allowed under the OPPS and when they are integral to covered ASC surgical procedures) 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. 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, and CY 2018 OPPS/ASC final rules with comment period (79 FR 66981 through 66982; 80 FR 70537 through 70538; 81 FR 79825 through 79826; and 82 FR 59475 through 59476, respectively), we did not make any other changes to these policies.

XV. Requests for Information (RFIs)

This section addresses three requests for information (RFIs). Upon reviewing the RFIs, respondents are encouraged to provide complete but concise responses. These RFIs are issued solely for information and planning purposes; neither RFI constitutes a Request for Proposal (RFP), application, proposal abstract, or quotation. The RFIs do not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, CMS is not seeking proposals through these RFIs and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to these RFIs; all costs associated with responding to these RFIs will be solely at the interested party's expense.

Failing to respond to either RFI will not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor each RFI announcement for additional information pertaining to the request. Please note that CMS will not respond to questions about the policy issues raised in these RFIs. CMS may or may not choose to contact individual responders. Such communications would only serve to further clarify written responses. Contractor support personnel may be used to review RFI responses. Responses to these RFIs are not offers and cannot be accepted by the U.S. Government to form a binding contract or issue a grant. Information obtained as a result of these RFIs may be used by the U.S. Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. These RFIs should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become U.S. Government property and will not be returned. CMS may publically post the comments received, or a summary thereof.

A. Request for Information on Promoting Interoperability and Electronic Healthcare Information Exchange Through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid-Participating Providers and Suppliers

Currently, Medicare- and Medicaid-participating providers and suppliers are at varying stages of adoption of health information technology (health IT). Many hospitals have adopted electronic health records (EHRs), and CMS has provided incentive payments to eligible hospitals, critical access hospitals (CAHs), and eligible professionals who have demonstrated meaningful use of certified EHR technology (CEHRT) under the Medicare EHR Incentive Program. As of 2015, 96 percent of Medicare- and Medicaid-participating non-Federal acute care hospitals had adopted certified EHRs with the capability to electronically export a summary of clinical care.[114] While both adoption of EHRs and electronic exchange of information have grown substantially among hospitals, significant obstacles to exchanging electronic health information across the continuum of care persist. Routine electronic transfer of information post-discharge has not been achieved by providers and suppliers in many localities and regions throughout the Nation.

CMS is firmly committed to the use of certified health IT and interoperable EHR systems for electronic healthcare information exchange to effectively help hospitals and other Medicare- and Medicaid-participating providers and suppliers improve internal care delivery practices, support the exchange of important information across care team members during transitions of care, and enable reporting of electronically specified clinical quality measures (eCQMs). The Office of the National Coordinator for Health Information Technology (ONC) acts as the principal Federal entity charged with coordination of nationwide efforts to implement and use health information technology and the electronic exchange of health information on behalf of the Department of Health and Human Services.

In 2015, ONC finalized the 2015 Edition health IT certification criteria (2015 Edition), the most recent criteria for health IT to be certified to under the ONC Health IT Certification Program. The 2015 Edition facilitates greater interoperability for several clinical health information purposes and enables health information exchange through new and enhanced certification criteria, standards, and implementation specifications. CMS requires eligible hospitals and CAHs in the Medicare and Medicaid EHR Incentive Programs and eligible clinicians in the Quality Payment Program (QPP) to use EHR technology certified to the 2015 Edition beginning in CY 2019.

In addition, several important initiatives will be implemented over the next several years to provide hospitals and other participating providers and suppliers with access to robust infrastructure that will enable routine electronic exchange of health information. Section 4003 of the 21st Century Cures Act (Pub. L. 114–255), enacted in 2016, and amending section 3000 of the Public Health Service Act (42 U.S.C. 300jj), requires HHS to take steps to advance the electronic exchange of health information and interoperability for participating providers and suppliers in various settings across the care continuum. Specifically, Congress directed that ONC ''. . . for the purpose of ensuring full network-to-network exchange of health information, convene public-private and public-public partnerships to build consensus and develop or support a trusted exchange framework, including a common agreement among health information networks nationally.'' In January 2018, ONC released a draft version of its proposal for the Trusted Exchange Framework and Common Agreement,[115] which outlines principles and minimum terms and conditions for trusted exchange to enable interoperability across disparate health information networks (HINs). The Trusted Exchange Framework (TEF) is focused on achieving the following four important outcomes in the long-term:

- Professional care providers, who deliver care across the continuum, can access health information about their patients, regardless of where the patient received care.
- Patients can find all of their health information from across the care continuum, even if they do not remember the name of the professional care provider they saw.
- Professional care providers and health systems, as well as public and private health care organizations and public and private payer organizations accountable for managing benefits and the health of populations, can receive necessary and appropriate information on groups of individuals without having to access one record at a time, allowing them to analyze population health trends, outcomes, and costs; identify at-risk populations; and track progress on quality improvement initiatives.
- The health IT community has open and accessible application programming interfaces (APIs) to encourage entrepreneurial, user-focused innovation that will make health information more accessible and improve EHR usability.

ONC will revise the draft TEF based on public comment and ultimately release a final version of the TEF that will subsequently be available for adoption by HINs and their participants seeking to participate in nationwide health information exchange. The goal for stakeholders that participate in, or serve as, a HIN is to ensure that participants will have the ability to seamlessly share and receive a core set of data from other network participants in accordance with a set of permitted purposes and applicable privacy and security requirements. Broad adoption of this framework and its associated exchange standards is intended to both achieve the outcomes described above while creating an environment more conducive to innovation.

In light of the widespread adoption of EHRs along with the increasing availability of health information exchange infrastructure predominantly among hospitals, we are interested in hearing from stakeholders on how we could use the CMS health and safety standards that are required for providers and suppliers participating in the Medicare and Medicaid programs (that is, the Conditions of Participation (CoPs), Conditions for Coverage (CfCs), and Requirements for Participation (RfPs) for Long-Term Care (LTC) Facilities) to further advance electronic exchange of information that supports safe, effective transitions of care between hospitals and community providers. Specifically, CMS might consider revisions to the current CMS CoPs for hospitals, such as: Requiring that hospitals transferring medically necessary information to another facility upon a patient transfer or discharge do so electronically; requiring that hospitals electronically send required discharge information to a community provider via electronic means if possible and if a community provider can be identified; and requiring that hospitals make certain information available to patients or a specified third-party application (for example, required

[114] These statistics can be accessed at: *https://dashboard.healthit.gov/quickstats/pages/FIG-Hospital-EHR-Adoption.php.*

[115] The draft version of the trusted Exchange Framework may be accessed at: *https://beta.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement.*

discharge instructions) via electronic means if requested.

On November 3, 2015, we published a proposed rule (80 FR 68126) to implement the provisions of the Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act) (Pub. L. 113–185) and to revise the discharge planning CoP requirements that hospitals (including short-term acute care hospitals, long-term care hospitals (LTCHs), rehabilitation hospitals, psychiatric hospitals, children's hospitals, and cancer hospitals), critical access hospitals (CAHs), and home health agencies (HHAs) would need to meet in order to participate in the Medicare and Medicaid programs. This proposed rule has not been finalized yet. However, several of the proposed requirements directly address the issue of communication between providers and between providers and patients, as well as the issue of interoperability:

- Hospitals and CAHs would be required to transfer certain necessary medical information and a copy of the discharge instructions and discharge summary to the patient's practitioner, if the practitioner is known and has been clearly identified;
- Hospitals and CAHs would be required to send certain necessary medical information to the receiving facility/post-acute care providers, at the time of discharge; and
- Hospitals, CAHs, and HHAs would need to comply with the IMPACT Act requirements that would require hospitals, CAHs, and certain post-acute care providers to use data on quality measures and data on resource use measures to assist patients during the discharge planning process, while taking into account the patient's goals of care and treatment preferences.

We published another proposed rule (81 FR 39448) on June 16, 2016, that updated a number of CoP requirements that hospitals and CAHs would need to meet in order to participate in the Medicare and Medicaid programs. This proposed rule has not been finalized yet. One of the proposed hospital CoP revisions in that rule directly addresses the issues of communication between providers and patients, patient access to their medical records, and interoperability. We proposed that patients have the right to access their medical records, upon an oral or written request, in the form and format requested by such patients, if it is readily producible in such form and format (including in an electronic form or format when such medical records are maintained electronically); or, if not, in a readable hard copy form or such other form and format as agreed to by the facility and the individual, including current medical records, within a reasonable timeframe. The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its recordkeeping system permits.

We also published a final rule (81 FR 68688) on October 4, 2016, that revised the requirements that LTC facilities must meet to participate in the Medicare and Medicaid programs. In this rule, we made a number of revisions based on the importance of effective communication between providers during transitions of care, such as transfers and discharges of residents to other facilities or providers, or to home. Among these revisions was a requirement that the transferring LTC facility must provide all necessary information to the resident's receiving provider, whether it is an acute care hospital, an LTCH, a psychiatric facility, another LTC facility, a hospice, a home health agency, or another community-based provider or practitioner (42 CFR 483.15(c)(2)(iii)). We specified that necessary information must include the following:

- Contact information of the practitioner responsible for the care of the resident;
- Resident representative information including contact information;
- Advance directive information;
- Special instructions or precautions for ongoing care;
- The resident's comprehensive care plan goals; and
- All other necessary information, including a copy of the resident's discharge or transfer summary and any other documentation to ensure a safe and effective transition of care.

We note that the discharge summary mentioned above must include reconciliation of the resident's medications, as well as a recapitulation of the resident's stay, a final summary of the resident's status, and the post-discharge plan of care. In addition, in the preamble to the rule, we encouraged LTC facilities to electronically exchange this information if possible and to identify opportunities to streamline the collection and exchange of resident information by using information that the facility is already capturing electronically.

Additionally, we specifically invite stakeholder feedback on the following questions regarding possible new or revised CoPs/CfCs/RfPs for interoperability and electronic exchange of health information:

- If CMS were to propose a new CoP/CfC/RfP standard to require electronic exchange of medically necessary information, would this help to reduce information blocking as defined in section 4004 of the 21st Century Cures Act?
- Should CMS propose new CoPs/CfCs/RfPs for hospitals and other participating providers and suppliers to ensure a patient's or resident's (or his or her caregiver's or representative's) right and ability to electronically access his or her health information without undue burden? Would existing portals or other electronic means currently in use by many hospitals satisfy such a requirement regarding patient/resident access as well as interoperability?
- Are new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information necessary to ensure patients/residents and their treating providers routinely receive relevant electronic health information from hospitals on a timely basis or will this be achieved in the next few years through existing Medicare and Medicaid policies, the implementing regulations related to the privacy and security standards of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–91), and implementation of relevant policies in the 21st Century Cures Act?
- What would be a reasonable implementation timeframe for compliance with new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information if CMS were to propose and finalize such requirements? Should these requirements have delayed implementation dates for specific participating providers and suppliers, or types of participating providers and suppliers (for example, participating providers and suppliers that are not eligible for the Medicare and Medicaid EHR Incentive Programs)?
- Do stakeholders believe that new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information would help improve routine electronic transfer of health information as well as overall patient/resident care and safety?
- Under new or revised CoPs/CfCs/RfPs, should non-electronic forms of sharing medically necessary information (for example, printed copies of patient/resident discharge/transfer summaries shared directly with the patient/resident or with the receiving provider or supplier, either directly transferred with the patient/resident or by mail or fax to the receiving provider or supplier) be permitted to continue if the receiving

provider, supplier, or patient/resident cannot receive the information electronically?

- Are there any other operational or legal considerations (for example, implementing regulations related to the HIPAA privacy and security standards), obstacles, or barriers that hospitals and other providers and suppliers would face in implementing changes to meet new or revised interoperability and health information exchange requirements under new or revised CMS CoPs/CfCs/RfPs if they are proposed and finalized in the future?
- What types of exceptions, if any, to meeting new or revised interoperability and health information exchange requirements should be allowed under new or revised CMS CoPs/CfCs/RfPs if they are proposed and finalized in the future? Should exceptions under the QPP, including CEHRT hardship or small practices, be extended to new requirements? Would extending such exceptions impact the effectiveness of these requirements?

We would also like to directly address the issue of communication between hospitals (as well as the other providers and suppliers across the continuum of patient care) and their patients and caregivers. MyHealthEData is a government-wide initiative aimed at breaking down barriers that contribute to preventing patients from being able to access and control their medical records. Privacy and security of patient data will be at the center of all CMS efforts in this area. CMS must protect the confidentiality of patient data, and CMS is completely aligned with the Department of Veterans Affairs (VA), the National Institutes of Health (NIH), ONC, and the rest of the Federal Government, on this objective.

While some Medicare beneficiaries have had, for quite some time, the ability to download their Medicare claims information, in pdf or Excel formats, through the CMS Blue Button platform, the information was provided without any context or other information that would help beneficiaries understand what the data were really telling them. For beneficiaries, their claims information is useless if it is either too hard to obtain or, as was the case with the information provided through previous versions of Blue Button, hard to understand. In an effort to fully contribute to the Federal Government's MyHealthEData initiative, CMS developed and launched the new Blue Button 2.0, which represents a major step toward giving patients meaningful control of their health information in an easy-to-access and understandable way. Blue Button 2.0 is a developer-friendly, standards-based application programming interface (API) that enables Medicare beneficiaries to connect their claims data to secure applications, services, and research programs they trust. The possibilities for better care through Blue Button 2.0 data are exciting, and might include enabling the creation of health dashboards for Medicare beneficiaries to view their health information in a single portal, or allowing beneficiaries to share complete medication lists with their doctors to prevent dangerous drug interactions.

To fully understand all of these health IT interoperability issues, initiatives, and innovations through the lens of its regulatory authority, CMS invites members of the public to submit their ideas on how best to accomplish the goal of fully interoperable health IT and EHR systems for Medicare- and Medicaid-participating providers and suppliers, as well as how best to further contribute to and advance the MyHealthEData initiative for patients. We are particularly interested in identifying fundamental barriers to interoperability and health information exchange, including those specific barriers that prevent patients from being able to access and control their medical records. We also welcome the public's ideas and innovative thoughts on addressing these barriers and ultimately removing or reducing them in an effective way, specifically through revisions to the current CMS CoPs, CfCs, and RfPs for hospitals and other participating providers and suppliers. We have received stakeholder input through recent CMS Listening Sessions on the need to address health IT adoption and interoperability among providers that were not eligible for the Medicare and Medicaid EHR Incentives program, including long-term and post-acute care providers, behavioral health providers, clinical laboratories and social service providers, and we would also welcome specific input on how to encourage adoption of certified health IT and interoperability among these types of providers and suppliers as well.

B. Request for Information on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20548 and 20549) and the FY 2015 IPPS/LTCH PPS proposed and final rules (79 FR 28169 and 79 FR 50146, respectively), we stated that we intend to continue to review and post relevant charge data in a consumer-friendly way, as we previously have done by posting hospital and physician charge information on the CMS website.[116] In the FY 2019 IPPS/LTCH PPS proposed rule, we also continued our discussion of the implementation of section 2718(e) of the Public Health Service Act, which aims to improve the transparency of hospital charges. This discussion in the FY 2019 IPPS/LTCH PPS proposed rule continued a discussion we began in the FY 2015 IPPS/LTCH PPS proposed rule and final rule (79 FR 28169 and 79 FR 50146, respectively). In all of these rules, we noted that section 2718(e) of the Public Health Service Act requires that each hospital operating within the United States, for each year, establish (and update) and make public (in accordance with guidelines developed by the Secretary) a list of the hospital's standard charges for items and services provided by the hospital, including for diagnosis-related groups (DRGs) established under section 1886(d)(4) of the Social Security Act. In the FY 2015 IPPS/LTCH PPS proposed and final rules, we reminded hospitals of their obligation to comply with the provisions of section 2718(e) of the Public Health Service Act and provided guidelines for its implementation. We stated that hospitals are required to either make public a list of their standard charges (whether that be the chargemaster itself or in another form of their choice) or their policies for allowing the public to view a list of those charges in response to an inquiry. In the FY 2019 IPPS/LTCH PPS proposed rule, we took one step to further improve the public accessibility of charge information. Specifically, effective January 1, 2019, we are updating our guidelines to require hospitals to make available a list of their current standard charges via the internet in a machine readable format and to update this information at least annually, or more often as appropriate.

In general, we encourage all providers and suppliers of health care services to undertake efforts to engage in consumer-friendly communication of their charges to help patients understand what their potential financial liability might be for services they obtain, and to enable patients to compare charges for similar services. We encourage providers and suppliers to update this information at least annually, or more often as appropriate, to reflect current charges.

We are concerned that challenges continue to exist for patients due to insufficient price transparency. Such challenges include patients being

[116] For example, Medicare Provider Utilization and Payment Data, available at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/index.html.*

surprised by out-of-network bills for physicians, such as anesthesiologists and radiologists, who provide services at in-network hospitals and other settings, and patients being surprised by facility fees, physician fees for emergency department visits, or by fees for provider and supplier services that the beneficiary might consider to be a part of an episode of care involving a hospitalization but that are not services furnished by the hospital. We also are concerned that, for providers and suppliers that maintain a list of standard charges, the charge data are not helpful to patients for determining what they are likely to pay for a particular service or facility encounter. In order to promote greater price transparency for patients, we are considering ways to improve the accessibility and usability of current charge information.

We also are considering potential actions that would be appropriate to further our objective of having providers and suppliers undertake efforts to engage in consumer-friendly communication of their charges to help patients understand what their potential financial liability might be for services they obtain from the provider or supplier, and to enable patients to compare charges for similar services across providers and suppliers, including when services could be offered in more than one setting, such as a freestanding physician office or a hospital outpatient department or an ambulatory surgical center. Therefore, we are seeking public comment from all providers and suppliers, including providers receiving payment under the OPPS, on the following:

- How should we define ''standard charges'' in provider and supplier settings? Is there one definition for those settings that maintain chargemasters, and potentially a different definition for those settings that do not maintain chargemasters? Should ''standard charges'' be defined to mean: Average or median rates for the items on a chargemaster or other price list or charge list; average or median rates for groups of items and/or services commonly billed together, as determined by the provider or supplier based on its billing patterns; or the average discount off the chargemaster, price list, or charge list amount across all payers, either for each separately enumerated item or for groups of services commonly billed together? Should ''standard charges'' be defined and reported for both some measure of the average contracted rate and the chargemaster, price list, or charge list? Or is the best measure of a provider's or supplier's standard charges its chargemaster, price list, or charge list?

- What types of information would be most beneficial to patients, how can health care providers and suppliers best enable patients to use charge and cost information in their decision-making, and how can CMS and providers and suppliers help third parties create patient-friendly interfaces with these data?

- Should providers and suppliers be required to inform patients how much their out-of- pocket costs for a service will be before those patients are furnished that service? How can information on out-of-pocket costs be provided to better support patient choice and decision-making? What changes would be needed to support greater transparency around patient obligations for their out-of-pocket costs? How can CMS help beneficiaries to better understand how copayment and coinsurance are applied to each service covered by Medicare? What can be done to better inform patients of their financial obligations? Should providers and suppliers play any role in helping to inform patients of what their out-of-pocket obligations will be?

- Can we require providers and suppliers to provide patients with information on what Medicare pays for a particular services performed by that provider or supplier. If so, what changes would need to be made by providers and suppliers. What burden would be added as a result of such a requirement?

In addition, we are seeking public comment on improving a Medigap patient's understanding of his or her out-of-pocket costs prior to receiving services, especially with respect to the following particular questions:

- How does Medigap coverage affect patients' understanding of their out-of-pocket costs before they receive care? What challenges do providers and suppliers face in providing information about out-of-pocket costs to patients with Medigap? What changes can Medicare make to support providers and suppliers that share out-of-pocket cost information with patients that reflects the patient's Medigap coverage? Who is best situated to provide patients with clear Medigap coverage information on their out-of-pocket costs prior to receipt of care? What role can Medigap plans play in providing information to patients on their expected out-of-pocket costs for a service? What State-specific requirements or programs help educate Medigap patients about their out-of-pocket costs prior to receipt of care?

C. Request for Information on Leveraging the Authority for the Competitive Acquisition Program (CAP) for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model

Building on President Trump's Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, the CMS Center for Medicare and Medicaid Innovation (Innovation Center) is soliciting public comment on key design considerations for developing a potential model that would test private market strategies and introduce competition to improve quality of care for beneficiaries, while reducing both Medicare expenditures and beneficiaries' out of pocket spending. CMS has sought similar feedback in a previous solicitation of comments [117] and, most recently, in the President's Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs.[118] Comments provided in response to these previous solicitations have been extremely helpful to CMS. In this request for information (RFI), we are seeking additional and more specific public feedback on a potential model design that would accelerate the move to a value-based health care system building upon the Competitive Acquisition Program (CAP) established under section 1847B of the Act, including but not limited to design features such as the potential model's scope, which providers and suppliers should be included or excluded from the model, the types of Medicare Part B drugs and biologicals that should be included or excluded from the potential model, the role of private-sector vendors in the model (''model vendors''), a defined population of beneficiaries to be addressed by the potential model,

[117] CMS included a solicitation of comments on the Competitive Acquisition Program (CAP) for Part B Drugs and Biologicals (81 FR 13247) in a proposed rule, on March 11, 2016, entitled ''Medicare Program; Part B Drug Payment Model'' (81 FR 13230). The solicitation of comments sought to help CMS determine if there was sufficient interest in the CAP program, and to gather public input if we were to consider developing and testing a future model that would be at least partly based on the authority for the CAP under section 1847B of the Act. The March 11, 2016 proposed rule was withdrawn on October 4, 2017 (82 FR 46182) to ensure agency flexibility in reexamining important issues related to the proposed payment model and exploring new options and alternatives with stakeholders as CMS develops potential payment models that support innovative approaches to improve quality, accessibility, and affordability, reduce Medicare program expenditures, and empower patients and doctors to make decisions about their health care.

[118] President Donald J. Trump's Blueprint to Lower Drug Prices, May 11, 2018. Available at: *https://www.whitehouse.gov/briefings-statements/president-donald-j-trumps-blueprint-lower-drug-prices/*.

appropriate beneficiary protections, possible inclusion of other payers, and options for model payments. We also are interested in how best to handle Medicare payment for the new high-cost therapies, and whether a potential CAP-like model could be an appropriate payment and delivery structure for these drugs and biologicals. We are soliciting comments on how a model could be structured to advance the goals of the President's blueprint, namely to increase competition, strengthen negotiation, create incentives for lower list prices, and lower out-of-pocket costs. Feedback on these questions will be important for shaping the potential model's design and operations. CMS appreciates the public's input on these important issues.

1. Current Medicare Payments for Part B Drugs

Medicare Part B covers and pays separately for a limited number of drugs. Drugs paid separately under Medicare Part B generally fall into three categories: Drugs, typically injectable, furnished incident to a physician's service in the physician office or other nonfacility setting (covered under sections 1832(a)(1) and 1861(s)(2)(A) of the Act), hospital outpatient settings (covered under sections 1832(a)(2)(B) and 1861(s)(2)(B) of the Act), or ambulatory surgical center (covered under sections 1832(a)(2)(F) and 1833(i)(1)(A) of the Act); drugs administered via a covered item of durable medical equipment (DME) (covered under section 1861(n) of the Act); and other categories of drugs specified by statute (generally in section 1861(s)(2) of the Act).

Many Medicare Part B drug expenditures are for drugs furnished ''incident to'' a physician's service. Sections 1861(s)(2)(A) and 1861(s)(2)(B) of the Act provide that ''incident to'' drugs are not usually self-administered; self-administered drugs, such as orally administered tablets and capsules, are not included in the ''incident to'' provisions. Payment for drugs furnished ''incident to'' a physician's service is specified at section 1842(o) of the Act. Drugs that are covered ''incident to'' a physician's service must represent a real cost to the physician (that is, the physician must incur a cost to obtain the drug); hence, the physician obtains these drugs using the ''buy and bill'' methodology.

In accordance with section 1842(o)(1)(C) of the Act, most ''incident to'' drugs are paid under the methodology in section 1847A of the Act. This means the Medicare payment is generally based on the average sales price (ASP) methodology, which includes a statutorily mandated 6-percent add-on. Under this methodology, expensive drugs receive higher add-on payment amounts than inexpensive drugs, potentially creating a financial incentive for providers and suppliers to furnish higher cost drugs. Specifically, because the 6-percent add-on results in increased Medicare payment for a higher-cost drug relative to a lower-cost drug, the use of more expensive drugs may generate more revenue for a health care provider, depending on the health care provider's acquisition costs for the drugs.[119] However, more expensive drugs generally result in greater cost-sharing for beneficiaries because patient cost-sharing is set at a percentage of the total Medicare payment amount. Meanwhile, the ASP-based methodology creates no direct incentives for furnishing high-value drug therapies.

The ASP payment amount determined under section 1847A of the Act reflects a weighted ASP for all National Drug Codes (NDCs) that are assigned to a Healthcare Common Procedure Coding System (HCPCS) code. The ASP payment amount does not vary based on the price an individual provider or supplier pays to acquire the drug, but reflects the price of all nonexcluded sales from all purchasers in the U.S. market. Payment determinations under the methodology in section 1847A of the Act also do not directly take into account the effectiveness of a particular drug. The payment determinations do not consider the cost of clinically comparable drugs that are billed for and paid under other HCPCS codes. The ASP is calculated quarterly using manufacturer-submitted data[120] on sales to all purchasers (with limited exceptions as articulated in section 1847A(c)(2) of the Act, such as sales to an entity that are merely nominal in amount and sales exempt from inclusion in the determination of Medicaid best price) with manufacturers' rebates, discounts, and price concessions included in the ASP calculation.

Medicare Part B also pays for drugs that are infused through a covered item of durable medical equipment (DME), such as drugs administered with an infusion pump and inhalation drugs administered through a nebulizer. Medicare payments for these drugs are described in section 1842(o)(1)(D) of the Act for DME infusion drugs and section 1842(o)(1)(G) of the Act for inhalation drugs.

Finally, Medicare Part B covers and pays for a number of drugs with specific benefit categories defined under section 1861(s) of the Act including: Immunosuppressive drugs; hemophilia blood clotting factors; certain oral anticancer drugs; certain oral anti-emetic drugs; pneumococcal pneumonia, influenza and hepatitis B vaccines; erythropoietin for trained home dialysis patients; and certain osteoporosis drugs. Payment for many of these drugs falls under section 1842(o) of the Act, and in accordance with section 1842(o)(1)(C) of the Act, most, but not all, drugs with specific benefit categories are paid under the methodology in section 1847A of the Act. A notable exception is that payment for pneumococcal pneumonia, influenza and hepatitis B vaccines is based on published AWP, specifically 95 percent AWP, if furnished in the physician office setting, payment is based on reasonable cost in the hospital outpatient setting.

Under Medicare Part B, drug payment depends on the site of care, the drug, and the statutory requirements. Beneficiaries' cost-sharing is generally 20 percent of the Medicare allowed amount. However, for a hospital outpatient service, beneficiaries are financially responsible for a copayment amount for a procedure up to the amount of the inpatient deductible for the year, which means that beneficiary cost-sharing for a separately payable drug or biological is limited to $1,340 in 2018 when the drug or biological is part of a covered outpatient hospital service, while the remaining portion of the Medicare allowed amount would be paid by the Medicare program.

From 2011 to 2016, Medicare drug spending increased from $17.6 billion to $28 billion under Medicare Part B, representing a compound annual growth rate (CAGR) of 9.8 percent, with per capita spending increasing 54 percent, from $532 to $818.[121] The number of Medicare Part B FFS beneficiaries and the number of these beneficiaries who received a Part B drug increased over the 5-year period (2011 through 2016). However, the increase in total Medicare drug spending during this period is more fully explained by increases in the prices of drugs for those beneficiaries

[119] MedPAC Report to the Congress Medicare and the Health Care Delivery System, June 2015, pp. 65–72. Available at: *http://medpac.gov/docs/default-source/reports/june-2015-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf?sfvrsn=0.*

[120] OMB Control Number 0938–0921.

[121] Spending and Enrollment Data from Centers for Medicare and Medicaid Services Office of Enterprise Data and Analytics.

who received them than by increases in enrollment and utilization.

Furthermore, the most recent National Health Expenditure Projections (2017–2026) noted ''among the largest health care goods and services, prescription drugs are projected to experience the fastest average annual spending growth in 2017–26 (6.3 percent per year).'' [122] This trend primarily reflects faster anticipated growth in drug prices, which is attributable to a larger share of drug spending being accounted for by specialty drugs over the coming decade.

2. Competitive Acquisition Program (CAP) for Part B Drugs

Section 1847B of the Act authorizes the CAP for Medicare Part B drugs and biologicals that are not paid on a cost or prospective payment basis. The CAP was established as an alternative to the average sales price (ASP) methodology that is specified in section 1847A of the Act described above. Instead of buying drugs for their offices, the CAP would allow physicians to voluntarily choose to participate in the CAP and place patient specific drug orders with an approved CAP vendor; the CAP vendor would acquire and distribute (or supply) the drugs to the physician's office and then bill Medicare and collect cost-sharing amounts from the beneficiary.

The CAP program was operational for a limited time. CMS conducted the initial bidding for CAP vendors in 2005. The first CAP contract period ran from July 1, 2006 until December 31, 2008. One entity participated in the program, as the CAP vendor, providing drugs assigned to approximately 180 HCPCS billing codes (including heavily utilized drugs in Medicare Part B) to physicians across the United States and certain Territories. Unlike the ''buy and bill'' process that is still used to obtain many Medicare Part B drugs, physicians who chose to participate in the CAP did not buy or take title to the drug. The CAP vendor supplied drugs in unopened containers (not pharmacy-prepared individualized doses like syringes containing a patient's prescribed dose). The CAP vendor's drug claims were processed by a designated Medicare claims processing contractor selected by CMS.

The parameters for the second round of the CAP vendor selection were essentially the same as those for the first round. While CMS received several qualified bids for the second contract period, contractual issues with the successful bidders led to the postponement of the program. The CAP has been suspended since January 1, 2009. After the CAP was suspended, we sought additional input from physicians and other interested parties about further improvements to the program. For example, we held Open Door Forums, met with stakeholders, and encouraged correspondence from stakeholders and physicians who participated in the CAP. Although we received some useful suggestions, several significant concerns could not be addressed under the existing statutory requirements. These concerns included uncertainty about the participation of non-pharmacy entities like wholesalers as approved CAP vendors under the statutory requirements, and the requirement for a beneficiary-specific drug order, which impacts use of a consignment approach to facilitate emergency/urgent access to drugs, and to manage inventory through automated dispensing systems in the office. Many stakeholders were also concerned about the complexity of the program and the level of financial risk, particularly for the entities selected as CAP vendors. Financial risks for vendors included unpaid beneficiary cost sharing, lost or damaged drugs, and unverified drug administrations (which prevented payment). The CAP also was hindered by low physician enrollment and that some physicians perceived physician election, drug ordering and billing processes, and post pay documentation as burdensome. Also, an evaluation of the CAP found that it was not associated with savings (*https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Research-Reports-Items/CMS1234237.html*).

More detailed information about the CAP is available on the following CMS web page and links within the web page: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/CompetitiveAcquisforBios/index.html.* The ''Downloads'' section of the following CMS web page includes a section with information about CAP vendor bidding, physician participation, and drugs provided under the CAP: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/CompetitiveAcquisforBios/vendorbackground.html.*

3. MedPAC Part B Drug Value Program (DVP) Proposal

In June 2017, the Medicare Payment Advisory Commission (MedPAC) recommended the development of a voluntary alternative to the ASP payment system, calling it the Part B Drug Value Program (DVP), along with changes to the existing Medicare payment policy for separately payable Part B drugs and biologicals. MedPAC stated in its June 2017 Report to Congress that the purpose of such a program would be to obtain lower prices for Medicare Part B drugs by using private vendors to negotiate with manufacturers and improve incentives for health care providers furnishing Medicare Part B drugs by making health care providers accountable for cost and quality through shared savings opportunities.[123] MedPAC noted that, although the CAP program faced challenges, the concept underlying the CAP—to create a voluntary alternative to the ASP system using private vendors to negotiate favorable prices and eliminate financial incentives for physicians to prescribe Medicare Part B drugs—still has appeal. The DVP would be designed differently from the CAP to address several issues encountered with the CAP program and to allow hospitals to obtain drugs through the DVP. MedPAC noted that CAP vendors had little leverage to negotiate discounts with manufacturers because they were required to offer a group of about 180 HCPCS codes, including many single-source drugs and biologicals used in Medicare Part B. By contrast, DVP vendors would be permitted to use tools (such as a formulary, step therapy, prior authorization, indication-based pricing, risk based contracting with savings passed back to the Medicare program, and, in certain circumstances, binding arbitration) to give the DVP vendors greater negotiating leverage with manufacturers.

MedPAC envisioned that the DVP would begin with a subset of drug classes. In addition, under the DVP, private vendors would negotiate prices for Medicare Part B drugs, but, unlike the CAP, DVP vendors would not purchase (take title of) or ship drugs to the voluntarily participating health care providers. Rather, participating health care providers would continue to buy drugs from established distribution channels, but at the DVP-negotiated prices, and the Medicare payment to participating health care providers would be at the same negotiated price. To encourage voluntary enrollment in the DVP, in addition to lowered financial risk associated with buying and billing for drugs at the set amounts established by a DVP vendor, participating health care providers

[122] National Health Expenditure Projections, 2017–26: Despite Uncertainty, Fundamentals Primarily Drive Spending Growth, available at: *https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2017.1655.*

[123] The MedPAC June 2017 *Report to the Congress: Medicare and the Health Care Delivery System. http://medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf?sfvrsn=0.*

would have shared savings opportunities through the DVP. According to MedPAC June 2017 report, the proposed shared savings opportunities for providers would not include providers taking on risk. Specifically, the shared savings with providers would occur ''if the DVP led to lower aggregate costs of Part B drugs, the savings would be shared with providers.'' Savings achieved through the DVP would also be shared with beneficiaries (through lower cost sharing), the DVP vendors, and the Medicare program. Nonparticipating health care providers would continue to buy drugs from traditional distribution channels and Medicare would pay based on the ASP system, although the ASP add-on would be reduced gradually. Other key elements of the DVP include its vendor structure, a shared savings component, tools to increase vendors' negotiating leverage, a reduction of the add-on in the ASP system, and exclusion of DVP prices from the ASP calculations.

In response to the Innovation Center New Direction RFI,[124] issued in September 2017, MedPAC encouraged the Innovation Center to consider its DVP proposal, suggesting that the Innovation Center could test use of private vendors to negotiate drug prices with manufacturers on a smaller scale in specific markets, and allow for voluntary provider participation, as a way to obtain lower prices for Medicare Part B drugs. The public comments that were received by the CMS Innovation Center in response to the New Direction RFI are available at: *https://innovation.cms.gov/initiatives/direction.* Numerous other stakeholders, such as the Coalition of State Rheumatology Organizations, CVS Health, and The Pew Charitable Trusts, also referenced or recommended similar approaches to MedPAC's DVP proposal in response to the New Direction RFI, involving the use of a private vendor to structure alternative payment arrangements for a small subset of therapies.[125]

4. Potential Model Goals and Considerations

Section 1115A of the Act authorizes the Innovation Center to test innovative payment and service delivery models expected to reduce program expenditures, while preserving or enhancing the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program beneficiaries. The CMS Innovation Center is exploring leveraging the authority for the CAP under section 1847B of the Act to test improvements to the CAP and to test whether allowing private-sector model vendors to enter into and administer value-based arrangements with manufacturers of separately payable Medicare Part B drugs and biologicals improves beneficiary access and quality of care while reducing Medicare expenditures. Such a CAP-like model would test an alternative to the current system, under which health care providers (physicians, hospital outpatient departments, and potentially other providers and suppliers) would acquire drugs through value-based agreements with manufacturers administered by CAP-like model vendors (''vendor-administered payment arrangements''), building on lessons learned from CMS' experience with the CAP. A potential benefit of a CAP-like model of this nature would be eliminating the financial risk to providers and suppliers of taking title to very high-cost drugs and biologicals.

Such a potential model would include competitively selected private-sector vendors that would establish vendor-administered payment arrangements with the manufacturers of separately payable Part B drugs and biologicals included in the model (''included drugs and biologicals''). CMS has considered that model vendors' vendor-administered payment arrangements under a potential model could be required to include value-based pricing strategies, such as outcomes-based agreements, indication-based pricing, payment over time, shared savings or performance-based payments based on the impact on total cost of care, and reduced beneficiary cost-sharing. This could more closely tie the Medicare payment and beneficiary cost-sharing for an included drug or biological to the value of such therapy, which we believe has the potential to reduce Medicare expenditures while preserving or enhancing the quality of care for beneficiaries. Such a model could start with a subset of therapies, with an increasing number of included drugs and biologicals over time. By introducing a competitive dynamic in Part B between manufacturers and model vendors and potentially among model vendors, such a model would aim to get lower drug prices for Medicare and for beneficiaries.

We are considering how to structure a model vendor role, and whether a CAP-like model test should include an approach similar to the CAP (where model vendors would purchase and take title to the included drugs and biologicals) or an approach similar to MedPAC's envisioned DVP (where providers and suppliers purchase and receive included drugs and biologicals through pricing arrangements and model vendors would not take title to the included drugs and biologicals). We also are considering, for example, whether testing either or both of these approaches may be appropriate for certain drugs and biologicals, such as testing one approach for high-cost drugs and biologicals, single source drugs and biologicals, or certain drug classes, and testing another approach for other types of drugs and biologicals.

We also are considering whether model vendors, if they did take title to included drugs and biologicals, would take possession of the included drugs and biologicals, or if existing distribution channels could be leveraged such that model vendors would take title to, but not possession of, the included drugs and biologicals and the included drugs and biologicals would be distributed directly to the providers and suppliers. In addition, we are considering whether, under a potential CAP-like model, providers and suppliers could have a formal custodial agreement with one or more model vendors, under which the model vendor would agree to ensure onsite availability of an included therapy without the provider or supplier taking ownership of the product, making payment, or otherwise being financially at risk for obtaining the product, subject to the provider's or supplier's obligation to ensure the physical safety and integrity of the included drug and biological until the included therapy is administered to an included beneficiary. In addition, we are considering how custodial agreements of this nature could address concerns with existing CAP requirements that CAP drugs could only be delivered upon receipt of a prescription, with limited exceptions. We are also considering whether providers and suppliers under such a custodial agreement with a model vendor could continue to collect beneficiary cost-sharing to address issues encountered under the CAP, such as eliminating the need for the provider or supplier to share beneficiary billing information with model vendors, reducing model vendors' financial risk for uncollected beneficiary cost-sharing, and lessening beneficiaries' burden associated with model vendors' billing for cost-sharing. However, potential financial relationships between providers and suppliers and model vendors could increase program risks, and we seek information on how CMS

[124] New Direction RFI and public comments are available at *https://innovation.cms.gov/initiatives/direction.*

might structure a potential model to avoid these risks while testing improvements to the CAP.

CMS is also considering how a potential CAP-like model could include other payers including Medicare Advantage organizations, State Medicaid agencies, as well as Medicaid Managed Care Organizations (MCOs). Specifically, we are considering ways to allow Medicare Advantage, State Medicaid agencies, and Medicaid MCOs to have access to the same or similar value-based vendor-administered payment arrangements available under a potential CAP-like model, such as by paying for included drugs and biologicals for their enrollees through model vendors.

We are soliciting public comments on these design considerations, on how to best initially test and then broaden the scope of a potential CAP-like model, and on the questions about a potential model identified below. These questions have been categorized into the following key areas: Included providers and suppliers; included drugs and biologicals; beneficiary cost-sharing, protections and fiscal considerations; model vendors; regulatory barriers and transparency issues; manufacturer participation; and model scope.

a. Included Providers and Suppliers

- Are there types of Part B providers and suppliers that should be included or excluded from a potential CAP-like model, and if so why?
- Certain physician specialties currently receive substantial revenue from Medicare payments for Part B drugs. For certain specialties (for example, rheumatology, ophthalmology and oncology) a significant portion of their overall Medicare payments are related to Part B drugs. Should a potential CAP-like model address concerns about a potential reduction in overall payments for physicians that currently rely on this revenue and, if so, how?
- What protections or incentives would be necessary for providers and suppliers to participate in a potential model that would require that included drugs and biologicals be acquired under a vendor-administered payment arrangement?

b. Included Drugs and Biologicals

- Which separately payable Part B drugs and biologicals or drug classes, would be appropriate to include in a potential CAP-like model in order to bring the greatest value to the Medicare program and to beneficiaries, and among these drugs and biologicals or classes thereof, which ones would be appropriate to include initially? Should separately payable Part B drugs and biologicals that are used in the treatment of substance use disorders and mental health disorders be included? Are there certain separately payable Part B drugs and biologicals or drug classes that should be excluded, and if so, why?
- Which specific drugs, drug classes, groups of drugs, or indications would be appropriate candidates for inclusion in a potential CAP-like model or in specific types of value-based pricing strategies? What rationale and supporting data are available to support adopting value-based payment for these candidates? For which of these candidates would claims data be an adequate information source for determining whether outcomes under a value-based agreement were met? Which drugs and biologicals or drug classes would be appropriate candidates for reducing or eliminating beneficiary coinsurance? How should modifications to beneficiary cost-sharing amounts be structured so that any reduced cost sharing does not lead to unintended competitive advantages?
- In addition to outcomes-based agreements, indication-based pricing arrangements, payment over time, shared savings or performance-based payment based on the impact on the total cost of care, what other potential value-based pricing strategies can CMS test that utilize market-based strategies in paying for Part B drugs? How could CMS ensure that payment arrangements are site neutral, where applicable? What current experience in the commercial or other markets should CMS consider?
- For outcomes-based agreements, what elements (*e.g.,* clinical measures, cost measures, quality measures, and other targets) should these agreements include? How would the outcomes of interest be measured? What information systems and infrastructure would be necessary for collection of outcomes data? Are there existing systems or data (such as claims data or quality measures) that could be leveraged to measure outcomes? What role could registries have in supporting outcomes-based agreements?

c. Beneficiary Cost Sharing, Protections and Fiscal Considerations

- How could a potential CAP-like model be structured to improve beneficiaries' access to Part B drugs and biologicals?
- How can access to and quality of care for beneficiaries be improved or maintained under a potential vendor-administered payment arrangement? Should these arrangements be constructed so beneficiaries share in the value created? How could the sharing of value with beneficiaries be structured?
- How can CMS ensure a potential CAP-like model includes beneficiary protections, including ensuring the quality of and access to care?
- What key considerations should CMS assess related to beneficiary cost-sharing, experience of care, choice of health care provider and drug or biological, and access to care in potentially designing such a model test?
- What challenges would need to be addressed to allow for collection of beneficiary outcomes data by model vendors or other CMS contractors?
- What tools and strategies should a potential model include to ensure program integrity and to minimize the potential for fraud, waste and abuse?

d. Model Vendors

- How could the role of the CAP vendor be improved such that model vendors, and included providers and suppliers, would not face unsurmountable challenges to model participation? What types of organizations should CMS consider as candidates to serve as the model vendors?
- As described above, CMS used a competitive process to select vendors for the CAP under section 1847B of the Act. What factors and selection criteria should CMS consider as part of a competitive selection process under a potential CAP-like model to identify those entities most likely to perform the responsibilities of a model vendor efficiently and effectively with minimal start up time? What methods should CMS consider for evaluation of submitted bids to obtain the best value for the Medicare program?
- What factors should CMS consider in setting the geographic areas that model vendors would serve? What are the benefits and challenges of setting larger geographic areas, or even a single nationwide geographic area, verses smaller geographic areas? If CMS establishes multiple geographic areas to be served by model vendors, should CMS allow entities that bid to perform model vendor responsibilities to submit a bid for one or more geographic areas or require entities that bid to perform model vendor responsibilities to do so for all areas included in a model? If bidders are allowed to choose to apply only for certain geographic areas, what strategies should CMS consider to ensure that qualified model vendors could be selected for each geographic area?
- How should CMS balance the need for potential model vendors to have

negotiating power (for example, sufficient volume) with the need to create competition across model vendors for developing vendor-based payment arrangements using innovative value-based pricing strategies? Should there be more than one model vendor that covers a specific geographic area? Should the number of model vendors in a specific geographic area be limited? Are there unique challenges that should be addressed for certain geographic areas, such as rural areas or the Territories, or for providers and suppliers in those areas?

- One suggested improvement to the CAP is to use a consignment approach. How could existing purchasing and distribution processes for included drugs and biologicals be leveraged to facilitate model vendor ownership prior to administration without a model vendor taking physical possession of the included drugs and biologicals, while ensuring timely onsite availability of included drugs and biologicals and flexibility for dosage changes?
- What are the potential risks with testing a consignment approach for model vendor-owned included drugs and biologicals, including high-cost therapies? What would be possible approaches for mitigating these risks?
- What terms and responsibilities should be included in formal custodial agreements between model vendors and included providers and suppliers to provide protections to model vendors, included providers and suppliers, and the Medicare program?
- What potential conflicts of interest might limit the success of a potential CAP-like model and what steps should CMS consider to mitigate this risk?
- What types of structures (such as group purchasing organizations, single or affiliated entities) could support a model vendor role for a potential CAP-like model for included drugs and biologicals?
- What financial protection(s) may be necessary to encourage private-sector vendor participation in a potential CAP-like model?
- How should CMS structure the payment arrangement between CMS and selected model vendors? Should CMS pay model vendors a fee that is not tied to the value of the included drugs and biologicals, discounts or rebates and, if so, how? Should the payment be tied to model vendor performance and, if so, how? How can CMS ensure that the payment arrangements with model vendors do not introduce perverse incentives?
- What, if any, formulary and/or utilization management strategies, such as step therapy, should model vendors be allowed to include in their value-based payment arrangements with manufacturers?

e. Regulatory Barriers and Transparency Issues

- What specific regulatory barriers currently exist under either the Medicare or Medicaid programs to value-based pricing strategies as part of a potential Medicare payment model that would test vendor-administered payment arrangements? How could CMS best address these barriers?
- What waivers of statutory and other requirements would need to be considered for purposes of testing a potential CAP-like model that would make included drugs and biologicals available to included providers and suppliers through vendor-administered payment arrangements?
- What specific engagement strategies, information sharing, and transparency would be necessary as part of a test of value-based vendor-administered payment arrangements with manufacturers in order to encourage participation and to provide beneficiaries, providers, and suppliers with important information in order for beneficiaries, providers, and suppliers to make person-centered health care decisions?
- What types of data would need to be shared with model vendors, manufacturers or other stakeholders to support model vendors' value-based payment arrangements with manufacturers?
- What are specific barriers that limit sharing data with model vendors or manufacturers? What safeguards should be in place regarding sharing data with potential model participants?
- How should the potential model be evaluated? What metrics should be reviewed or collected? What benchmarks should be used for purposes of the model for evaluation?

f. Manufacturer Participation

- What features should CMS consider that would incentivize manufacturers to participate in vendor-administered payment arrangements? Should participation by manufacturers be mandatory?
- How would drug prices and manufacturer price reporting for included drugs and biologicals be impacted by the potential CAP-like model test?

g. Model Scope

In designing models, CMS must consider the size and scope of the potential model, which impacts how many participants may be eligible for a model, to ensure an effective and valid model test and evaluation.

- What features should CMS consider to ensure a potential CAP-like model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures?
- Under a potential CAP-like model, how geographically broad should a model be in order to allow for a robust model test and evaluation?
- Are there certain states, localities, geographies, or other areas that should be excluded from the model? If so, what compelling reason exists for such exclusion?
- How could a CAP-like model be structured to allow for Medicare Advantage organizations, State Medicaid agencies, and Medicaid MCOs to have access to model vendor pricing under the model?
- Under what circumstances would allowing Medicare Advantage organizations, State Medicaid agencies, and Medicaid MCOs to pay for included drugs and biologicals for their enrollees through a model vendor's vendor-administered arrangement with a manufacturer not be appropriate?
- What are the potential interactions of a potential CAP-like model with existing CMS Innovation Center models? What steps should CMS consider to minimize potential overlap or impacts on existing models?

XVI. Proposed Additional Hospital Inpatient Quality Reporting (IQR) Program Policies

A. Background

We refer readers to the FY 2010 IPPS/LTCH PPS final rule (74 FR 43860 through 43861) and the FY 2011 IPPS/LTCH PPS final rule (75 FR 50180 through 50181) for detailed discussions of the history of the Hospital IQR Program, including the statutory history, and to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50217 through 50249), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49660 through 49692), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57148 through 57150), and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38323 through 38411) for the measures and program policies we have adopted for the Hospital IQR Program through the FY 2020 payment determination and subsequent years. In addition to the proposal discussed in this section, we also refer readers to the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20470 through 20500) for a full discussion of the Hospital IQR Program and its proposed policies.

B. Proposed Updates to the HCAHPS Survey Measure (NQF #0166) for the FY 2024 Payment Determination and Subsequent Years

1. Background of the HCAHPS Survey in the Hospital IQR Program

CMS partnered with the Agency for Healthcare Research and Quality (AHRQ) to develop the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) patient experience of care survey (NQF #0166) [126] (hereinafter referred to as the HCAHPS Survey). We adopted the HCAHPS Survey in the Hospital IQR Program (at the time called the Reporting Hospital Quality Data Annual Payment Update Program) in the CY 2007 OPPS final rule with comment period (71 FR 68202 through 68204) beginning with the FY 2008 payment determination and for subsequent years. We refer readers to the FY 2010 IPPS/LTCH PPS final rule (74 FY 43882), the FY 2011 IPPS/LTCH PPS final rule (75 FR 50220 through 50222), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641 through 51643), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53537 through 53538), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50819 through 50820), and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38328 to 38342) for details on previously-adopted HCAHPS Survey requirements.

The HCAHPS Survey (OMB Control Number 0938–0981) is the first national, standardized, publicly reported survey of patients' experience of hospital care and asks discharged patients 32 questions about their recent hospital stay. The HCAHPS Survey is administered to a random sample of adult patients who receive medical, surgical, or maternity care between 48 hours and 6 weeks (42 calendar days) after discharge and is not restricted to Medicare beneficiaries.[127] Hospitals must survey patients throughout each month of the year.[128] The HCAHPS Survey is available in official English, Spanish, Chinese, Russian, Vietnamese, and Portuguese versions. The HCAHPS Survey and its protocols for sampling, data collection and coding, and file submission can be found in the current HCAHPS *Quality Assurance Guidelines,* which is available on the official HCAHPS website at: *http://www.hcahpsonline.org/en/quality-assurance/.* AHRQ carried out a rigorous scientific process to develop and test the HCAHPS Survey instrument. This process entailed multiple steps, including: A public call for measures; literature reviews; cognitive interviews; consumer focus groups; multiple opportunities for additional stakeholder input; a 3-State pilot test; small-scale field tests; and notice-and-comment rulemaking. In May 2005, the HCAHPS Survey was first endorsed by the NQF.[129]

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38328 through 38342), out of an abundance of caution, in the face of a nationwide epidemic of opioid overprescription, we finalized a refinement to the HCAHPS Survey measure as used in the Hospital IQR Program by removing the previously adopted pain management questions and incorporating new Communication About Pain questions beginning with patients discharged in January 2018, for the FY 2020 payment determination and subsequent years.[130] These three survey questions within the HCAHPS Survey, collectively known as the Communication About Pain questions,[131] address how providers communicate with patients about pain. These questions are as follows:

- HP1: ''During this hospital stay, did you have any pain?''

☐ Yes
☐ No

- HP2: ''During this hospital stay, how often did hospital staff talk with you about how much pain you had?''

☐ Never
☐ Sometimes
☐ Usually
☐ Always

- HP3: ''During this hospital stay, how often did hospital staff talk with you about how to treat your pain?''

☐ Never
☐ Sometimes
☐ Usually
☐ Always

In addition, we finalized public reporting on the Communication About Pain questions, such that hospital performance data on those questions would be publicly reported on the *Hospital Compare* website beginning October 2020, using CY 2019 data. We also stated that we would provide performance results based on CY 2018 data on the Communication About Pain questions to hospitals in confidential preview reports, upon the availability of four quarters of data, as early as July 2019. We believed implementing the Communication About Pain questions as soon as feasible was necessary to address any perceived conflict between appropriate management of opioid use and patient satisfaction by relieving any potential pressure physicians may feel to overprescribe opioids (82 FR 38333).

2. Proposed Updates to the HCAHPS Survey: Removal of Communication About Pain Questions

Since finalization of the Communication About Pain questions, we have received feedback that some stakeholders are concerned that, although the revised questions focus on communications with patients about their pain and treatment of that pain, rather than how well their pain was controlled, the questions still could potentially impose pressure on hospital staff to prescribe more opioids in order to achieve higher scores on the HCAHPS Survey. In addition, in its final report, the President's Commission on Combating Drug Addiction and the Opioid Crisis recommended removal of the HCAHPS Pain Management questions in order to ensure providers are not incentivized to offer opioids to raise their HCAHPS Survey score.[132]

Other potential factors outside the control of CMS quality program requirements may contribute to the perception of a link between the Communication About Pain questions and opioid prescribing practices, including: misuse of the HCAHPS Survey (such as using it for outpatient emergency room care instead of inpatient care, or using it for determining individual physician performance); failure to recognize that the HCAHPS Survey excludes certain populations from the sampling frame (such as those with a primary substance use disorder diagnosis); and the addition of supplemental pain-related

[126] The HCAHPS measure also includes the NQF-endorsed Care Transition Measure (CTM–3) (NQF #0228), which we added in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53513 through 53516). We added the Communication About Pain composite measure in the FY 2018 IPPS/LTCH PPS final rule (38328 through 38342), and stated that we would seek NQF endorsement for this measure.

[127] We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38328 to 38342, 38398) and to the official HCAHPS website at: *http://www.hcahpsonline.org* for details on HCAHPS requirements.

[128] Ibid.

[129] Available at: *http://www.qualityforum.org/Publications/2008/08/National_Voluntary_Consensus_Standards_for_Hospital_Care_2007__Performance_Measures.aspx.*

[130] In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79855 through 79862), the Hospital VBP Program removed the Pain Management dimension of the HCAHPS Survey in the Patient and Caregiver-Centered Experience of Care/Care Coordination domain of the Hospital VBP Program beginning with the FY 2018 program year. Under the Hospital VBP Program, payment adjustments are tied to hospitals' performance on the measures that are used to calculate each hospital's Total Performance Score.

[131] Available at: *http://hcahpsonline.org/en/survey-instruments/.*

[132] Available at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-15-2017.pdf.*

survey questions by the hospital that are not formally part of the HCAHPS Survey or otherwise required by CMS.

Because some hospitals have identified patient experience of care as a potential source of competitive advantage, we have heard from stakeholders that some hospitals may be disaggregating their raw HCAHPS Survey data to compare, assess, and incentivize individual physicians, nurses, and other hospital staff. Some hospitals also may be using the HCAHPS Survey to assess their emergency and outpatient departments. To be clear, the HCAHPS Survey was never designed or intended to be used in these ways.[133] In our HCAHPS Quality Assurance Guidelines,[134] which sets forth current survey administration protocols, we strongly discourage the unofficial use of HCAHPS scores for comparisons within hospitals, such as for comparisons of particular wards, floors, and individual staff hospital members. We also support the standardization of HCAHPS Survey administration and data collection methodologies by requiring hospitals/survey vendors to participate in introductory and annual update trainings.

We continue to believe that pain management is a critical part of routine patient care on which hospitals should focus and an important concern for patients, their families, and their caregivers. It is important to reiterate that the HCAHPS Survey does not specify any particular type of pain control method. The revised questions focus entirely on communication about pain with patients and do not refer to, recommend, or imply that any particular type of treatment is appropriate (82 FR 38333). In addition, appropriate pain management includes communication with patients about pain-related issues, setting expectations about pain, shared decision-making, proper prescription practices, and alternative treatments for pain management.

Although we are not aware of any scientific studies that support an association between scores on the prior or current iterations of the Communication About Pain questions and opioid prescribing practices, out of an abundance of caution and to avoid any potential unintended consequences, we are proposing to update the HCAHPS Survey by removing the Communication About Pain questions effective with January 2022 discharges, for the FY 2024 payment determination and subsequent years. This would reduce the overall length of the HCAHPS Survey from 32 to 29 questions, and the final four quarters of reported Communication About Pain data (comprising data from the first, second, third, and fourth quarters 2021) would be publicly reported on *Hospital Compare* in October 2022 and then subsequently discontinued. As stated above, in its final report, the President's Commission on Combating Drug Addiction and the Opioid Crisis recommended removal of the HCAHPS Pain Management Survey questions in order to ensure providers are not incentivized to offer opioids to raise their HCAHPS Survey score.[135]

In proposing removal of the Communication About Pain questions, we are not proposing to change how performance scores are calculated for the remaining questions on the HCAHPS Survey. The Hospital IQR Program is a quality data reporting program; payments to hospitals will not be affected so long as hospitals timely submit data on required measures and meet all other program requirements. We would continue to use the remaining 29 questions of the HCAHPS Survey to assess patients' experience of care, and would continue to publicly report hospital scores on those questions in order to ensure patients and consumers have access to these data while making decisions about their care. Patients and providers can continue to review data from responses to the remaining 29 questions of the HCAHPS Survey on the *Hospital Compare* website.

In crafting our proposal, we considered whether the Communication About Pain questions should be retained in both the HCAHPS Survey and the Hospital IQR Program but with a further delay in public reporting. For example, instead of public reporting starting in October 2020 as previously finalized, we could delay public reporting of the Communication About Pain questions until October 2021. We are interested in feedback on whether the Communication About Pain questions should be retained in both the HCAHPS Survey and the Hospital IQR Program but with a further delay in public reporting. Delay in public reporting would allow further time to engage a broad range of stakeholders and assess their feedback regarding use of the Communication About Pain questions in the HCAHPS Survey and the Hospital IQR Program and to assess the impact of the new Communication About Pain questions. However, we chose to propose to remove the Communication About Pain questions as discussed above instead, so providers do not perceive that there are incentives for prescribing opioids to increase survey scores.

In crafting our proposal, we also considered proposing earlier removal of the Communication About Pain questions from the HCAHPS Survey effective as early as January 2020 discharges, for the FY 2022 payment determination and subsequent years. However, we believe removing the questions effective with January 2020 discharges would not allow sufficient time to make necessary updates to the data collection tools, including the CMS data submission warehouse and associated reporting tools, as well as to update the HCAHPS Survey administration protocols and the survey tool itself. In addition, our proposal to make these updates effective later, with January 2022 discharges, would allow time to assess the potential impact of using the Communication About Pain questions while monitoring unintended consequences. It would also allow time for empirical testing for any potential effect the removal of the Communication About Pain questions might have on responses to the remaining non-pain related survey items.

We are inviting public comment on our proposal as discussed above and whether the questions should be removed from the HCAHPS Survey and Hospital IQR Program. We are particularly interested in receiving feedback on any potential implications on patient care related to removing these questions. We also are interested in feedback from stakeholders on: (1) The importance of receiving feedback from patients related to communication about pain management and the importance of publicly reporting this information for use both by patients in healthcare decision-making and by hospitals in focusing their quality improvement efforts; (2) additional analyses demonstrating a relationship between the use of pain questions in patient surveys and prescribing behavior, including unpublished data, if available; (3) input from clinicians and other providers concerning whether it would be valuable for CMS to issue

[133] Tefera L, Lehrman WG, and Conway P. ''Measurement of the Patient Experience: Clarifying Facts, Myths, and Approaches.'' *Journal of the American Medical Association.* Available at: *http://jama.jamanetwork.com/article.aspx?articleid=2503222.*

[134] HCAHPS *Quality Assurance Guidelines* (v. 13.0), available at: *http://www.hcahpsonline.org/en/quality-assurance/.*

[135] Final Report, The President's Commission on Combating Drug Addiction and the Opioid Crisis, available at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-15-2017.pdf.*

guidance suggesting that hospitals do not administer any surveys with pain-related questions, including adding hospital-specific supplemental items to HCAHPS, as well as the potential implementation of a third party quality assurance program to assure that hospitals are not misusing survey data by creating pressure on individual clinicians to provide inappropriate clinical care; (4) information from clinicians and other providers concerning instances of hospital administrators using results from the HCAHPS Survey to compare individual clinician performance directly to other clinicians at the same facility or institution and examples where, as a result, clinicians have felt pressured to prescribed opioids inappropriately (in terms of either quantity or appropriateness for particular patients); (5) suggestions for other measures that would capture facets of pain management and related patient education, for instance, for collecting data about a hospital's pain management plan, and provide that information back to consumers; and (6) how other measures could take into account provider-supplied information on appropriate pain management and whether patients are informed about the risks of opioid use and about non-opioid pain management alternatives.

XVII. 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. For CY 2019, we are proposing to change the format of the OPPS Addenda A, B, and C, by adding a column entitled ''Copayment Capped at the Inpatient Deductible of $1,340.00'' where we would 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). We are requesting public comments on this proposed change of the OPPS Addenda A, B, and C for CY 2019.

To view the Addenda to this proposed rule pertaining to proposed CY 2019 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 ''1695–P'' from the list of regulations. All OPPS Addenda to this proposed rule are contained in the zipped folder entitled ''2019 OPPS 1695–P Addenda'' at the bottom of the page. To view the Addenda to this proposed rule period pertaining to CY 2019 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 ''1695–P'' from the list of regulations. All ASC Addenda to this proposed rule are contained in the zipped folders entitled ''Addendum AA, BB, DD1, DD2, and EE.''

XVIII. 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 this proposed rule, 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 2018 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; and 82 FR 59476 through 59479, 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. Below we discuss only the changes in burden that would result from the newly proposed provisions in this proposed rule.

In section XIII.B.4.b. of this proposed rule, we are proposing to remove a total of 10 measures. Specifically, beginning with the CY 2020 payment determination, we are proposing to remove: (1) OP–27: Influenza Vaccination Coverage Among Healthcare Personnel; and beginning with the CY 2021 payment determination, we are proposing to remove: (2) OP–5: Median Time to ECG; (3) OP–9: Mammography Follow-up Rates; (4) OP–11: Thorax CT Use of Contrast Material; (5) OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into Their Qualified/Certified EHR System as Discrete Searchable Data; (6) OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT; (7) OP–17: Tracking Clinical Results between Visits; (8) OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients; (9) OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use; and (10) OP–31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery. The reduction in burden associated with these proposals is discussed below in sections XVIII.B.3. and 4. of this proposed rule.

In section XIII.D.2. of this proposed rule, we are proposing to update the frequency with which we would release HOPD Specifications Manuals such that instead of every 6 months, we would release specifications manuals every 6 to 12 months beginning with CY 2019 and for subsequent years. In section XIII.C.2. of this proposed rule, beginning with the CY 2020 payment determination, we are proposing to remove the Notice of Participation (NOP) form as a requirement for the Hospital OQR Program and to update 42 CFR 419.46(a) to reflect these policies. As discussed below, we do not expect these proposals to affect our collection of information burden estimates.

2. Proposal To Update the Frequency of Releasing Hospital Outpatient Quality Reporting Specifications Manuals Beginning With CY 2019 and for Subsequent Years

In section XIII.D.2. of this proposed rule, we are proposing to update the frequency with which we would release Hospital Outpatient Quality Reporting Specifications Manuals, such that instead of every 6 months, we would release specifications manuals every 6 to 12 months beginning with CY 2019 and for subsequent years. We anticipate that this proposed change would reduce hospital confusion, as potentially releasing fewer manuals per year reduces the need to review updates as frequently as previously necessary. However, because this proposed change does not affect Hospital OQR Program participation requirements or data reporting requirements, we do not expect a change in the information collection burden experienced by hospitals.

3. Estimated Burden of Hospital OQR Program Proposals for the CY 2020 Payment Determination and Subsequent Years

a. Proposal To Remove the Notice of Participation (NOP) Form Requirement

In section XIII.C.2.b. of this proposed rule, beginning with the CY 2020 payment determination, we are proposing to remove the NOP form as a requirement. As a result, to be a participant in the Hospital OQR Program, hospitals would need to: (1) Register on the QualityNet website; (2) identify and register a QualityNet security administrator, and (3) submit data. In addition, we are proposing to update 42 CFR 419.46(a) to reflect these policies. We have previously estimated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75171) that the burden associated with administrative requirements including completing program requirements, system requirements, and managing facility operations is 42 hours per hospital or 138,600 hours across 3,300 hospitals. We believe that the proposal to remove the NOP, if finalized, would reduce administrative burden experienced by hospitals by only a nominal amount, as it is not required every year, but only at the start of a hospital's participation. As a result, this proposal does not influence our information collection burden estimates.

b. Proposed Removal of OP–27 for the CY 2020 Payment Determination and Subsequent Years

In section XIII.B.4.b. of this proposed rule, we are proposing to remove the OP–27: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) measure beginning with the CY 2020 payment determination and for subsequent years. The burden associated with OP–27, a National Healthcare Safety Network (NHSN) measure, is accounted for under a separate information collection request, OMB control number 0920–0666. Because burden associated with submitting data for this measure is captured under a separate OMB control number, we are not providing an estimate of the information collection burden associated with this measure for the Hospital OQR Program.

4. Estimated Burden of Hospital OQR Program Proposals for the CY 2021 Payment Determination and Subsequent Years

a. Proposed Removal of Chart-Abstracted Measures for the CY 2021 Payment Determination and Subsequent Years

In section XIII.B.4.b. of this proposed rule, we are proposing to remove one chart-abstracted measure for the CY 2021 payment determination and subsequent years: OP–5: Median Time to ECG. With regard to chart-abstracted measures for which patient-level data is submitted directly to CMS, we have previously estimated it would take 2.9 minutes, or 0.049 hour, per measure to collect and submit the data for each submitted case (80 FR 70582). In addition, based on the most recent data, we estimate that 947 cases are reported per hospital for chart-abstracted measures. Therefore, we estimate that it will take approximately 46 hours (0.049 hours × 947 cases) to collect and report data for each chart-abstracted measure. Accordingly, we believe that the removal of this chart-abstracted measure for the CY 2021 payment determination would reduce burden by 151,800 hours (46 hours × 3,300 hospitals) and $5.6 million (151,800 hours × $36.58 [136]).

[136] In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59477), we finalized a hourly labor cost to hospitals of $36.58 and specified that this cost included both wage ($18.29) and 100 percent overhead and fringe benefit costs (an additional $18.29). The estimate for this duty is available in the Bureau of Labor Statistics report on Occupation Employment and Wages for May 2016, 29–2071 Medical Records and Health Information Technicians at: *https://www.bls.gov/oes/2016/may/oes292071.htm.*

b. Proposed Removal of Measures Submitted Via a Web-based Tool for the CY 2021 Payment Determination and Subsequent Years

In section XIII.B.4.b. of this proposed rule, we are proposing to remove five measures submitted via a web-based tool beginning with the CY 2021 payment determination and for subsequent years: OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into Their Qualified/Certified EHR System as Discrete Searchable Data; OP–17: Tracking Clinical Results between Visits; OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients; OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use; and OP–31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery, a voluntary measure.

As we stated in the CY 2016 OPPS/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 proposal to remove OP–12, OP–17, OP–29, and OP–30 for the CY 2021 payment determination would reduce burden by 0.668 hours per hospital (4 measures × 0.167 hours per measure) and 2,204 hours (0.668 hours × 3,300 hospitals) across 3,300 hospitals. In addition, we estimate that OP–29 and OP–30 measures require 25 additional minutes (0.417 hours) per case per measure to chart-abstract and that a hospital would each abstract 384 cases per year (this number is based on previous analysis (78 FR 75171) where we estimate that each of the approximately 3,300 responding hospitals will have volume adequate to support quarterly sample sizes of 96 cases, for a total of 384 cases (96 cases per quarter × 4 quarters) to be abstracted by each hospital annually for one new measure) for each of these measures. Therefore, we estimated an additional burden reduction of 1,056,845 hours (3,300 hospitals × 0.417 hours × 384 cases per measure × 2 measures) for all participating hospitals for OP–29 and OP–30. In total, we estimate a burden reduction of 1,059,049 hours (2,204 hours for web submission + 1,056,845 hours for chart-abstraction of OP–29 and OP–30) and $38.7 million (1,059,049 hours × $36.58) for the proposed removal of those four web-based

measures from the Hospital OQR Program.

In addition, we estimate that approximately 20 percent of hospitals, or 660 hospitals (3,300 hospitals × 0.2), elect to report OP–31 on a voluntary basis, resulting in an additional burden reduction of 110 hours (0.167 hours per hospital × 660 hospitals) for web submission. We also estimate that OP–31 requires 25 additional minutes (0.417 hours) per case to chart-abstract and that a hospital would abstract 384 cases per year for this measure. Therefore, we estimate that the additional chart-abstraction burden reduction for this measure would be 105,684 hours (660 hospitals × 0.417 hours per case × 384 cases) for participating hospitals. In total, we anticipate a burden reduction of 105,794 hours (110 hours for web-submission + 105,684 hours for chart-abstraction) and $3.9 million (105,794 hours × $36.58) for the proposed removal of OP–31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.

In total, we estimate that the removal of five web-based measures (OP–12, OP–17, OP–29, OP–30, and OP–31) would reduce burden by 1,164,843 hours (1,059,049 hours for the removal of four measures + 105,794 hours for the removal of one voluntary measure) and $42.6 million (1,164,843 hours × $36.58).

c. Proposed Removal of Claims-Based Measures for the CY 2021 Payment Determination and Subsequent Years

In section XIII.B.4.b. of this proposed rule, we are proposing to remove three claims-based measures beginning with the CY 2021 payment determination: OP–9: Mammography Follow-up Rates; OP–11: Thorax CT Use of Contrast Material; and OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT. Claims-based measures are derived through analysis of administrative claims data and do not require additional effort or burden on hospitals. As a result, we do not expect these proposals to affect collection of information burden for the CY 2021 payment determination.

In total for the CY 2021 payment determination, we expect the information collection burden would be reduced by 151,800 hours due to the proposed removal of one chart-abstracted measure, and 1,164,843 hours due to the proposed removal of five measures submitted via a web-based tool. In total, we estimate an information collection burden reduction of 1,316,643 hours (1,164,843 hours + 151,800 hours) and $48.2 million (1,316,643 hours × $36.58) for the CY 2021 payment determination.

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, and CY 2018 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; and 82 FR 59479 through 59481, 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. Below we discuss only the changes in burden that would result from the newly proposed provisions in this proposed rule.

In section XIV.B.3.c. of this proposed rule, we are proposing to remove one measure beginning with the CY 2020 payment determination, ASC–8: Influenza Vaccination Coverage Among Healthcare Personnel, and seven measures beginning with the CY 2021 payment determination: ASC–1: Patient Burn; ASC–2: Patient Fall; ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; ASC–4: All-Cause Hospital Transfer/Admission; ASC–9: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients; ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use; and ASC–11: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery. We expect these proposals would reduce the overall burden of reporting data for the ASCQR Program, as discussed below.

2. Estimated Burden of ASCQR Program Proposals Beginning With CY 2020 Payment Determination and Subsequent Years: Proposed Removal of ASC–8 for the CY 2020 Payment Determination and Subsequent Years

In section XIV.B.3.c. of this proposed rule, we are proposing the removal of one measure beginning with the CY 2020 payment determination, ASC–8: Influenza Vaccination Coverage Among Healthcare Personnel. Data for ASC–8 are submitted via a non-CMS online data submission tool, to the NHSN. However, we note that the information collection burden associated with ASC–8, a NHSN measure, is accounted for under a separate information collection request, OMB control number 0920–0666. As such, we are not providing an estimate of the information collection burden associated with this measure under the ASCQR Program OMB control number.

3. Estimated Burden of ASCQR Program Proposed Measure Removals for the CY 2021 Payment Determination

In section XIV.B.3.c. of this proposed rule, we are proposing to remove seven measures beginning with the CY 2021 payment determination: ASC–1: Patient Burn; ASC–2: Patient Fall; ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; ASC–4: All-Cause Hospital Transfer/Admission; ASC–9: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients; ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use; and ASC–11: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.

a. Proposed Removal of QDC Claims-based Measures for the CY 2021 Payment Determination and Subsequent Years

In section XIV.B.3.c. of this proposed rule, we are proposing to remove four QDC claims-based measures from the ASCQR Program measure set beginning with the CY 2021 payment determination: 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. Data used to calculate scores for these measures are collected via Part A and Part B Medicare administrative claims and Medicare enrollment data; therefore, ASCs are not required to report any additional data. Because these measures do not require ASCs to submit any additional data, we do not believe there would be any information collection burden change associated with removing these measures.

b. Proposed Removal of Chart-Abstracted Measures for the CY 2021 Payment Determination and Subsequent Years

In section XIV.B.3.c. of this proposed rule, we are proposing to remove three chart-abstracted measures from the ASCQR Program measure set beginning

with the CY 2021 payment determination: ASC–9: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients; ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use; and ASC–11: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery. We believe 3,937 ASCs would experience a reduction in information collection burden associated with our proposals to remove ASC–9 and ASC–10 from the ASCQR Program measure set. For ASC–11, a voluntary measure, we previously estimated that approximately 20 percent of ASCs (5,260 ASCs nationwide × 0.20), 1,052, would elect to submit these data on a voluntary basis and, thus, would experience a reduction in information collection burden associated with reporting.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79864), we finalized our estimates that each participating ASC would spend 0.25 hours (15 minutes) per case per measure per year to collect and submit the required data for the ASC–9, ASC–10, and ASC–11 measures. We estimate that the average number of patients per ASC is 63 based on the historic average. In addition, we estimate the total annual information collection burden per ASC to be 15 hours and 45 minutes (15.75 hours) per measure (0.25 hours × 63 cases). Therefore, for ASC–9 and ASC–10, we estimate the total annualized information collection burden associated with each measure to be 62,008 hours (3,937 ASCs × 15.75 hours per ASC) and $2,268,253 (62,008 hours × $36.58 per hour[137]). For ASC–11, we estimate a total annual information collection burden of 16,569 hours (1,052 ASCs × 15.75 hours) and $606,094 (16,569 hours × $36.58 per hour). Therefore, we estimate a total reduction in information collection burden of 140,585 hours (62,008 hours + 62,008 hours + 16,569 hours) and $5,142,600 ($2,268,253 + $2,268,253 + $606,094) as a result of our proposals to remove ASC–9; ASC–10; and ASC–11.

Therefore, as a result of our proposals to remove seven measures from the ASCQR measure set for the CY 2021 payment determination, ASC–1; ASC–2; ASC–3; ASC–4; ASC–9; ASC–10; and ASC–11, we estimate a total annual reduction in information collection burden of 140,585 hours and $5,142,600. The reduction in information collection burden associated with these requirements is available for review and comment under OMB control number 0938–1270.

D. ICRs for the Proposed Update to the HCAHPS Survey Measure in the Hospital IQR Program

As described in section XVI. of this proposed rule, we are proposing to update the HCAHPS Survey measure by removing the Communication About Pain questions beginning with patients discharged in January 2022, for the FY 2024 payment determination and subsequent years. While we anticipate that the removal of these questions will reduce the burden associated with reporting this measure, as further discussed below, the burden estimate for the Hospital IQR Program excludes the burden associated with the HCAHPS Survey measure, which is submitted under a separate information collection request and approved under OMB control number 0938–0981. For discussion of the burden estimate for the Hospital IQR Program under OMB control number 0938–1022, we refer readers to the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20555 through 20559). For details on the burden estimate specifically for the HCAHPS Survey, including use of the Communication About Pain questions, we refer readers to the notice published in the **Federal Register** on Information Collection for the National Implementation of the Hospital CAHPS Survey (83 FR 21296 through 21297). We note that a revised information collection request under OMB control number 0938–0981 will be submitted to OMB based on the proposed update to the HCAHPS Survey in accordance with this proposed rule.

As noted above, the proposal to remove the Communication About Pain questions does not change the estimated burden for the Hospital IQR Program under the program's OMB control number 0938–1022. However, we believe that overall cost and burden will change slightly for hospitals and HCAHPS Survey respondents. Under HCAHPS Survey OMB control number 0938–0981, it is estimated that the average cost and hour burdens for hospitals are $4,000 and 1 hour per hospital for HCAHPS data collection activities. Because these estimates include administrative activities and overhead costs, we believe our proposal to remove the Communication About Pain questions from the HCAHPS Survey would not reduce these estimates of hospital burden or would only nominally and temporarily increase the average cost and hour burdens associated with the removal of these questions from the survey given the need to adjust the survey instrument and instructional materials and, therefore, marginally reduce the burden due to the shortening of the survey instrument.

Under HCAHPS Survey OMB control number 0938–0981, the average time for a respondent to answer the 32 question survey is estimated at 8 minutes, which we estimate to be 0.25 minutes per question (8 minutes/32 questions = 0.25 minutes per question). In addition, under this OMB control number, the number of respondents is estimated at 3,104,200 respondents. In this proposed rule, we are proposing to remove 3 questions, which we estimate would reduce the time burden by 0.75 minutes (0.25 minutes per question × 3 questions), or 0.0125 hours (0.75 minutes/60 minutes) per respondent. We anticipate a total hourly burden reduction for respondents of 38,803 hours (0.0125 hours × 3,104,200 respondents). Further, under OMB control number 0938–0981, the cost of respondent time is based on the average hourly earnings of $26.71 per hour, as reported by the U.S. Bureau of Labor Statistics final January 2018 estimates available on the website at: *https://www.bls.gov/eag/eag.us.htm.*[138] We anticipate a total cost reduction for respondents associated with the proposal to remove the 3 Communication About Pain questions of $1,036,428 (38,803 total hours × respondent earnings estimate of $26.71 per hour).

E. Total Reduction in Burden Hours and in Costs

The total reduction in the burden hours for the above ICRs is 1,496,031 hours, and the reduction in cost is $54.3 million ($48.2 million + $5.1 million + $1 million).

XIX. 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 proposed rule, and, when we

[137] In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59479 through 59480), we finalized an hourly labor cost to hospitals of $36.58 and specified that this cost included both wage and overhead and fringe benefit costs. The estimate for this duty is available in the Bureau of Labor Statistics report on Occupation Employment and Wages for May 2016, 29–2071 Medical Records and Health Information Technicians at: *https://www.bls.gov/oes/2016/may/oes292071.htm.*

[138] Average hourly earnings of $26.71 per hour based on the average hourly earnings of all employees on private non-farm payrolls, seasonally adjusted, per the U.S. Bureau of Labor Statistics.

proceed with a subsequent document(s), we will respond to those comments in the preamble to that document.

XX. Economic Analyses

A. Statement of Need

This proposed rule 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 2019. 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 proposing to revise the APC relative payment weights using claims data for services furnished on and after January 1, 2017, through and including December 31, 2017, and processed through December 31, 2017, and updated cost report information.

We note that we are proposing to control for unnecessary increases in the volume of outpatient 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). We expect that by removing the payment differential, we will control unnecessary volume increases both in terms of the number of covered outpatient services furnished and the costs of those services.

This proposed rule also is necessary to make updates to the ASC payment rates for CY 2019, 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 2019. 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 addition, for CYs 2019 through 2023, we are proposing to update the ASC payment system rates using the hospital market basket update instead of the CPI–U but are requesting evidence from commenters to justify this higher payment update. We believe that this proposal could 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 Proposed Rule

We have examined the impacts of this proposed rule, as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (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 proposed rule contains the impact and other economic analyses for the provisions we are proposing to make for CY 2019.

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 proposed rule 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 proposed rule 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 this proposed rule. We are soliciting public comments on the regulatory impact analysis in this proposed rule, and we will address any public comments we receive in the final rule with comment period, as appropriate.

We estimate that the proposed total increase in Federal government expenditures under the OPPS for CY 2019, compared to CY 2018, due only to the proposed changes to OPPS in this proposed rule, would be approximately $90 million. Taking into account our estimated changes in enrollment, utilization, and case-mix for CY 2019, we estimate that the OPPS expenditures, including beneficiary cost-sharing, for CY 2019 would be approximately $74.6 billion; approximately $4.9 billion higher than estimated OPPS expenditures in CY 2018. We note that these spending estimates include the CY 2019 proposal to control for unnecessary increases in the volume of outpatient service by paying for clinic visits furnished at excepted off-campus PBDs at a PFS-equivalent rate. Because the proposed provisions of the OPPS are part of a proposed 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 42 displays the distributional impact of the proposed CY 2019 changes in OPPS payment to various groups of hospitals and for CMHCs.

We are proposing for CY 2019 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 are proposing to continue our policy to pay separately payable drugs and biological products at 95 percent of the AWP. 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 estimate that the proposed 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 2018, and the proposal to control for unnecessary increases in the volume of covered outpatient department services described in section X.B. of this proposed rule) would increase total OPPS payments by 1.3 percent in CY 2019. The proposed changes to the APC relative payment weights, the proposed changes to the wage indexes, the proposed continuation of a payment adjustment for rural SCHs, including EACHs, and the proposed payment adjustment for cancer hospitals would not increase OPPS payments because

these proposed changes to the OPPS are budget neutral. However, these proposed updates would change the distribution of payments within the budget neutral system. We estimate that the total proposed change in payments between CY 2018 and CY 2019, considering all proposed budget neutral payment adjustments, proposed changes in estimated total outlier payments, proposed pass-through payments, the proposed application of the frontier State wage adjustment, and the proposal to control for unnecessary increases in the volume of outpatient as described in section X.B. of this proposed rule, in addition to the application of the proposed 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, would decrease total estimated OPPS payments by 0.1 percent.

We estimate the total increase (from proposed changes to the ASC provisions in this proposed rule 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 2019 compared to CY 2018, to be approximately $240 million. Because the proposed provisions for the ASC payment system are part of a proposed rule that is economically significant, as measured by the $100 million threshold, we have prepared a regulatory impact analysis of the proposed changes to the ASC payment system that, to the best of our ability, presents the costs and benefits of this portion of this proposed rule. Tables 43 and 44 of this proposed rule display the redistributive impact of the proposed CY 2019 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 Proposed OPPS Changes in This Proposed Rule

a. Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the proposed CY 2019 policy changes on various hospital groups. We post on the CMS website our hospital-specific estimated payments for CY 2019 with the other supporting documentation for this proposed rule. 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–1695–P'' 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 proposed rule. We show hospital-specific data only for hospitals whose claims were used for modeling the impacts shown in Table 42 below. 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 proposed rule for a discussion of the hospitals whose claims we do not use for ratesetting and impact purposes.

We estimate the effects of the proposed 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 proposed policy changes in order to isolate the effects associated with specific policies or updates. 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 Proposal To Control for Unnecessary Increases in the Volume of Outpatient Services

In section X.B. of this proposed rule, we discuss our CY 2019 proposal to control for unnecessary increases in the volume of outpatient service by paying for clinic visits furnished at an off-campus provider-based department 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, we are proposing 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). For a discussion of the PFS relativity adjuster that will now also be used to pay for all outpatient clinic visits provided at all 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 proposed rule.

To develop an estimated impact of this proposal, we began with CY 2017 outpatient claims data used in ratesetting for the CY 2019 proposed 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 comprehensive APC 8011 (Comprehensive Observation Services) or packaged into another comprehensive APC because in those instances separate 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 proposed policy that includes the effects of estimated changes in enrollment, utilization, and case-mix based on the FY 2019 President's budget approximates the estimated decrease in total payment under the OPPS at $760 million, with Medicare OPPS payments decreasing by $610 million and beneficiary copayments decreasing by $150 million in CY 2019. This estimate is utilized for the accounting statement displayed in Table 45 of this proposed rule because the impact of this proposed CY 2019 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 proposed in this rule.

We note 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. We remind readers that this estimate could change in the final rule based on a number of factors such as the availability of updated data, changes in the final payment policy, and/or the method of assessing the payment impact in the final rule. As discussed in more detail in section X.B. of this proposed rule, we are seeking public comment on both our proposed payment policy for clinic visits furnished at off-campus provider based departments as well as how to apply methods for controlling overutilization of services more broadly.

c. Estimated Effects of Proposal To Apply the 340B Drug Payment Policy to Nonexcepted Off-Campus Departments of Hospitals

In section X.C. of this proposed rule, we discuss our proposal to pay average sales price (ASP) minus 22.5 percent for 340B-acquired drugs furnished by nonexcepted, off-campus provider-based departments (PBDs) beginning in CY 2019. This is consistent with the payment methodology adopted in CY 2018 for 340B-acquired drugs furnished

in hospital departments paid under the OPPS.

To develop an estimated impact of this proposal, we began with CY 2017 outpatient claims data used in ratesetting for the CY 2019 proposed OPPS. We then flagged all claim lines that contained modifier ''PN'' because the presence of this modifier indicates that such claims were billed for services furnished by a nonexcepted off-campus department of a hospital paid under the PFS. We further subset this population by identifying 340B hospitals that billed for status indicator ''K'' drugs or biologicals (that is, nonpass-through, separately payable drugs) because such drugs may have been subject to the 340B discount. We found 115 unique nonexcepted off-campus PBDs associated with 340B hospitals billed for status indicator ''K'' drugs. Their ''K'' billing represents approximately $180 million in Medicare payments (including beneficiary copayments) based on a payment rate of ASP+6 percent. Based on our proposed adjustment, for CY 2019, we estimate that the Medicare Program and beneficiaries would save approximately $48.5 million, under the Physician Fee Schedule. This estimate represents an upper bound of potential savings under the Physician Fee Schedule for this proposed policy change and does not include adjustments for beneficiary enrollment, case-mix, or potential offsetting behaviors. Accordingly, this estimate could change in the final rule based on a number of factors such as the availability of updated data, changes in the final payment policy, and/or the method of assessing the payment impact in the final rule.

d. Estimated Effects of Proposed OPPS Changes on Hospitals

Table 42 below shows the estimated impact of this proposed rule on hospitals. Historically, the first line of the impact table, which estimates the proposed 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 42, 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 2019, we are proposing to pay CMHCs for partial hospitalization services under APC 5853 (Partial Hospitalization for CMHCs), and we are proposing 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 proposed rule.

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 proposed IPPS market basket percentage increase for FY 2019 is 2.8 percent (83 FR 20381). Section 1833(t)(3)(F)(i) of the Act reduces that 2.8 percent by the multifactor productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, which is proposed to be 0.8 percentage point for FY 2019 (which is also the proposed MFP adjustment for FY 2019 in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20381 through 20382)), and sections 1833(t)(3)(F)(ii) and 1833(t)(3)(G)(v) of the Act further reduce the market basket percentage increase by 0.75 percentage point, resulting in the proposed OPD fee schedule increase factor of 1.25 percent. We are using the proposed OPD fee schedule increase factor of 1.25 percent in the calculation of the proposed CY 2019 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 2019 estimates in Table 42 of this proposed rule.

To illustrate the impact of the proposed CY 2019 changes, our analysis begins with a baseline simulation model that uses the CY 2018 relative payment weights, the FY 2018 final IPPS wage indexes that include reclassifications, and the final CY 2018 conversion factor. Table 42 shows the estimated redistribution of the proposed increase or decrease in payments for CY 2019 over CY 2018 payments to hospitals and CMHCs as a result of the following factors: the impact of the APC reconfiguration and recalibration changes between CY 2018 and CY 2019 (Column 2); the wage indexes and the provider adjustments (Column 3); the combined impact of all of the proposed changes described in the preceding columns plus the proposed 1.25 percent OPD fee schedule increase factor update to the conversion factor (Column 4); the proposed off-campus provider-based departments visits payment policy (Column 5), and the estimated impact taking into account all proposed payments for CY 2019 relative to all payments for CY 2018, including the impact of proposed changes in estimated outlier payments, the proposed frontier State wage adjustment, and proposed 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 proposing to maintain the current adjustment percentage for CY 2019. Because the proposed updates to the conversion factor (including the proposed update of the OPD fee schedule increase factor), the estimated cost of the proposed rural adjustment, and the estimated cost of projected pass-through payment for CY 2019 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 proposed wage index changes on the hospital. However, total payments made under this system and the extent to which this proposed rule would redistribute money during implementation also will depend on changes in volume, practice patterns, and the mix of services billed between CY 2018 and CY 2019 by various groups of hospitals, which CMS cannot forecast.

Overall, we estimate that the proposed rates for CY 2019 would decrease Medicare OPPS payments by an estimated 0.1 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 0.1 percent decrease in Medicare payments to all other hospitals. These estimated payments would not significantly impact other providers.

Column 1: Total Number of Hospitals

The first line in Column 1 in Table 42 shows the total number of facilities (3,806), including designated cancer and

children's hospitals and CMHCs, for which we were able to use CY 2017 hospital outpatient and CMHC claims data to model CY 2018 and CY 2019 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 2018 or CY 2019 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 proposed rule. 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 (3,695), 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 44 CMHCs at the bottom of the impact table and discuss that impact separately below.

Column 2: APC Recalibration—All Proposed Changes

Column 2 shows the estimated effect of proposed APC recalibration. Column 2 also reflects any proposed changes in multiple procedure discount patterns or conditional packaging that occur as a result of the proposed changes in the relative magnitude of payment weights. As a result of proposed APC recalibration, we estimate that urban hospitals would experience no change, with the impact ranging from an increase of 0.5 percent to a decrease of 0.3 percent, depending on the number of beds. Rural hospitals would experience an increase of 0.3 percent, with the impact ranging from a decrease of 0.2 percent to an increase of 0.5 percent, depending on the number of beds. Major teaching hospitals would experience a decrease of 0.3 percent.

Column 3: Proposed Wage Indexes and the Effect of the Proposed Provider Adjustments

Column 3 demonstrates the combined budget neutral impact of the proposed APC recalibration; the proposed updates for the wage indexes with the proposed FY 2019 IPPS post-reclassification wage indexes; the proposed rural adjustment; and the proposed cancer hospital payment adjustment. We modeled the independent effect of the proposed budget neutrality adjustments and the proposed OPD fee schedule increase factor by using the relative payment weights and wage indexes for each year, and using a CY 2018 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. This column excludes the effects of the proposed frontier State wage index adjustment, which is not budget neutral and is included in Column 6. We did not model a budget neutrality adjustment for the rural adjustment for SCHs because we are proposing to continue the rural payment adjustment of 7.1 percent to rural SCHs for CY 2019, as described in section II.E. of this proposed rule. We also did not model 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 2019 of 0.89, which is the same ratio that was reported for the CY 2018 OPPS/ASC final rule with comment period (82 FR 59266). We note that, in accordance with section 16002 of the 21st Century Cures Act, we are proposing to apply a budget neutrality factor calculated as if the cancer hospital adjustment target payment-to-cost ratio was 0.89, not the 0.88 target payment-to-cost ratio we are applying in section II.F. of this proposed rule.

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 proposed CY 2019 scaled weights and a CY 2018 conversion factor that included a budget neutrality adjustment for the effect of the proposed changes to the wage indexes between CY 2018 and CY 2019. The proposed FY 2019 wage policy would result in modest redistributions.

Column 4: All Proposed Budget Neutrality Changes Combined With the Proposed Market Basket Update

Column 4 demonstrates the combined impact of all of the proposed changes previously described and the proposed update to the conversion factor of 1.25 percent. Overall, these proposed changes would increase payments to urban hospitals by 1.3 percent and to rural hospitals by 1.5 percent. Urban hospitals would receive an increase in line with the 1.3 percent overall increase for all facilities after the update is applied to the proposed budget neutrality adjustments. The increase for classes of rural hospitals would be more variable with sole community hospitals receiving a 1.3 percent increase and other rural hospitals receiving an increase of 1.7 percent.

Column 5—Proposed Off-Campus PBD Visits Payment Policy

Column 5 displays the estimated effect of our proposed CY 2019 policy to pay for clinic visit HCPCS code G0463 ((Hospital outpatient clinic visit for assessment and management of a patient) when billed with modifier ''PO'' at a PFS-equivalent rate. We note that the numbers provided in this column isolate the estimated effect of this proposed 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 proposed off-campus PBD visits policy.

Column 6: All Proposed Changes for CY 2019

Column 6 depicts the full impact of the proposed CY 2018 policies on each hospital group by including the effect of all proposed changes for CY 2019 and comparing them to all estimated payments in CY 2018. Column 6 shows the combined budget neutral effects of Columns 2 through 3; the proposed OPD fee schedule increase; the effect of the proposed off-campus provider-based department visits policy, the impact of the proposed frontier State wage index adjustment; the impact of estimated OPPS outlier payments, as discussed in section II.G. of this proposed rule; the proposed 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 XIII. of this proposed rule); and the difference in proposed 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 2018 update (and assumed, for modeling purposes, to be the same number for CY 2019), we included 29 hospitals in our model because they had both CY 2017 claims data and recent cost report data. We estimate that the cumulative effect of all proposed changes for CY 2019 would decrease payments to all facilities by 0.1 percent for CY 2019. We modeled the independent effect of all proposed changes in Column 6 using the final relative payment weights for CY 2018 and the proposed relative payment weights for CY 2019. We used the final conversion factor for CY 2018 of $78.636 and the proposed CY 2019 conversion factor of $79.546 discussed in section II.B. of this proposed rule.

Column 6 contains simulated outlier payments for each year. We used the 1-year charge inflation factor used in the proposed FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20581) of 4.2 percent (1.04205) to increase individual costs on the CY 2017 claims, and we used the most recent overall CCR in the July 2018 Outpatient Provider-Specific File (OPSF) to estimate outlier payments for CY 2018. Using the CY 2017 claims and a 4.2 percent charge inflation factor, we currently estimate that outlier payments for CY 2018, using a multiple threshold of 1.75 and a fixed-dollar threshold of $4,150, would be approximately 1.02 percent of total payments. The estimated current outlier payments of 1.02 percent are incorporated in the comparison in Column 6. We used the same set of claims and a charge inflation factor of 8.6 percent (1.085868) and the CCRs in the April 2018 OPSF, with an adjustment of 0.987842, to reflect relative changes in cost and charge inflation between CY 2017 and CY 2019, to model the proposed CY 2019 outliers at 1.0 percent of estimated total payments using a multiple threshold of 1.75 and a fixed-dollar threshold of $4,600. The charge inflation and CCR inflation factors are discussed in detail in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20582).

Overall, we estimate that facilities would experience a decrease of 0.1 percent under this proposed rule in CY 2019 relative to total spending in CY 2018. This projected increase (shown in Column 6) of Table 42 reflects the proposed 1.25 percent OPD fee schedule increase factor, minus 1.2 percent for the proposed off-campus provider-based department visits policy, minus 0.13 percent for the proposed change in the pass-through payment estimate between CY 2018 and CY 2019, plus a proposed increase of 0.02 percent for the difference in estimated outlier payments between CY 2018 (1.02 percent) and CY 2019 (proposed 1.00 percent). We estimate that the combined effect of all proposed changes for CY 2019 would decrease payments to urban hospitals by 0.1 percent. Overall, we estimate that rural hospitals would experience a 0.1 percent decrease as a result of the combined effects of all proposed changes for CY 2019. Among hospitals, by teaching status, we estimate that the impacts resulting from the combined effects of all proposed changes would include a decrease of 0.8 percent for major teaching hospitals and an increase of 0.5 percent for nonteaching hospitals. Minor teaching hospitals would experience an estimated decrease of 0.2 percent.

In our analysis, we also have categorized hospitals by type of ownership. Based on this analysis, we estimate that voluntary hospitals would experience a decrease of 0.2 percent, proprietary hospitals would experience an increase of 0.7 percent, and governmental hospitals would experience a decrease of 0.3 percent.

TABLE 42—ESTIMATED IMPACT OF THE PROPOSED CY 2019 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

	Number of hospitals	Proposed APC recalibration (all proposed changes)	Proposed new wage index and provider adjustments	All proposed budget neutral changes (combined cols 2 and 3) with market basket update	Proposed off-campus provider-based department visits policy	All proposed changes
	(1)	(2)	(3)	(4)	(5)	(6)
ALL FACILITIES *	3,806	0.0	0.0	1.3	−1.2	−0.1
ALL HOSPITALS (excludes hospitals permanently held harmless and CMHCs)	3,695	0.0	0.0	1.3	−1.2	−0.1
URBAN HOSPITALS	2,900	0.0	0.0	1.3	−1.2	−0.1
LARGE URBAN (GT 1 MILL.)	1,534	0.0	−0.1	1.2	−1.0	0.1
OTHER URBAN (LE 1 MILL.)	1,366	0.0	0.1	1.3	−1.4	−0.2
RURAL HOSPITALS	795	0.3	0.0	1.5	−1.3	−0.1
SOLE COMMUNITY	367	0.2	−0.1	1.3	−1.5	−0.4
OTHER RURAL	428	0.4	0.0	1.7	−1.2	0.3
BEDS (URBAN):						
0—99 BEDS	980	0.5	−0.2	1.6	−0.8	0.7
100–199 BEDS	844	0.2	−0.2	1.3	−1.0	0.1
200–299 BEDS	463	0.1	0.1	1.4	−0.9	0.3
300–499 BEDS	399	−0.1	0.0	1.2	−1.2	−0.2
500 + BEDS	214	−0.3	0.1	1.1	−1.6	−0.6
BEDS (RURAL):						
0—49 BEDS	326	0.5	0.1	1.8	−0.5	1.1
50–100 BEDS	287	0.3	0.0	1.6	−1.6	−0.2
101–149 BEDS	96	0.3	0.0	1.6	−1.0	0.4
150–199 BEDS	48	0.3	−0.2	1.4	−2.1	−1.0
200 + BEDS	38	−0.2	−0.2	0.9	−1.2	−0.5
REGION (URBAN):						
NEW ENGLAND	140	0.2	0.3	1.7	−2.1	−0.4
MIDDLE ATLANTIC	336	0.0	−0.2	1.0	−0.9	0.0
SOUTH ATLANTIC	463	0.0	−0.2	1.1	−1.1	−0.1

TABLE 42—ESTIMATED IMPACT OF THE PROPOSED CY 2019 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM—Continued

	Number of hospitals	Proposed APC recalibration (all proposed changes)	Proposed new wage index and provider adjustments	All proposed budget neutral changes (combined cols 2 and 3) with market basket update	Proposed off-campus provider-based department visits policy	All proposed changes
	(1)	(2)	(3)	(4)	(5)	(6)
EAST NORTH CENT	468	0.0	−0.2	1.1	−1.6	−0.7
EAST SOUTH CENT	175	−0.1	0.1	1.2	−0.4	0.6
WEST NORTH CENT	180	−0.2	0.1	1.1	−1.3	−0.5
WEST SOUTH CENT	501	0.1	0.2	1.5	−1.0	0.3
MOUNTAIN	207	0.0	−0.6	0.7	−1.2	−0.6
PACIFIC	384	0.0	0.6	1.9	−1.1	0.5
PUERTO RICO	46	−0.8	−1.0	−0.5	0.0	−0.6
REGION (RURAL):						
NEW ENGLAND	21	0.0	−0.4	0.9	−4.1	−3.4
MIDDLE ATLANTIC	54	0.3	0.1	1.7	−2.0	−0.5
SOUTH ATLANTIC	121	0.2	−0.1	1.4	−0.4	0.9
EAST NORTH CENT	121	0.4	−0.1	1.6	−1.5	−0.2
EAST SOUTH CENT	154	0.2	0.2	1.6	−0.6	0.9
WEST NORTH CENT	96	0.0	0.0	1.2	−1.7	−0.8
WEST SOUTH CENT	152	0.7	0.2	2.1	−0.5	1.4
MOUNTAIN	53	0.1	−0.3	1.1	−0.8	0.7
PACIFIC	23	0.3	−0.6	1.0	−2.1	−1.3
TEACHING STATUS:						
NON-TEACHING	2,578	0.3	−0.1	1.4	−0.8	0.5
MINOR	769	0.0	0.1	1.3	−1.3	−0.2
MAJOR	348	−0.3	0.1	1.1	−1.8	−0.8
DSH PATIENT PERCENT:						
0	10	−0.9	0.2	0.5	0.0	0.9
GT 0–0.10	258	0.4	−0.2	1.4	−0.8	0.5
0.10–0.16	244	0.2	−0.3	1.1	−0.7	0.4
0.16–0.23	574	0.1	−0.1	1.2	−1.2	−0.1
0.23–0.35	1,110	0.0	0.1	1.4	−1.4	−0.2
GE 0.35	958	−0.1	0.0	1.2	−1.2	−0.2
DSH NOT AVAILABLE**	541	1.6	−0.1	2.8	−0.6	2.0
URBAN TEACHING/DSH:						
TEACHING & DSH	1,009	−0.1	0.1	1.2	−1.5	−0.4
NO TEACHING/DSH	1,366	0.2	−0.1	1.3	−0.7	0.5
NO TEACHING/NO DSH	9	1.2	−0.1	2.3	0.0	2.1
DSH NOT AVAILABLE**	515	1.5	−0.1	2.7	−0.6	1.9
TYPE OF OWNERSHIP:						
VOLUNTARY	1,970	0.0	0.0	1.3	−1.3	−0.2
PROPRIETARY	1,248	0.3	−0.2	1.4	−0.4	0.7
GOVERNMENT	477	−0.2	0.2	1.3	−1.4	−0.3
CMHCs	44	−19.1	0.3	−17.8	0.0	−17.9

Column (1) shows total hospitals and/or CMHCs.

Column (2) includes all proposed CY 2019 OPPS policies and compares those to the CY 2018 OPPS.

Column (3) shows the budget neutral impact of updating the wage index by applying the proposed FY 2019 hospital inpatient wage index. The proposed rural SCH adjustment would continue our current policy of 7.1 percent so the budget neutrality factor is 1. The proposed budget neutrality adjustment for the cancer hospital adjustment is 1 because in CY 2019 the target payment-to-cost ratio is the same as it was in CY 2018 (0.88).

Column (4) shows the impact of all budget neutrality adjustments and the addition of the proposed 1.25 percent OPD fee schedule update factor (2.8 percent reduced by 0.8 percentage point for the productivity adjustment and further reduced by 0.75 percentage point as required by law).

Column (5) shows the impact of the proposal to pay for the visit service furnished at excepted off-campus provider-based departments at an MPFS equivalent rate.

Column (6) shows the additional proposed adjustments to the conversion factor resulting from the frontier adjustment, a change in the pass-through estimate, and adding estimated outlier payments.

*These 3,806 providers include children and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs.

**Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term care hospitals.

e. Estimated Effects of Proposed OPPS Changes on CMHCs

The last line of Table 42 demonstrates the isolated impact on CMHCs, which furnish only partial hospitalization services under the OPPS. In CY 2018, CMHCs are paid under APC 5853 (Partial Hospitalization (3 or more services) for CMHCs). We modeled the impact of this APC policy assuming CMHCs will continue to provide the same number of days of PHP care as seen in the CY 2019 claims data used for this 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 would experience an overall 17.9 percent decrease in payments from CY 2018 (shown in Column 6). We note that this includes the trimming methodology described in section VIII.B. of this proposed rule.

Column 3 shows that the estimated impact of adopting the proposed FY 2019 wage index values would result in a small increase of 0.3 percent to CMHCs. Column 4 shows that combining this proposed OPD fee schedule increase factor, along with proposed changes in APC policy for CY 2019 and the proposed FY 2019 wage index updates, would result in an estimated decrease of 17.8 percent. Column 5 shows that the off-campus provider-based department visits payment proposal has no effect on CMHCs. Column 6 shows that adding the proposed changes in outlier and pass-through payments would result in a total 17.9 percent decrease in payment for CMHCs. This reflects all proposed changes to CMHCs for CY 2019.

f. Estimated Effect of Proposed OPPS Changes on Beneficiaries

For services for which the beneficiary pays a copayment of 20 percent of the payment rate, the beneficiary's payment would increase for services for which the OPPS payments would rise and would decrease for services for which the OPPS payments would fall. For further discussion on the calculation of the national unadjusted copayments and minimum unadjusted copayments, we refer readers to section II.I. of this 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 would be 18.5 percent for all services paid under the OPPS in CY 2019. The estimated aggregate beneficiary coinsurance reflects general system adjustments, including the proposed CY 2019 comprehensive APC payment policy discussed in section II.A.2.b. of this proposed rule.

g. Estimated Effects of Proposed 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 XII. of this proposed rule. No types of providers or suppliers other than hospitals, CMHCs, and ASCs would be affected by the proposed changes in this proposed rule.

h. Estimated Effects of Proposed OPPS Changes on the Medicare and Medicaid Programs

The effect on the Medicare program is expected to be an increase of $90 million in program payments for OPPS services furnished in CY 2019. 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 proposed changes in this proposed rule would increase these Medicaid payments by approximately $7 million in CY 2019. This Medicaid impact is determined by starting with the estimated increase in Medicare payments of approximately $90 million, resulting in a beneficiary cost-sharing increase of approximtely $22 million. Currently, there are approximately 10 million dual-eligible beneficiaries, which represents approximtely one-third of Part B FFS 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 $7 million Medicaid impact, approximately $4 million would be paid by the Federal Government and $3 million would be paid by the State programs. We refer readers to our discussion of the impact on beneficiaries in section XX.C.1.f. of this proposed rule.

i. Alternative OPPS Policies Considered

Alternatives to the OPPS changes we are proposing to make and the reasons for our selected alternatives are discussed throughout this proposed rule.

• Alternatives Considered for the Methodology for Assigning Skin Substitutes to High or Low Cost Groups

We refer readers to section V.B.1.d. of this proposed rule for a discussion of our proposal to assign any skin substitute product that was assigned to the high cost group in CY 2018 to the high cost group in CY 2019, 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 2019 MUC or PDC threshold. We will continue to assign products that exceed either the overall CY 2019 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 2019 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 XII.D.3. of this proposed rule for a discussion of our proposal to change the packaging policy for certain drugs when administered in the ASC setting and provide 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, we are also soliciting comments on whether we should pay separately for other non-opioid treatments for pain under the OPPS and the ASC payment system. We also considered and are soliciting comments on an alternative policy that would use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to establish an incentive payment for non-opioid alternatives that would apply to drugs and devices in the hospital and ASC settings that are not currently separately paid, are supported by evidence that demonstrates such drugs and devices are effective at treating acute or chronic pain, and would result in decreased use of prescription opioid drugs and any associated opioid addiction.

2. Estimated Effects of Proposed CY 2019 ASC Payment System Policies

Most ASC payment rates are calculated by multiplying the ASC conversion factor by the ASC relative payment weight. As discussed fully in section XII. of this proposed rule, we are proposing to set the CY 2019 ASC relative payment weights by scaling the proposed CY 2019 OPPS relative payment weights by the proposed ASC scalar of 0.8854. 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 43 and 44 below.

Beginning in CY 2011, section 3401 of the Affordable Care Act requires that the annual update to the ASC payment system (which we are proposing will be the hospital market basket for CY 2019) 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 2019 payment determinations will be based on the application of a 2.0 percentage point reduction to the annual update factor, which we are proposing will be the hospital market basket for CY 2019. We calculated the proposed CY 2019 ASC conversion factor by adjusting the CY 2018 ASC conversion factor by 1.0003 to account for changes in the pre-floor and pre-reclassified hospital wage indexes between CY 2018 and CY 2019 and by applying the proposed CY 2019 MFP-adjusted hospital market basket update factor of 2.0 percent (projected hospital market basket update of 2.8 percent minus a projected productivity adjustment proposed to be 0.8 percentage point). The proposed CY 2019 ASC conversion factor is $46.500.

a. Limitations of Our Analysis

Presented here are the projected effects of the proposed changes for CY 2019 on Medicare payment to ASCs. A key limitation of our analysis is our inability to predict changes in ASC service-mix between CY 2017 and CY 2019 with precision. We believe the net effect on Medicare expenditures resulting from the proposed CY 2019 changes would 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 would experience changes in payment that differ from the aggregated estimated impacts presented below.

b. Estimated Effects of Proposed 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 2019 payments would 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 2019 updates to the ASC payment system on Medicare payments to ASCs, assuming the same mix of services, as reflected in our CY 2017 claims data. Table 43 depicts the estimated aggregate percent change in payment by surgical specialty or ancillary items and services group by comparing estimated CY 2018 payments to estimated proposed CY 2019 payments, and Table 44 shows a comparison of estimated CY 2018 payments to estimated proposed CY 2019 payments for procedures that we estimate would receive the most Medicare payment in CY 2018.

In Table 43, 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 43.

- 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 2018 ASC Payments were calculated using CY 2017 ASC utilization (the most recent full year of ASC utilization) and CY 2018 ASC payment rates. The surgical specialty and ancillary items and services groups are displayed in descending order based on estimated CY 2018 ASC payments.
- Column 3—Estimated CY 2019 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 are attributable to proposed updates to ASC payment rates for CY 2019 compared to CY 2018.

As shown in Table 43, 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 2019 would result in no change in aggregate payment amounts for eye and ocular adnexa procedures, a 4-percent increase in aggregate payment amounts for nervous system procedures, 3-percent increase in aggregate payment amounts for digestive system procedures, a 4-percent increase in aggregate payment amounts for musculoskeletal system procedures, a 2-percent increase in aggregate payment amounts for genitourinary system procedures, and a 1-percent increase in aggregate payment amounts for integumentary 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 increases due to the 2.0 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 2.0 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 no change in proposed aggregate eye and ocular adnexa procedure payments due to a reduction in hospital reported costs for the primary payment grouping for this category under the OPPS. This lowers the payment weights for eye and ocular adnexa procedure payments and, overall, offsets the proposed 2.0 percent ASC rate update for these procedures. For a table that includes estimated changes for selected procedures, we refer readers to Table 44 provided later in this section.

Also displayed in Table 43 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 would increase by 2 percent for CY 2019.

TABLE 43—ESTIMATED IMPACT OF THE PROPOSED CY 2019 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE CY 2019 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP

Surgical specialty group	Estimated CY 2018 ASC payments (in millions)	Estimated CY 2019 percent change
(1)	(2)	(3)
Total	$4,772	2
Eye and ocular adnexa	1,737	0
Nervous system	993	4
Digestive system	873	3
Musculoskeletal system	574	4
Genitourinary system	188	2
Integumentary system	145	1
Ancillary items and services	64	2

Table 44 below shows the estimated impact of the proposed updates to the revised ASC payment system on aggregate ASC payments for selected surgical procedures during CY 2019. The table displays 30 of the procedures receiving the greatest estimated CY 2018 aggregate Medicare payments to ASCs. The HCPCS codes are sorted in descending order by estimated CY 2018 program payment.

- Column 1—CPT/HCPCS code.
- Column 2—Short Descriptor of the HCPCS code.
- Column 3—Estimated CY 2018 ASC Payments were calculated using CY 2017 ASC utilization (the most recent full year of ASC utilization) and the CY 2018 ASC payment rates. The estimated CY 2018 payments are expressed in millions of dollars.
- Column 4—Estimated CY 2019 Percent Change reflects the percent differences between the estimated ASC payment for CY 2018 and the estimated payment for CY 2019 based on the proposed update.

TABLE 44—ESTIMATED IMPACT OF THE PROPOSED CY 2019 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/HCPCS code	Short descriptor	Estimated CY 2018 ASC payment (in millions)	Estimated CY 2019 percent change
(1)	(2)	(3)	(4)
66984	Cataract surg w/iol 1 stage	$1,206	0
45380	Colonoscopy and biopsy	228	4
63685	Insrt/redo spine n generator	221	−2
43239	Egd biopsy single/multiple	180	2
63650	Implant neuroelectrodes	166	0
45385	Colonoscopy w/lesion removal	156	4
64483	Inj foramen epidural l/s	101	14
0191T	Insert ant segment drain int	96	4
66982	Cataract surgery complex	89	0
64635	Destroy lumb/sac facet jnt	75	1
66821	After cataract laser surgery	69	1
29827	Arthroscop rotator cuff repr	65	2
64493	Inj paravert f jnt l/s 1 lev	63	14
62323	Njx interlaminar lmbr/sac	53	11
64590	Insrt/redo pn/gastr stimul	51	3
G0105	Colorectal scrn; hi risk ind	47	4
G0121	Colon ca scrn not hi rsk ind	42	4
45378	Diagnostic colonoscopy	41	4
64721	Carpal tunnel surgery	34	1
15823	Revision of upper eyelid	33	−1
29881	Knee arthroscopy/surgery	29	−1
C9740	Cysto impl 4 or more	28	2
64561	Implant neuroelectrodes	26	1
67042	Vit for macular hole	26	1
29880	Knee arthroscopy/surgery	25	−1
26055	Incise finger tendon sheath	25	−3
28285	Repair of hammertoe	24	−1
63655	Implant neuroelectrodes	24	5
52000	Cystoscopy	23	−1
G0260	Inj for sacroiliac jt anesth	22	12

c. Estimated Effects of Proposed ASC Payment System Policies on Beneficiaries

We estimate that the proposed CY 2019 update to the ASC payment system would be generally positive for beneficiaries with respect to the new procedures we are proposing to add to the ASC list of covered surgical procedures and for those we are proposing to designate as office-based for CY 2019. For example, using 2017 utilization data and proposed CY 2019 OPPS and ASC payment rates, we estimate that if 5 percent of cardiac catheterization procedures would migrate from the hospital outpatient setting to the ASC setting as a result of this proposed policy, Medicare payments would be reduced by approximately $35 million in CY 2019 and total beneficiary copayments would decline by approximately $14 million in CY 2019. 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). 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 would be if the ASC coinsurance amount exceeds the inpatient deductible. The statute requires that copayment amounts under the OPPS not exceed the inpatient deductible.) Beneficiary coinsurance for services migrating from physicians' offices to ASCs may decrease or increase under the revised 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 OPPS payment rates, services that are performed a majority of the time in a physician office are paid the lesser of ASC charges or at the office-based amount payable under the PFS. Because ASC payment rates for services that are performed a majority of the time in the physician office are paid the lesser of ASC charges or at the office-based amount payable under the PFS, we do not believe that the increase in ASC payment rates that would result from this proposal would cause any significant migration of services from the physician office setting to the ASC setting. For those additional procedures that we are proposing to designate as office-based in CY 2019, the beneficiary coinsurance amount under the ASC payment system generally would 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).

d. Alternative ASC Payment Policies Considered

Alternatives to the ASC changes we are proposing to make and the reasons for our selected alternatives are discussed throughout this proposed rule.

• Alternatives Considered for the CY 2019 ASC Rate Update

As discussed in section XII. of this proposed rule with comment period, for CY 2019 through CY 2023 (5 years total), in response to stakeholder concerns regarding the application of CPI–U to update ASC payment rates, we are proposing to update ASC payment rates using the hospital market basket and to revise our regulations under 42 CFR 416.171(a), which address the annual update to the ASC conversion factor, to reflect this proposal.

As an alternative proposal, we are considering whether to continue applying the CPI–U as the update factor. If we were to update ASC payment rates for CY 2019 with an update factor based on CPI–U, the update would have been 1.3 percent (the 2.1 percent CPI–U less the 0.8 percent MFP update). This update factor would have resulted in increased payments to ASCs in CY 2019 of approximately $40 million, compared to the increased payments to ASCs in CY 2019 of approximately $70 million as a result of the 2.0 percent update based on the hospital market basket.

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/omb/circulars_a004_a-4#a*),we have prepared accounting statements to illustrate the impacts of the proposed OPPS and ASC changes in this proposed rule. The first accounting statement, Table 45 below, illustrates the classification of expenditures for the CY 2019 estimated hospital OPPS incurred benefit impacts associated with the proposed CY 2019 OPD fee schedule increase. This $90 million in additional Medicare spending estimate includes the $700 million in additional Medicare spending associated with updating the CY 2018 OPPS payment rates by the hospital market basket update for CY 2019, offset by the $610 million in Medicare savings associated with the proposal to pay for clinic visits furnished at off-campus PBDs at a PFS-equivalent rate. Additionally, we estimate that proposed OPPS changes in this proposed rule would increase copayments that Medicaid may make on behalf of Medicaid recipients who are also Medicare beneficiaries by approximately $7 million in CY 2019. The second accounting statement, Table 46 below, illustrates the classification of expenditures associated with the proposed 2.0 percent CY 2019 update to the ASC payment system, based on the provisions of this proposed rule and the baseline spending estimates for ASCs. Both tables classify most estimated impacts as transfers.

TABLE 45—ACCOUNTING STATEMENT: CY 2019 ESTIMATED HOSPITAL OPPS TRANSFERS FROM CY 2018 TO CY 2019 ASSOCIATED WITH THE PROPOSED CY 2019 HOSPITAL OUTPATIENT OPD FEE SCHEDULE INCREASE

Category	Transfers
Annualized Monetized Transfers	$90 million.
From Whom to Whom	Federal Government to outpatient hospitals and other providers who receive payment under the hospital OPPS.
Total	$90 million.

TABLE 46—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2018 TO CY 2019 AS A RESULT OF THE PROPOSED CY 2019 UPDATE TO THE ASC PAYMENT SYSTEM

Category	Transfers
Annualized Monetized Transfers	$70 million.
From Whom to Whom	Federal Government to Medicare Providers and Suppliers.
Total	$70 million.

TABLE 47—ESTIMATED COSTS, COST SAVINGS, AND BENEFITS

Category	Costs	Cost savings
ICR Burden Savings		$54.3 million.*
Regulatory Familiarization	$2.9 million *	

* The annual estimates are in 2017 year dollars.
** Regulatory familiarization costs occur upfront only.

4. Effects of Proposed 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 2018 payment determination, we determined that 36 hospitals did not meet the requirements to receive the full OPD fee schedule increase factor. Many of these hospitals (18 of the 36), chose not to participate in the Hospital OQR Program for the CY 2018 payment determination. We are not proposing to add any quality measures to the Hospital OQR Program measure set for the CY 2020 or CY 2021 payment determinations, and are proposing to remove 10 measures from the program measure set, as discussed in section XIII.B.4.b. of this proposed rule. Therefore, we do not believe that these proposals would increase the number of hospitals that do not receive a full annual payment update for the CY 2020 or CY 2021 payment determinations.

In section XIII.B.4.b. of this proposed rule, we are proposing to remove a total of 10 measures. Specifically, beginning with the CY 2020 payment determination, we are proposing to remove: (1) OP–27: Influenza Vaccination Coverage Among Healthcare Personnel; and beginning with the CY 2021 payment determination, we are proposing to remove: (2) OP–5: Median Time to ECG; (3) OP–9: Mammography Follow-up Rates; (4) OP–11: Thorax CT Use of Contrast Material; (5) OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into Their Qualified/Certified EHR System as Discrete Searchable Data; (6) OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT; (7) OP–17: Tracking Clinical Results between Visits; (8) OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients; (9) OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use; and (10) OP–31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery. The reduction in burden associated with these proposals is discussed further below.

In section XIII.B.4.a. of this proposed rule, beginning with the effective date of the CY 2019 OPPS/ASC final rule with comment period, we are proposing to update one removal factor and to add one removal factor. We are also proposing to codify our measure removal policies and factors at proposed 42 CFR 419.46(h) effective upon finalization of the CY 2019 OPPS/ASC final rule and for subsequent years. In addition, in section XIII.D.2. of this proposed rule, we are proposing to update the frequency with which we will release Hospital Outpatient Quality Reporting Specifications Manuals, such that instead of every 6 months, we would release Specifications Manuals every 6 to 12 months beginning with CY 2019 and for subsequent years. In section XIII.C.2. of this proposed rule, beginning with the CY 2020 payment determination, we are proposing to remove the Notice of Participation (NOP) form as a requirement for the Hospital OQR Program and to update 42 CFR 419.46(a)(3) to reflect these policies. Finally, in section XIII.D.4.b. of this proposed rule, we are proposing to change the data collection period for OP–32: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy from one year to three years beginning with the CY 2020 payment determination. As discussed below, we do not expect these proposals to affect our burden estimates. However, as further explained in section XVIII.B. of this proposed rule, we believe that there will be an overall decrease in the estimated information collection burden for hospitals due to the other proposed policies. We refer readers to section XVIII.B. of this proposed rule for a summary of our information collection burden estimate calculations. The effects of these proposals are discussed in more detail further below.

b. Estimated Effects of Hospital OQR Program Beginning With the Effective Date of the CY 2019 OPPS/ASC Final Rule With Comment Period

In section XIII.B.4.a. of this proposed rule, we are proposing to: (1) Update measure removal Factor 7; (2) add one new removal factor; and (3) codify our removal factors policy at 42 CFR 419.46(h). We do not expect a change in the information collection burden or other costs experienced by hospitals because these changes do not affect Hospital OQR Program participation requirements or data reporting requirements.

c. Proposal To Update the Frequency of Releasing the Hospital Outpatient Quality Reporting Specifications Manual Beginning With CY 2019 and for Subsequent Years

In section XIII.D.2. of this proposed rule, we are proposing to update the frequency with which we will release a Hospital Outpatient Quality Reporting Specifications Manual such that instead of every 6 months, we would release

Specifications Manuals every 6 to 12 months beginning with CY 2019. We anticipate that this proposed change will reduce hospital confusion, as potentially releasing fewer manuals per year reduces the need to review updates as frequently as previously necessary. However, because this change does not affect Hospital OQR Program participation requirements or data reporting requirements, we do not estimate a change in our calculation of the information collection burden experienced by hospitals.

d. Estimated Effects of Hospital OQR Program Proposals for the CY 2020 Payment Determination and Subsequent Years

(1) Proposal To Remove the Notice of Participation (NOP) Form Requirement

In section XIII.C.2. of this proposed rule, beginning with the CY 2020 payment determination, we are proposing to remove the NOP form as a requirement. As a result, to be a participant in the Hospital OQR Program, hospitals would need to: (1) Register on the QualityNet website, (2) identify and register a QualityNet security administrator, and (3) submit data. In addition, we are proposing to update 42 CFR 419.46(a) to reflect these policies. We believe that the proposal to remove the NOP, if finalized, would reduce administrative burden experienced by hospitals by only a nominal amount. As a result, this proposal does not influence our information collection burden estimates. We refer readers to section XVIII.B. of this proposed rule, where our burden calculations for the Hospital OQR Program are discussed in detail. In addition, we do anticipate that this proposal will reduce the possibility of hospitals failing to meet Hospital OQR Program requirements due to a failure to submit the NOP.

(2) Proposed Extension of the Collection Period for OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy

In section XIII.D.4.b. of this proposed rule, we are proposing to increase the data collection period for OP–32: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy from 1 year to 3 years beginning with the CY 2020 payment determination. We expect this proposal to increase the reliability of OP–32 data allowing better information to be publicly reported. However, the proposal does not change our data reporting requirements, such that hospitals will be required to continue reporting claims data that are used to calculate this measure. Therefore, we do not expect a change in the information collection burden experienced by hospitals.

(3) Proposed Removal of OP–27 for the CY 2020 Payment Determination and Subsequent Years

In section XIII.B.4.b. of this proposed rule, we are proposing to remove OP–27: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) beginning with the CY 2020 payment determination and for subsequent years. The burden associated with OP–27, a NHSN measure, is accounted for under a separate Paperwork Reduction Act Package, OMB control number 0920–0666. Because burden associated with submitting data for this measure is captured under a separate OMB control number, we are not providing an estimate of the information collection burden associated with this measure for the Hospital OQR Program. Aside from burden associated with information collection however, we also anticipate that hospitals will experience a general burden and cost reduction associated with this proposal stemming from no longer having to review and track program requirements associated with this measure.

e. Estimated Effects of Hospital OQR Program Proposals for the CY 2021 Payment Determination and Subsequent Years

(1) Proposed Removal of Chart-Abstracted Measures for the CY 2021 Payment Determination and Subsequent Years

In section XIII.B.4.b. of this proposed rule, we are proposing to remove OP–5: Median Time to ECG, a chart-abstracted measure, for the CY 2021 payment determination and subsequent years. We believe that the removal of this chart-abstracted measure for the CY 2021 payment determination would reduce collection of information burden by 153,130 hours and $5.6 million (153,130 hours × $36.58), as discussed in section XVIII.B. of this proposed rule. Aside from burden associated with information collection however, we also anticipate that hospitals will experience a general burden and cost reduction associated with this proposal stemming from no longer having to review and track program requirements associated with this measure.

(2) Proposed Removal of Measures Submitted Via a Web-Based Tool for the CY 2021 Payment Determination and Subsequent Years

In section XIII.B.4.b. of this proposed rule, we are proposing to remove five measures submitted via a web-based tool beginning with the CY 2021 payment determination and for subsequent years: OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into Their Qualified/Certified EHR System as Discrete Searchable Data; OP–17: Tracking Clinical Results between Visits; OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients; OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use; and OP–31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery. As discussed in section XVIII.B. of this proposed rule, we anticipate a burden reduction of 1,164,843 hours and $42.6 million associated with the removal of OP–12, OP–17, OP–29, OP–30, and OP–31 for the CY 2021 payment determination. Aside from burden associated with information collection however, we also anticipate that hospitals will experience a general burden and cost reduction associated with these proposals stemming from no longer having to implement, review, track, and maintain program requirements associated with these measures.

(3) Proposed Removal of Claims-Based Measures for the CY 2021 Payment Determination and Subsequent Years

In section XIII.B.4.b. of this proposed rule, we are proposing to remove three claims-based measures beginning with the CY 2021 payment determination: OP–9: Mammography Follow-up Rates; OP–11: Thorax CT Use of Contrast Material; and OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT. These claims-based measures are calculated using only data already reported to the Medicare program for payment purposes, therefore, we do not believe removing these measures will affect the information collection burden on hospitals. Nonetheless, we anticipate that hospitals would experience a general burden reduction associated with these proposals stemming from no longer having to review and track various associated program requirements.

In total for the CY 2021 payment determination, we expect information collection burden would be reduced by 151,800 hours due to our proposal to remove one chart-abstracted measure, and 1,164,843 hours due to our proposals to remove five measures submitted via a web-based tool. In total, we estimate an information collection burden reduction of 1,316,643 hours (1,164,843 hours + 151,800 hours) and $48.2 million (1,317,973 hours × $36.58) for the CY 2021 payment determination.

6. Effects of Proposed Requirements for the ASCQR Program

a. Background

In section XIV. of this proposed rule, we discuss our proposals to adopt policies affecting the ASCQR Program. For the CY 2018 payment determination, of the 6,683 ASCs that met eligibility requirements for the ASCQR Program, 233 ASCs did not meet the requirements to receive the full annual payment update. We note that, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79874), we used the CY 2016 payment determination numbers as a baseline, and estimated that approximately 200 ASCs will not receive the full annual payment update in CY 2019 due to failure to meet the ASCQR Program requirements (CY 2017 and CY 2018 payment determination information were not yet available). We are not proposing to add any new quality measures to the ASCQR Program measure set for the CY 2020 payment determination and subsequent determinations, and we do not believe that the other measures we previously adopted would cause any additional ASCs to fail to meet the ASCQR Program requirements. Therefore, we do not believe that these proposals would increase the number of ASCs that do not receive a full annual payment update for the CY 2020 payment determination. Below we discuss only the effects that would result from the newly proposed provisions in this proposed rule.

In section XIV.B.3.c. of this proposed rule, we are proposing to remove one measure beginning with the CY 2020 payment determination, ASC–8: Influenza Vaccination Coverage Among Healthcare Personnel, and to remove seven measures beginning with the CY 2021 payment determination: ASC–1: Patient Burn; ASC–2: Patient Fall; ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; ASC–4: All-Cause Hospital Transfer/Admission; ASC–9: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients; ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use; and ASC–11: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery. We expect these proposals would reduce the overall burden of reporting data for the ASCQR Program, as discussed further below.

In addition, in sections XIV.B.3.b. and XIV.D.4.b. of this proposed rule, beginning with the effective date of the CY 2019 OPPS/ASC final rule with comment period, we are proposing to: (1) Remove one measure removal factor; (2) add two new measure removal factors, and (3) update 42 CFR 416.320(c) to better reflect our measure removal policies; we are also proposing to: (4) Extend the reporting period for ASC–12: Facility Seven-Day Risk Standardized Hospital Visit Rate after Outpatient Colonoscopy from 1 to 3 years beginning with the CY 2020 payment determination. As discussed below, we do not expect these proposals would affect our burden estimates. However, as further explained in section XVIII.C. of this proposed rule, we believe that there would be an overall decrease in the estimated information collection burden for ASCs due to the other proposed policies. We refer readers to section XVIII.C. of this proposed rule for a summary of our information collection burden estimate calculations. The effects of these proposals are discussed in more detail below.

b. Estimated Effects of ASCQR Program Proposals Beginning With the Effective Date of the CY 2019 OPPS/ASC Final Rule With Comment Period

In section XIV.B.3.a. of this proposed rule, we are proposing, beginning with the effective date of the CY 2019 OPPS/ASC final rule with comment period, to remove one measure removal factor, add two new measure removal factors, and update 42 CFR 416.320(c) to better reflect our measure removal policies for the ASCQR Program. Because these changes do not affect ASCQR Program participation requirements or data reporting requirements, we do not expect these proposals would change the information collection burden or other costs experienced by ASCs.

c. Estimated Effects of ASCQR Program Proposals for the CY 2020 Payment Determination and Subsequent Years

(1) Proposed Extension of the Reporting Period for ASC–12: Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy

In section XIV.D.4.b. of this proposed rule, we are proposing to increase the data reporting period for ASC–12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy from 1 year to 3 years beginning with the CY 2020 payment determination. We expect this proposal to increase the reliability of ASC–12 data allowing better information to be publicly reported. However, the proposal does not change our data reporting requirements, because ASC–12 is a claims-based measure that is calculated based on claims data that facilities already submit to CMS. Therefore, we do not expect a change in the information collection burden or other costs experienced by ASCs.

(2) Proposed Removal of ASC–8 for the CY 2020 Payment Determination and Subsequent Years

In section XIV.B.3.c. of this proposed rule, we are proposing to remove one measure from the ASCQR Program measure set beginning with the CY 2020 payment determination, ASC–8: Influenza Vaccination Coverage Among Healthcare Personnel. As discussed in section XVIII.C.3.b. of this proposed rule, the information collection burden associated with ASC–8, a NHSN measure, is accounted for under a separate information collection request, OMB control number 0920–0666. As such, we are not providing an estimate of the information collection burden associated with this measure under the ASCQR Program control number. Aside from burden associated with information collection however, we anticipate that facilities would experience a general burden and cost reduction associated with this proposal stemming from no longer having to review and track program requirements associated with this measure.

d. Estimated Effects of ASCQR Program Proposals for the CY 2021 Payment Determination and Subsequent Years

In section XIV.B.3.c. of this proposed rule we are proposing to remove seven measures from the ASCQR Program measure set beginning with the CY 2021 payment determination: ASC–1: Patient Burn; ASC–2: Patient Fall; ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; ASC–4: All-Cause Hospital Transfer/

Admission; ASC–9: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients; ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use; and ASC–11: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.

(1) Proposed Removal of QDC Claims-based Measures for the CY 2021 Payment Determination and Subsequent Years

In section XIV.B.3.c. of this proposed rule, we are proposing to remove four QDC claims-based measures from the ASCQR Program measure set beginning with the CY 2021 payment determination: 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. As discussed in section XVIII.C.4.a. of this proposed rule, these measures do not require ASCs to report any additional data, and we do not believe there would be any information collection burden change associated with our proposals to remove these measures. Aside from burden associated with information collection however, we anticipate that facilities would experience a general burden and cost reduction associated with these proposals stemming from no longer having to review and track program requirements associated with these measures.

(2) Proposed Removal of Chart-Abstracted Measures for the CY 2021 Payment Determination and Subsequent Years

In section XIV.B.3.c. of this proposed rule, we are proposing to remove three chart-abstracted measures from the ASCQR Program measure set beginning with the CY 2021 payment determination: ASC–9: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients; ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use; and ASC–11: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery. As discussed in section XVIII.C.4.b. of this proposed rule, we believe our proposals to remove ASC–9; ASC–10; and ASC–11, if finalized, would result in a burden reduction for ASCs. For ASC–9 and ASC–10, we estimate the total annualized burden reduction associated with each measure to be 62,008 hours and $2,268,253 (62,008 hours × $36.58 per hour). For ASC–11, a voluntary measure, we estimate a total annual burden reduction of 16,569 hours and $606,094 (16,569 hours × $36.58 per hour). Aside from burden associated with information collection however, we anticipate that facilities would experience a general burden and cost reduction associated with these proposals stemming from no longer having to review and track program requirements associated with these measures.

Therefore, as noted in section XVIII.C.4. of this proposed rule, we believe our proposals to remove seven measures from the ASCQR measure set for the CY 2021 payment determination would result in a total annual reduction in information collection burden of 140,585 hours (62,008 hours + 62,008 hours + 16,569 hours) and $5,142,600 ($2,268,253 + $2,268,253 + $606,094).

D. Effects of the Proposed Update to the HCAHPS Survey Measure in the Hospital IQR Program

As discussed in section XVI. of this proposed rule, we are proposing to update the HCAHPS Survey measure by removing the ''Communication About Pain'' questions beginning with patients discharged in January 2022, for the FY 2024 payment determination and subsequent years. We anticipate that the removal of these questions will result in only a nominal and temporary increase on the information collection burden on providers associated with adjusting the survey instrument and instructional materials, and a burden decrease for survey respondents. We note that the burden estimate for the Hospital IQR Program under the program's OMB control number 0938–1022 excludes the burden associated with the HCAHPS Survey measure, which is submitted under a separate information collection request and approved under OMB control number 0938–0981. We address the anticipated information collection burden reduction in section XVIII.D. of this proposed rule.

E. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed 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 the rule, we assume that the total number of unique commenters on last year's proposed rule will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters will review this year's proposed rule in detail, and it is also possible that some reviewers will choose not to comment on the proposed rule. For these reasons, we believe that the number of past commenters would be a fair estimate of the number of reviewers of this proposed rule. We welcome any comments on the approach in estimating the number of entities that will review this proposed rule.

We also recognize that different types of entities are, in many cases, affected by mutually exclusive sections of this proposed rule, and, therefore, for the purposes of our estimate, we assume that each reviewer reads approximately 50 percent of the rule. In this proposed rule, we are seeking public comments.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $107.38 per hour, including overhead and fringe benefits (*https://www.bls.gov/oes/current/naics4_621100.htm*). Assuming an average reading speed, we estimate that it will take approximately 8 hours for the staff to review half of this proposed rule. For each facility that reviews the rule, the estimated cost is $859.04 (8 hours × $107.38). Therefore, we estimate that the total cost of reviewing this regulation is $2,912,146 ($859.04 × 3,390 reviewers).

F. 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, we estimate that most hospitals, ASCs and CMHCs are small entities as that term is used in the RFA. For purposes of the RFA, most hospitals are considered small businesses according to the Small Business Administration's size standards with total revenues of $38.5 million or less in any single year or by the hospital's not-for-profit status. Most ASCs and most CMHCs are considered small businesses with total revenues of $15 million or less in any single year. For details, see the Small Business Administration's ''Table of Small Business Size Standards'' at *http://www.sba.gov/content/table-small-business-size-standards.*

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 603 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 proposed rule would increase payments to small rural hospitals by less than 3 percent; therefore, it should not have a significant impact on approximately 613 small rural hospitals.

The analysis above, together with the remainder of this preamble, provides a regulatory flexibility analysis and a regulatory impact analysis.

G. 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 $150 million. This proposed rule does not mandate any requirements for State, local, or tribal governments, or for the private sector.

H. 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 proposed rule, if finalized, would be a deregulatory action for the purposes of Executive Order 13771. We estimate that this proposed rule would generate $43.5 million in annualized cost savings at a 7-percent discount rate, discounted relative to 2016, over a perpetual time horizon.

I. Conclusion

The changes we are proposing to make in this proposed rule would affect all classes of hospitals paid under the OPPS and would affect both CMHCs and ASCs. We estimate that most classes of hospitals paid under the OPPS would experience a modest increase or a minimal decrease in payment for services furnished under the OPPS in CY 2019. Table 42 demonstrates the estimated distributional impact of the OPPS budget neutrality requirements that would result in a 0.1 percent decrease in payments for all services paid under the OPPS in CY 2019, after considering all of the proposed changes to APC reconfiguration and recalibration, as well as the proposed OPD fee schedule increase factor, proposed wage index changes, including the proposed frontier State wage index adjustment, estimated payment for outliers, the proposed off-campus provider-based department visits payment policy, and proposed changes to the pass-through payment estimate. However, some classes of providers that are paid under the OPPS would experience more significant gains or losses in OPPS payments in CY 2019.

The proposed updates to the ASC payment system for CY 2019 would affect each of the approximately 5,500 ASCs currently approved for participation in the Medicare program. The effect on an individual ASC would depend on its mix of patients, the proportion of the ASC's patients who are Medicare beneficiaries, the degree to which the payments for the procedures offered by the ASC are changed under the ASC payment system, and the extent to which the ASC provides a different set of procedures in the coming year. Table 43 demonstrates the estimated distributional impact among ASC surgical specialties of the proposed MFP-adjusted hospital market basket update factor of 1.25 percent for CY 2019.

XXI. 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 proposed rule 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 42 of this proposed rule, we estimate that OPPS payments to governmental hospitals (including State and local governmental hospitals) would decrease by 0.3 percent under this proposed rule. 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 proposed rule, in conjunction with the remainder of this document, demonstrate that this proposed rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866, the RFA, and section 1102(b) of the Act.

This proposed rule would 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 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

For reasons stated in the preamble of this document, the Centers for Medicare & Medicaid Services is proposing to amend 42 CFR chapter IV as set forth below:

PART 416—AMBULATORY SURGICAL SERVICES

■ 1. The authority citation for part 416 continues to read as follows:

Authority: Secs. 1102, 1138, and 1871 of the Social Security Act (42 U.S.C. 1302, 1320b–8, and 1395hh) and section 371 of the Public Health Service Act (42 U.S.C. 273).

■ 2. Section 416.164 is amended by revising paragraph (a)(4) and adding paragraph (b)(6) to read as follows:

§ 416.164 Scope of ASC services.

(a) * * *

(4) Drugs and biologicals for which separate payment is not allowed under the hospital outpatient prospective payment system (OPPS), with the exception of non-opioid pain management drugs that function as a supply when used in a surgical procedure;

* * * * *

(b) * * *

(6) Non-opioid pain management drugs that function as a supply when used in a surgical procedure.

* * * * *

■ 3. Section 416.171 is amended by revising paragraphs (a)(2) and (b)(1) and (2) to read as follows:

§ 416.171 Determination of payment rates for ASC services.

(a) * * *

(2) *Conversion factor for CY 2009 and subsequent calendar years.* The conversion factor for a calendar year is equal to the conversion factor calculated for the previous year, updated as follows:

(i) For CY 2009, the update is equal to zero percent;

(ii) For CY 2010 through CY 2018, the update is the Consumer Price Index for All Urban Consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved.

(iii) For CY 2019 through CY 2023, the update is the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act.

(iv) For CY 2024 and subsequent years, the update is the Consumer Price Index for All Urban Consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved.

(v) For CY 2014 through CY 2018, the Consumer Price Index for All Urban Consumers update determined under paragraph (a)(2)(ii) of this section is reduced by 2.0 percentage points for an ASC that fails to meet the standards for reporting of ASC quality measures as established by the Secretary for the corresponding calendar year.

(vi) For CY 2019 through CY 2023, the hospital inpatient market basket update determined under paragraph (a)(2)(iii) of this section is reduced by 2.0 percentage points for an ASC that fails to meet the standards for reporting of ASC quality measures as established by the Secretary for the corresponding calendar year.

(vii) For CY 2024 and subsequent years, the Consumer Price Index for All Urban Consumers update determined under paragraph (a)(2)(iv) of this section is reduced by 2.0 percentage points for an ASC that fails to meet the standards for reporting of ASC quality measures as established by the Secretary for the corresponding calendar year.

(viii) *Productivity adjustment.* (A) For CY 2011 through CY 2018, the Consumer Price Index for All Urban Consumers determined under paragraph (a)(2)(ii) of this section, after application of any reduction under paragraph (a)(2)(iv) of this section, is reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

(B) For CY 2019 through CY 2023, the hospital inpatient market basket update determined under paragraph (a)(2)(iii) of this section, after application of any reduction under paragraph (a)(2)(vi) of this section, is reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

(C) For CY 2024 and subsequent years, the Consumer Price Index for All Urban Consumers determined under paragraph (a)(2)(iv) of this section, after application of any reduction under paragraph (a)(2)(vii) of this section, is reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

(D) The application of the provisions of paragraph (a)(2)(viii)(A), (B), or (C) of this section may result in the update being less than zero percent for a year, and may result in payment rates for a year being less than the payment rates for the preceding year.

(b) * * *

(1) Covered ancillary services specified in § 416.164(b), with the exception of radiology services and certain diagnostic tests as provided in § 416.164(b)(5) and non-opioid pain management drugs that function as a supply when used in a surgical procedure as provided in § 416.164(b)(6).

(2) The device portion of device-intensive procedures, which are procedures that—

(i) Involve implantable devices assigned a CPT or HCPCS code;

(ii) Utilize devices (including single-use devices) that must be surgically inserted or implanted; and

(iii) Have a HCPCS code-level device offset of greater than 30 percent when calculated according to the standard OPPS ASC ratesetting methodology.

* * * * *

■ 4. Section 416.320 is amended by revising paragraph (c) to read as follows:

§ 416.320 Retention and removal of quality measures under the ASCQR Program.

* * * * *

(c) *Removal of quality measures*—(1) *General rule for the removal of quality measures.* Unless a measure raises specific safety concerns as set forth in paragraph (b) of this section, CMS will use the regular rulemaking process to remove, suspend, or replace quality measures in the ASCQR Program to allow for public comment.

(2) *Factors for consideration of removal of quality measures.* CMS will weigh whether to remove measures based on the following factors:

(i) *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);

(ii) *Factor 2:* Performance or improvement on a measure does not result in better patient outcomes;

(iii) *Factor 3:* A measure does not align with current clinical guidelines or practice;

(iv) *Factor 4:* The availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic;

(v) *Factor 5:* The availability of a measure that is more proximal in time to desired patient outcomes for the particular topic;

(vi) *Factor 6:* The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic;

(vii) *Factor 7:* Collection or public reporting of a measure leads to negative unintended consequences other than patient harm; and

(viii) *Factor 8:* The costs associated with a measure outweigh the benefit of its continued use in the program.

(3) *Criteria to determine topped-out measures.* For the purposes of the ASCQR Program, a measure is considered to be topped-out under paragraph (c)(2)(i) of this section when it meets both of the following criteria:

(i) Statistically indistinguishable performance at the 75th and 90th percentiles (defined as when the difference between the 75th and 90th percentiles for an ASC's measure is within two times the standard error of the full data set); and

(ii) A truncated coefficient of variation less than or equal to 0.10.

(4) *Application of measure removal factors.* The benefits of removing a measure from the ASCQR Program will be assessed on a case-by-case basis. A measure will not be removed solely on the basis of meeting any specific factor or criterion.

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

■ 5. The authority citation for part 419 continues to read as follows:

Authority: Secs. 1102, 1833(t), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395l(t), and 1395hh).

■ 6. Section 419.32 is amended by adding paragraph (b)(1)(iv)(B)(*10*) to read as follows:

§ 419.32 Calculation of prospective payment rates for hospital outpatient services.

* * * * *

(b) * * *

(1) * * *

(iv) * * *

(B) * * *

(*10*) For calendar year 2019, a multifactor productivity adjustment (as determined by CMS) and 0.75 percentage point.

* * * * *

■ 7. Section 419.46 is amended by revising paragraphs (a)(1) through (3) and adding paragraph (h) to read as follows:

§ 419.46 Participation, data submission, and validation requirements under the Hospital Outpatient Quality Reporting (OQR) Program.

(a) * * *

(1) Register on the QualityNet website before beginning to report data;

(2) Identify and register a QualityNet security administrator as part of the registration process under paragraph (a)(1) of this section; and

(3) Submit at least one data element.

* * * * *

(h) *Retention and removal of quality measures under the Hospital OQR Program.* (1) *General rule for the retention of quality measures.* Quality measures adopted for the Hospital OQR Program measure set for a previous payment determination year are retained for use in subsequent payment determination years, except when they are removed, suspended, or replaced as set forth in paragraphs (h)(2) and (3) of this section.

(2) *Immediate measure removal.* For cases in which CMS believes that the continued use of a measure as specified raises patient safety concerns, CMS will immediately remove a quality measure from the Hospital OQR Program and will promptly notify hospitals and the public of the removal of the measure and the reasons for its removal through the Hospital OQR Program ListServ and the QualityNet website.

(3) *Measure removal, suspension, or replacement through the rulemaking process.* Unless a measure raises specific safety concerns as set forth in paragraph (h)(2) of this section, CMS will use the regular rulemaking process to remove, suspend, or replace quality measures in the Hospital OQR Program to allow for public comment.

(i) *Factors for consideration of removal of quality measures.* CMS will weigh whether to remove measures based on the following factors:

(A) *Factor 1:* Measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped out'' measures);

(B) *Factor 2:* Performance or improvement on a measure does not result in better patient outcomes;

(C) *Factor 3:* A measure does not align with current clinical guidelines or practice;

(D) *Factor 4:* The availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic;

(E) *Factor 5:* The availability of a measure that is more proximal in time to desired patient outcomes for the particular topic;

(F) *Factor 6:* The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic;

(G) *Factor 7:* Collection or public reporting of a measure leads to negative unintended consequences other than patient harm; and

(H) *Factor 8:* The costs associated with a measure outweigh the benefit of its continued use in the program.

(ii) *Criteria to determine topped-out measures.* For the purposes of the Hospital OQR Program, a measure is considered to be topped-out under paragraph (h)(3)(i)(A) of this section when it meets both of the following criteria:

(A) Statistically indistinguishable performance at the 75th and 90th percentiles (defined as when the difference between the 75th and 90th percentiles for a hospital's measure is within two times the standard error of the full data set); and

(B) A truncated coefficient of variation less than or equal to 0.10.

(iii) *Application of measure removal factors.* The benefits of removing a measure from the Hospital OQR Program will be assessed on a case-by-case basis. Under this case-by-case approach, a measure will not be removed solely on the basis of meeting any specific factor.

■ 8. Section 419.48 is amended by—

■ a. Revising paragraph (a);

■ b. Redesignating paragraphs (b) and (c) as paragraphs (c) and (d), respectively;

■ c. Adding a new paragraph (b);

■ d. Revising redesignated paragraph (d); and

■ e. Adding paragraph (e).

The revisions and additions read as follows:

§ 419.48 Definition of excepted items and services.

(a) Excepted items and services are items or services that are furnished—

(1) On or after January 1, 2017—

(i) By a dedicated emergency department (as defined at § 489.24(b) of this chapter); or

(ii) By an excepted off-campus provider-based department defined in paragraph (c) of this section that has not impermissibly relocated or changed ownership.

(2) On or after January 1, 2019—

(i) By a dedicated emergency department (as defined at § 489.24(b) of this chapter); or

(ii) By an excepted off-campus provider-based department described in paragraph (a)(1)(ii) of this section only from those clinical families of services described in paragraph (b) of this section for which the excepted off-campus provider-based department furnished an item or service (and subsequently billed for that item or service under the OPPS) during the following baseline periods:

(A) For an off-campus provider-based department that first furnished a covered OPD service on or before November 1, 2014, November 1, 2014 through November 1, 2015;

(B) For an off-campus provider-based department that first furnished a covered OPD service between November 2, 2014 and November 1, 2015, during a 1-year baseline period that begins on the first date the off-campus provider-based department furnished a covered OPD service; or

(C) For an off-campus provider-based department that first furnished a covered OPD service after November 2, 2015, during a 1-year baseline period that begins on the first date the off-campus provider-based department furnished a covered OPD service. This paragraph (a)(2)(ii)(C) only applies to provider-based departments that met the exception criteria as defined at either section 1833(t)(21)(B)(iii) or section 1833(t)(21)(B)(iv) of the Act.

(b) For purposes of paragraph (a)(2)(ii) of this section, ''clinical families of services'' means the following:

(1) Airway endoscopy.

(2) Blood product exchange.

(3) Cardiac/pulmonary rehabilitation.

(4) Diagnostic/screening test and related procedures.

(5) Drug administration and clinical oncology.

(6) Ear, nose throat (ENT).

(7) General surgery and related procedures.

(8) Gastrointestinal (GI).

(9) Gynecology.

(10) Major imaging.

(11) Minor imaging.

(12) Musculoskeletal surgery.

(13) Nervous system procedures.

(14) Ophthalmology.

(15) Pathology.

(16) Radiation oncology.

(17) Urology.

(18) Vascular/endovascular/cardiovascular.

(19) Visits and related services.

* * * * *

(d) Payment for items and services that do not meet the definition in paragraph (a)(1) of this section will generally be made under the Medicare Physician Fee Schedule on or after January 1, 2017.

(e) Payment for items and services that do not meet the definition in paragraph (a)(2) of this section will generally be made under the Medicare Physician Fee Schedule on or after January 1, 2019.

Dated: June 26, 2018.

Seema Verma,

Administrator, Centers for Medicare and Medicaid Services.

Dated: June 28, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2018–15958 Filed 7–25–18; 4:15 pm]

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Part III

Department of Education

34 CFR Parts 668, 674, 682, et al.

Student Assistance General Provisions, Federal Perkins Loan Program, Federal Family Education Loan Program, and William D. Ford Federal Direct Loan Program; Proposed Rule

DEPARTMENT OF EDUCATION

34 CFR Parts 668, 674, 682, and 685

RIN 1840–AD26

[Docket ID ED–2018–OPE–0027]

Student Assistance General Provisions, Federal Perkins Loan Program, Federal Family Education Loan Program, and William D. Ford Federal Direct Loan Program

AGENCY: Office of Postsecondary Education, Department of Education.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Secretary proposes to create Institutional Accountability regulations that would amend the regulations governing the William D. Ford Federal Direct Loan (Direct Loan) Program to establish a Federal standard for evaluating and a process for adjudicating borrower defenses to repayment for loans first disbursed on or after July 1, 2019, and provide for actions the Secretary may take to collect from schools financial losses due to successful borrower defense to repayment discharges. The Secretary also proposes to withdraw (*i.e.* rescind) certain amendments to the regulations already published but not yet effective.

DATES: We must receive your comments on or before August 30, 2018.

ADDRESSES: Submit your comments through the Federal eRulemaking Portal or via postal mail, commercial delivery, or hand delivery. We will not accept comments submitted by fax or by email or those submitted after the comment period. To ensure that we do not receive duplicate copies, please submit your comments only once. In addition, please include the Docket ID at the top of your comments.

If you are submitting comments electronically, we strongly encourage you to submit any comments or attachments in Microsoft Word format. If you must submit a comment in Adobe Portable Document Format (PDF), we strongly encourage you to convert the PDF to print-to-PDF format or to use some other commonly used searchable text format. *Please do not submit the PDF in a scanned format.* Using a print-to-PDF format allows the Department to electronically search and copy certain portions of your submissions.

- *Federal eRulemaking Portal:* Go to *www.regulations.gov* to submit your comments electronically. Information on using *Regulations.gov*, including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under ''Help.''
- *Postal Mail, Commercial Delivery, or Hand Delivery:* The Department strongly encourages commenters to submit their comments electronically. However, if you mail or deliver your comments about the proposed regulations, address them to Jean-Didier Gaina, U.S. Department of Education, 400 Maryland Ave. SW, Mail Stop 294–20, Washington, DC 20202.

Privacy Note: The Department's policy is to make comments received from members of the public available for public viewing on the Federal eRulemaking Portal at *www.regulations.gov.* Therefore, commenters should be careful to include in their comments only information that they wish to make publicly available.

FOR FURTHER INFORMATION CONTACT: For further information related to Borrower Defenses to Repayment, Pre-dispute Arbitration Agreements, Internal Dispute Processes, and Guaranty Agency Fees, Barbara Hoblitzell at (202) 453–7583 or by email at: *Barbara.Hoblitzell@ed.gov* or Annmarie Weisman at (202) 453–6712 or by email at: *Annmarie.Weisman@ed.gov.* For information related to False Certification Loan Discharge, and Closed School Loan Discharge, Brian Smith at (202) 453–7440 or by email at: *Brian.Smith@ed.gov.* For information regarding Financial Responsibility and Institutional Accountability, John Kolotos at (202) 453–7646 or by email at: *John.Kolotos@ed.gov.* For information regarding Recalculation of Subsidized Usage Periods and Interest Accrual, Ian Foss at (202) 377–3681 or by email at: *Ian.Foss@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at (800) 877–8339.

SUPPLEMENTARY INFORMATION:

Executive Summary

Purpose of This Regulatory Action:

Section 455(h) of the Higher Education Act of 1965, as amended (HEA), authorizes the Secretary to specify in regulation which acts or omissions of an institution of higher education a borrower may assert as a defense to repayment of a Direct Loan. Current regulations in 34 CFR 685.206(c) governing defenses to repayment have been in effect since 1995 but, until recently, were rarely used. Those regulations specify that a borrower may assert as a defense to repayment ''any act or omission of the school attended by the student that would give rise to a cause of action against the school under applicable State law.''

On November 1, 2016, the Department published final regulations (81 FR 75926) (the 2016 final regulations) on the topic of borrower defenses to repayment. The 2016 final regulations were developed following negotiated rulemaking and after receiving and considering public comments on a notice of proposed rulemaking. Certain provisions of the 2016 final regulations have been delayed until July 1, 2019 (83 FR 6458).

These proposed regulations are designed to:

- Provide students with a balanced, meaningful process that relies on a single, Federal standard rather than 50 State standards to ensure that borrower defense to repayment discharges are handled swiftly, carefully, and fairly;
- Encourage students to seek remedies from institutions that have committed acts or omissions that constitute misrepresentation and cause harm to the student;
- Ensure that institutions rather than taxpayers bear the burden of billions of dollars [1] in losses from approvals of borrower defense to repayment discharges;
- Enable institutions to respond to borrower defense to repayment claims and provide evidence to support their response;
- Discourage institutions from committing fraud or other acts or omissions that constitute misrepresentation or from closing precipitously;
- Enable the Department to properly evaluate institutional financial risk in order to protect students and taxpayers;
- Provide students with additional time to qualify for a closed school loan discharge;
- Address the concerns expressed by negotiators, as well as in a suit filed by an association against the Department, that large financial liabilities resulting from the unclear borrower defense standard in the 2016 final regulations could cripple or force the closure of colleges and universities, even as they produce positive outcomes for students and provide students with accurate and complete information relating to enrollment;
- Reduce uncertainty about the future of the Federal financial aid system itself due to the strain on the government of large numbers of borrower defense to repayment discharges; and

[1] The Department estimated that borrower defense activity under the 2016 final regulation would have an estimated $14.9 billion net budget impact for the 2017 to 2026 loan cohorts. 71 FR 76055.

• Most of all, to ensure that millions of American students and borrowers are provided with accurate information to inform their enrollment decisions and to ensure that students are not subjected to narrowed educational options as a result of unwarranted school closures.

The goal of the Department is to enable students to make informed decisions on the front end of college enrollment, rather than to grant them financial remedies after-the-fact when lost time cannot be recouped and new educational opportunities may be sparse. Postsecondary students are adults who can be reasonably expected to make informed decisions and who must take personal accountability for the decisions they make. Institutions are prohibited from misleading students by providing false or incomplete information, and remedies should be provided to a student when misrepresentation on the part of an institution causes financial harm to that student. Regardless, students have a responsibility when enrolling at an institution or taking student loans to be sure they have explored their options carefully and weighed the available information to make an informed choice. The Department has an obligation to enforce the Master Promissory Note, which makes clear that students are not relieved of their repayment obligations if later they regret the choices they made.

Through these proposed regulations, the Department is considering whether to reaffirm the Department's original interpretation of the statute, which persisted for 20 years and provided borrowers an opportunity to raise defenses to the repayment of Direct Loans only in response to collection actions by the Department, or to continue with the Department's 2015 interpretation, which allowed borrowers to raise defenses to repayment in affirmative claims. The Department adopted that interpretation in response to advocacy efforts on behalf of student borrowers who had attended institutions owned by Corinthian Colleges, Inc., but without negotiated rulemaking.

This new interpretation to allow affirmative claims was codified in the Department's 2016 final regulations. The 2015 reinterpretation was designed to expand loan forgiveness for borrowers who had attended Corinthian institutions, which, following a sequence of events, closed precipitously after the Department placed the institutions on HCM1 status and added a delay in title IV reimbursement that is typically not associated with HCM1. The Department's closed school loan discharge regulations provide that a student who was attending a school at the time of its closure, who did not complete his or her program of study prior to the school's closure, and who meets other criteria may receive a discharge of Federal student loans obtained for the student's enrollment at the institution. 34 CFR 674.33, 682.402, and 685.214. But the Department wished to extend loan forgiveness to borrowers who may not have qualified for this closed school loan discharge, so it created new policies for accepting affirmative claims.

The Department's experience with these affirmative claims has informed this NPRM. That experience has led the Department to realize that a clear Federal standard is required in order to adjudicate borrower defense claims in a fair and equitable manner. The Department has also heard concerns during the process about the Department's statutory authority to adjudicate these claims in an affirmative posture and about whether the process for adjudicating these claims appropriately balances the competing interests of borrowers, institutions, and taxpayers.

Among other issues enumerated throughout this document, the Department is concerned that a process that allows for borrowers to submit affirmative claims, where there are minimal consequences for submitting an unjustified claim, could potentially create improper incentives for borrowers with unsubstantiated allegations against schools to seek loan discharges. For example, a borrower may attempt to seek loan forgiveness simply because he or she is dissatisfied with the education received or with his or her ability to get a particular job, rather than as a result of a misrepresentation by the institution. This situation could easily increase the burden on the Department of identifying legitimate claims among those that do not meet the defense to repayment standard. And with nothing to lose by submitting a claim, a borrower could be tempted to submit a claim whether or not he or she has been harmed. The Department does not have sufficient information to determine the extent of this potential incentive effect. As of January 2018, it had received 138,989 claims, of which 23 percent had been processed, and only 2 percent of the processed claims were associated with schools other than Corinthian and ITT, but that targeted rather than random sample is insufficiently representative to support conclusions on the issue at this point.

In any case, an influx of affirmative claims could itself cause harm to borrowers. For example, even if the Department can accurately distinguish between genuine and frivolous claims, the time it takes to do so may prolong the time it takes to provide relief to deserving borrowers. And borrowers not entitled to relief may find themselves worse off if they receive a forbearance while the claim was being processed, because interest would accrue and increase the amount the borrower would be required to repay when the loan reenters repayment.

In addition, the Department is concerned that several features of the 2016 final regulations might have put the Department in the untenable position of forgiving billions of dollars of Federal student loans based on potentially unfounded accusations. Specifically, those regulations would allow the Department to afford relief to borrowers without providing an opportunity for institutions to adequately tell their side of the story. And they would allow the Department to afford relief to entire groups of borrowers, including those who did not apply for relief or who were potentially not harmed by the institution.

However, despite these concerns, the Department is considering the continuation of its current practice of accepting affirmative claims from borrowers not in a collections status. A policy that limits borrower defense eligibility to defensive claims may have the unintended effect of treating borrowers harmed by a misrepresentation who default on their loans better than other defrauded borrowers who stay out of default by responsibly enrolling in income-driven repayment plans and making payments on their loan.

In addition, lessons learned from the recent mortgage crisis raise concerns that limiting borrower defense eligibility to defensive claims could lead some relief-seeking borrowers to strategically default. Researchers observed similar strategic behavior by homeowners in response to a 2008 mortgage modification program offered by a large financial institution to borrowers who were at least sixty days delinquent.[2] The study found that the program's structure, which relied on the borrower's repayment status, yielded a thirteen percent increase in the probability of that financial institution's borrowers rolling over from current to delinquent status—evidence of strategic behavior by borrowers aiming to take advantage of mortgage modifications. A

[2] *http://www.nber.org/papers/w17065.pdf.*

similar behavioral response from relief-seeking borrowers choosing to enter default could result in a range of troubling unintended consequences, including damage to borrower credit scores, increased default collection costs for taxpayers, and increases to institutional cohort default rates.

The Department is trying very carefully to balance relief for borrowers who have been harmed by acts of institutional wrongdoing, with its obligation to the taxpayer to provide reliable stewardship of Federal dollars. With more than a trillion dollars in outstanding student loans, the Department must uphold its fiduciary responsibilities and exercise caution in forgiving student loans to ensure that it does not create an existential threat to a program that lacks typical credit and underwriting standards.

With so much at stake for all parties, it seems reasonable that consumer complaints should continue to be adjudicated through existing legal channels that put experienced judges or arbitrators in the position of weighing the evidence and rendering an impartial decision. Significant reputational damage could be done to an institution from an affirmative borrower defense claim long before an institution is given an opportunity to contest that claim in a recoupment proceeding. Such damage could weaken or even force institutions to close, regardless of the truth, extent, or other circumstances surrounding the unverified claims. And if the institution prevails in a recoupment proceeding, it is the taxpayer who is left responsible for the claims the Department approved in error.

These concerns have led the Department to reconsider and seek public comment on whether it should reaffirm the Department's original interpretation of the statute, which provided borrowers an opportunity to raise defenses to the repayment of Direct Loans only in response to collection actions by the Department. The Department is interested in comments about its statutory authority to consider defenses to the repayment of Direct Loans in an affirmative posture, and about the risks and benefits of doing so.

However, the Department is also considering continuing to accept affirmative claims from borrowers not in a collections action. In either case, the Department would need to implement provisions that would protect institutions and taxpayers against frivolous claims. Our initial review of pending claims suggests that some borrowers may believe that the process allows for a discharge based on a borrower's dissatisfaction with the education he or she received or the outcomes he or she realized following enrollment, even in the absence of a misrepresentation on the part of the institution. That is not the case. As stated in the Master Promissory Note the borrower signs when initiating their first loan, the borrower is expected to repay the loan even if the borrower fails to complete the program or is dissatisfied with the institution or his or her outcomes. The Department seeks comments from the public regarding what types of provisions or requirements could be used to reduce frivolous claims while still ensuring a borrower a fair and meaningful opportunity to seek relief in the event of fraud.

The Department is also proposing to change its approach to a possible group adjudication of borrower defense claims. The 2016 final regulations would enable the Department to initiate affirmative claims on behalf of entire groups of borrowers, if the Secretary determines that there are common facts and claims that apply to the group. However, in this NPRM, the Department is proposing a uniform standard based on a misrepresentation made with knowledge of its false, misleading, or deceptive nature or with a reckless disregard for the truth. As this proposed standard is dependent upon a fact-specific inquiry, the Department does not believe that the group process is appropriate to include in these proposed regulations. Further, a group discharge process could place an extraordinary burden on both the Department and the taxpayer, and the Department has reconsidered whether such a process appropriately balances the need to reduce burden on borrowers and the Department with the obligation to protect taxpayer funds. Because an institution can refuse to provide an official transcript for a borrower whose loan has been forgiven, group discharges could render some borrowers unable to verify their credentials or work in the field for which they trained and have enjoyed employment.

Moreover, the Department believes that a review of claims on an individual basis is necessary to ensure that it affords appropriate relief to borrowers who suffered harm from an alleged misrepresentation. Since publication of the 2016 final regulations, the Department has conducted further analyses of the tens of thousands of defense to repayment applications for Corinthian students that the Department has received to date. Those analyses have demonstrated that students enrolled at Corinthian who submitted defense to repayment applications may not all have been harmed to the same extent. An individual process would offer all borrowers fair and equal access to defense to repayment relief. And these proposed regulations would not eliminate the opportunity for Corinthian or other students with loans first disbursed prior to July 1, 2019, to seek debt relief under the 2015 interpretation of the regulation.

The Department proposes a new Federal standard to govern claims on loans made after July 1, 2019 based on an alleged misrepresentation. Under that standard, a borrower may assert as a defense to repayment an eligible institution's misrepresentation—that is, a statement, act, or omission by the school to the borrower that is (i) false, misleading, or deceptive, (ii) made with knowledge of its false, misleading, or deceptive nature or with a reckless disregard for the truth, and (iii) directly and clearly related to the making of a Direct Loan for enrollment at the school or the provision of educational services for which the loan was made. To relate to the ''provision of educational services,'' a misrepresentation must relate to the borrower's program of study. Such misrepresentations can relate, for example, to the educational resources provided by the institution that are required by an accreditation agency or a State licensing or authorizing agency for the completion of the student's educational program.

The proposed standard for a borrower defense discharge differs from the standard selected in the 2016 final regulations, which was based on the Department's authority during enforcement actions. The 2016 final regulations adopted the misrepresentation standard at 34 CFR 668.71, and provided that defenses to repayment may additionally be based upon breaches of contract and certain types of judgments. The proposed standard would not provide for a defense to repayment based on such breaches of contract or other judgments. Instead, such breaches or judgments may be considered as evidence of a misrepresentation, to the extent they bear on an act or omission related to the educational services provided. The Department believes this approach will assist it to quickly and fairly review each and every application and provide equitable relief to borrowers who were harmed.

The Department's proposed standard also does not distinguish between the types of institutions that committed the misrepresentation. Appendix A of the 2016 final regulations, by contrast, took the position that a student who attended a selective, non-profit institution would

not receive debt relief even if the institution committed an act that would otherwise entitle the borrower a defense to repayment because, in the opinion of the Department, the education received was valuable despite the misrepresentation. We cannot adequately support assumptions about the inherent quality of any institution, including a selective non-profit institution. The Department accordingly does not propose to maintain this position.

The Department does propose to maintain the standard of evidence or proof required to make a successful claim that was included in the 2016 final regulations—a preponderance of the evidence. The Department believes that this standard will allow claims to be asserted and handled in a manner that is genuinely fair to students, taxpayers, and institutions, especially since a borrower in collections could have left the institution many years prior to making a claim, which would make it exceedingly difficult to meet a higher evidentiary standards. However, if the Department chooses to continue to accept affirmative claims, where barriers to submitting such claims are very low and there are no penalties for a borrower who submits an unjustified claim, the Department believes that a higher evidentiary standard may be appropriate. The Department seeks comments from the public about whether or not a clear and convincing evidence standard would be appropriate if the Department chooses to continue to accept affirmative claims and, if so, whether that clear and convincing standard should apply solely to affirmative claims or to both affirmative and defensive claims.

Finally, the Department proposes to limit the period of time during which the Secretary may recoup funds discharged under these regulations. Specifically, for loans disbursed on or after July 1, 2019, the Secretary would have five years from the date of the final determination on a borrower's defense to repayment application to initiate a proceeding to recover from the school the amount of the losses incurred by the Secretary on the discharged loans.

In addition to the changes to the borrower defense regulations discussed above, we seek in this NPRM to strengthen the Department's ability to protect the Federal taxpayer from the consequences of a school's precipitous closure by amending the Department's financial responsibility regulations. The proposed regulations identify actions or events that the Secretary may consider in determining whether a school is financially responsible, provide that the Secretary may accept other types of surety or financial protection in lieu of letters of credit, clarify that the Department may impose a limitation on a school by changing a school's participation status from ''fully certified'' to ''provisionally certified'', and update the Department's regulations as to initial and final decisions that may be made by a hearing official in a fine, limitation, suspension, or termination proceeding to incorporate the proposed alternate means of financial protection to the Department. These proposed regulations balance the need for consumer protection, regulatory enforcement, and fairness to schools. They seek to hold schools accountable, provide prospective and continuing students with information necessary to make informed choices, and mitigate actions that pose an existential threat to institutions. A school's precipitous closure—as opposed to a well-planned, accreditor approved teach-out—puts students, borrowers, and taxpayers at unnecessary risk.

Further, through these proposed regulations, the Department seeks to encourage schools that are closing to go through an orderly closure, which includes offering appropriate teach-outs to their students. Since 2015, precipitous closures have led to large numbers of defense to repayment and closed school discharge applications. We believe that closing schools should be encouraged to offer accreditor-approved and, if applicable, State authorizer-approved teach-out plans. Such plans allow students the reasonable opportunity to complete their academic programs, either at another location after the school has closed or through an orderly wind-down process before the school officially closes.

We also propose changes to the Department's current false certification regulations. The Department believes that in cases when the borrower is unable to obtain an official transcript or diploma from the high school, postsecondary institutions should be able to rely on an attestation from a borrower that the borrower earned a high school diploma since the Department relies on a similar attestation in processing a student's Free Application for Federal Student Aid (FAFSA). This policy change provides assurances to students that they will have a reasonable opportunity to pursue postsecondary education when they cannot obtain an official transcript or diploma, and to institutions that they will not face significant liabilities years later if a student's status cannot be verified. Therefore, we are proposing regulatory language that when a borrower provides an institution an attestation of his or her high school graduation status for purposes of admission to the institution, the borrower may not subsequently qualify for a false certification discharge based on not having a high school diploma.

We do not propose to adopt the changes relating to pre-dispute arbitration agreements and class action waivers that are in the 2016 final regulations. In those regulations, the Department took the position that the HEA gives the Department broad authority to impose conditions on schools that wish to participate in a Federal benefit program and that regulation of the use of pre-dispute arbitration agreements and class action waivers was necessary to ''protect the interests of the United States and promote the purposes'' of the Direct Loan Program under Section 454(a)(6) of the HEA, 20 U.S.C. 1087d(a)(6). We continue to recognize, as explained in the preamble to the 2016 final regulations, that pre-dispute arbitration agreements and class action waivers, in some circumstances, may not be well understood by consumers and may not facilitate the Department's awareness of potential issues faced by students at a school. However, in re-weighing all applicable factors, including the current legal landscape, we have determined that the Department should take a position more in line with the benefits of arbitration and the strong Federal policy favoring it.

Several potential benefits of arbitration are relevant here. Arbitration is often a more efficient and less adversarial means of dispute resolution than time-consuming and expensive litigation that may result in borrowers waiting years to obtain a fair hearing and any relief. Arbitration may also allow borrowers to obtain greater relief than they would in a consumer class action case where attorneys often benefit most. Moreover, arbitration may reduce the expense of litigation that a university would otherwise pass on to students in the form of higher tuition and fees. Arbitration also eases burdens on the overtaxed U.S. court system.

For all of these reasons, the Department has decided that the 2016 final regulations' provisions on class action waivers and pre-dispute arbitration should not be included in these proposed regulations. As stated above, we believe that borrower defense to repayment should be a last resort for borrowers. Arbitration is one means of dispute resolution through which borrowers may be able to obtain relief without filing a defense to repayment

with the Department. The Department does not propose to prevent that means. But because pre-dispute arbitration agreements or class-action waivers may limit the availability of certain alternative means of dispute resolution, we propose changes that would provide borrowers with a better understanding of the dispute resolution processes available to them when they enroll at a school.

The proposed regulations also update the appendices to subpart L of 34 CFR part 668 to account for changes in accounting standards and terminology.

Incorporation by Reference

In proposed § 668.175(d) with respect to the zone alternative, we reference the following accounting standards: FASB ASC 850, Accounting Standards Update (ASU) 2015–01, and ASC 225. FASB ASC 850 addresses disclosures of transactions between related parties. These disclosures are considered to be related party transactions even though they may not be given accounting recognition. While not providing accounting or measurement guidance for such transactions, FASB ASC 850 requires their disclosure nonetheless.

Accounting Standards Update (ASU) No. 2015–01 addresses extraordinary and unusual items, to simplify income statement classification by removing the concept of extraordinary items from United States generally accepted accounting principles (U.S. GAAP).

ASC 225 provides general income statement guidance. Specifically, it addresses the classification and resulting presentation and disclosure of extraordinary events and transactions. It also addresses the presentation and disclosure of unusual and infrequently occurring items that do not meet the extraordinary criteria, and speaks to business interruption insurance. The types of costs and losses covered by business interruption insurance typically include items such as gross margin that was lost or not earned due to the suspension of normal operations.

These items are accessible to the public on the Financial Accounting Standards Board (FASB) website, *www.fasb.org.*

Summary of the Major Provisions of This Regulatory Action:

For the Direct Loan Program, we propose new regulations governing borrower defenses that would—

- Establish a new Federal standard for borrower defenses to repayment submitted by borrowers with loans first disbursed on or after July 1, 2019;
- Establish a process for the assertion and resolution of borrower defenses to repayment for loans first disbursed on or after July 1, 2019;
- Provide schools and borrowers with opportunities to provide evidence and arguments when a defense to repayment application has been filed and to provide an opportunity for each to respond to the other's submitted evidence;
- Require a borrower to sign an attestation to ensure that financial harm is not the result of the borrower's workplace performance, disqualification for a job for reasons unrelated to the education received, a personal decision to work less than full-time or not at all, or the borrower's decision to change careers.
- Establish a time limit for the Secretary to initiate an action to collect from the responsible school the amount of any loans first disbursed on or after July 1, 2019, that are subject to a successful borrower defense to repayment discharge for which the school is liable;
- Provide for remedial actions the Secretary may take to collect from the responsible school the amount of any loans subject to a successful borrower defense to repayment discharge for which the school is liable; and
- Establish institutional responsibility and financial liability for losses incurred by the Secretary for repayment of loan amounts discharged by the Secretary on the basis of a borrower defense to repayment discharge.

The proposed regulations would also revise the Student Assistance General Provisions regulations to—

- Provide for schools that require Federal student loan borrowers to sign pre-dispute arbitration agreements or class action waivers as a condition of enrollment to make a plain language disclosure of those requirements to prospective and enrolled students and place that disclosure on its website where information regarding admissions and tuition and fees is presented; and
- Provide for schools that require Federal student loan borrowers to sign pre-dispute arbitration agreements or class action waivers as a condition of enrollment to include information in the borrower's entrance counseling regarding the school's internal dispute and arbitration processes.
- Amend the financial responsibility provisions to establish the conditions or events that have or may have an adverse material effect on an institution's financial condition and which warrant financial protection for the Department, update the definitions of terms used to calculate an institution's composite score to conform with changes in accounting standards but provide a six year phase-in to enable the Department adequate time to update the Composite Score regulations accordingly through future negotiated rulemaking, and expand the types of financial protection acceptable to the Secretary.

The proposed regulations would also—

- Revise the Perkins Loan, FFEL, and Direct Loan programs' closed school discharge regulations to extend the window for a borrower to qualify for a closed school discharge to 180 days;
- Revise the Perkins Loan, FFEL, and Direct Loan programs' closed school discharge regulations to specify that if a closing school provides an opportunity to complete the program of study approved by the school's accrediting agency and, if applicable, the school's State authorizing agency, the borrower would not qualify for a closed school discharge;
- Modify the conditions under which a Direct Loan borrower may qualify for a false certification discharge by specifying that, in cases when the borrower could not reasonably provide the school an official transcript or diploma from the borrower's high school, but provided an attestation to the school that the borrower was a high school graduate, the borrower would not qualify for a false certification discharge based on not having a high school diploma;
- Prohibit guaranty agencies from charging collection costs to a defaulted borrower who enters into a repayment agreement with the guaranty agency within 60 days of receiving notice of default from the agency;
- Prohibit guaranty agencies from capitalizing interest on a loan that is sold following the completion of loan rehabilitation;
- Reflect the Department's policy regarding the impact that a discharge of a Direct Subsidized Loan has on the 150 Percent Direct Subsidized Loan Limit; and
- Update composite score calculations to reflect recent changes in FASB accounting standards and provide for a six year phase-in process to provide the Department sufficient time to update the Composite Score regulations accordingly through negotiated rulemaking.

In addition, for the reasons set forth below, we propose to withdraw (*i.e.,* rescind) specified provisions of the final regulations we published on November 1, 2016 (81 FR 75926) (the 2016 final regulations) that were delayed until July 1, 2019, pertaining to borrower defenses to repayment and related issues.

Please refer to the *Summary of Proposed Changes* section of this notice of proposed rulemaking (NPRM) for more details on the major provisions contained in this NPRM.

Costs and Benefits: As further detailed in the *Regulatory Impact Analysis,* the benefits of the proposed regulations include: (1) An updated and clarified process and the creation of a Federal standard to streamline the administration of defense to repayment applications; (2) improved financial protections for the Federal government and taxpayers by requiring institutions to incur the losses associated with a successful defense to repayment application and reducing the likelihood of taxpayers incurring costs related to paying claims submitted by students who were not harmed; (3) additional information to help students, prospective students, and their families make educated decisions based on information about a school's mandatory arbitration or class action waiver requirements and to effectively use arbitration when necessary; (4) an extended window for a borrower to qualify for a closed school discharge and revisions incentivizing completion of educational programs; (5) revised conditions under which a Direct Loan borrower may qualify for a false certification discharge to ensure that students who are unable to obtain a high school transcript have an opportunity to participate in postsecondary education and that a student's intentional misrepresentation of his or her high school graduation status cannot then be used to justify a false certification discharge; (6) restrictions on guaranty agencies from charging collection costs to a defaulted borrower who enters into a repayment agreement with the guaranty agency within 60 days of receiving notice of default from the agency, and from capitalizing interest on a loan that is sold following the completion of loan rehabilitation; (7) recalculating subsidized usage periods, as appropriate, when a borrower has received a loan discharge; and (8) updating the calculation of composite scores to reflect changes in FASB standards, but also providing a six-year phase in to provide time for the Department to update its composite score regulations through future negotiated rulemaking.

Costs include the paperwork burden associated with the required reporting and disclosures to ensure compliance with the proposed regulations, the cost to affected schools of providing financial protection, and the cost to taxpayers of borrower defense claims that are not reimbursed by schools. There may also be costs to borrowers who may be reluctant to go into default, even if they have a claim that would result in loan relief or partial loan relief, and therefore do not benefit from that loan relief. There may also be costs to borrowers who use the legal system to seek damages from an institution rather than relying on the government to adjudicate consumer complaints.

Invitation to Comment: We invite you to submit comments regarding these proposed regulations.

To ensure that your comments have maximum effect in developing the final regulations, we urge you to identify clearly the specific section or sections of the proposed regulations that each of your comments addresses, and provide relevant information and data whenever possible, even when there is no specific solicitation of data and other supporting materials in the request for comment. We also urge you to arrange your comments in the same order as the proposed regulations. Please do not submit comments that are outside the scope of the specific proposals in this NPRM, as we are not required to respond to such comments.

We invite you to assist us in complying with the specific requirements of Executive Orders 12866 and 13563 and their overall requirement of reducing regulatory burden that might result from these proposed regulations. Please let us know of any further ways we could reduce potential costs or increase potential benefits while preserving the effective and efficient administration of the Department's programs and activities.

During and after the comment period, you may inspect all public comments about the proposed regulations by accessing *Regulations.gov.* You may also inspect the comments in person at 400 Maryland Ave. SW, Washington, DC, between 8:30 a.m. and 4:00 p.m., Eastern Time, Monday through Friday of each week except Federal holidays. To schedule a time to inspect comments, please contact one of the persons listed under **FOR FURTHER INFORMATION CONTACT.**

Assistance to Individuals with Disabilities in Reviewing the Rulemaking Record: On request, we will provide an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for the proposed regulations. To schedule an appointment for this type of accommodation or auxiliary aid, please contact one of the persons listed under **FOR FURTHER INFORMATION CONTACT.**

Background

The Secretary proposes to amend parts 668, 674, 682, and 685 of title 34 of the Code of Federal Regulations (CFR). The regulations in 34 CFR part 668 pertain to Student Assistance General Provisions. The regulations in 34 CFR part 674 pertain to the Perkins Loan Program. The regulations in 34 CFR part 682 pertain to the FFEL Program. The regulations in 34 CFR part 685 pertain to the Direct Loan Program.

We are proposing these amendments to: (1) Specify that the standard used to identify an act or omission of a school that provides the basis for a borrower defense to repayment discharge will depend on when the Direct Loan was first disbursed; (2) establish a new Federal standard that the Department will use to determine whether a school's act or omission constitutes a basis for a borrower defense to repayment discharge for loans disbursed on or after July 1, 2019; (3) provide an opportunity for an institution to know that a defense to repayment application has been lodged against it and to respond to claims made in that application; (4) establish the procedures to be used by a borrower to initiate a borrower defense to repayment application for loans first disbursed on or after July 1, 2019; (5) establish a time limit for the Secretary to initiate action to collect from the responsible school the amount of any loans first disbursed on or after July 1, 2019 that are subject to an approved borrower defense to repayment discharge; (6) establish the procedures that the Department would use to determine the liability of a school for the amount of any loan discharges and reimbursement of loan payments resulting from successful borrower defenses to repayment; (7) establish the conditions or events upon which an institution is or may be required to provide to the Department financial protection, such as a letter of credit, to help protect the Federal government and taxpayers, against potential institutional liabilities; (8) institute requirements to ensure borrowers are informed and educated about pre-dispute arbitration agreements and class action waivers that students are required to sign by the school as a condition of enrollment; (9) revise the closed school discharge regulations to extend the window for a borrower to qualify for a closed school discharge and specify that if a closing school provides a borrower an opportunity to complete his or her academic program through a teach-out plan approved by the school's accrediting agency and, if applicable, the school's State

authorizing agency, the borrower would not qualify for a closed school discharge; (10) amend the eligibility criteria for the false certification loan discharge by specifying that, in cases when a borrower could not provide the school an official high school transcript or diploma but provided an attestation that the borrower was a high school graduate, the borrower would not qualify for a false certification discharge based on not having a high school diploma; (11) clarify the conditions under which FFEL Program loan holders may capitalize the interest due on a loan to be consistent with the Department's practice for loans it holds; (12) reflect the conditions under which the discharge of a Direct Subsidized Loan will lead to the elimination or recalculation of a Subsidized Usage Period under the 150 Percent Direct Subsidized Loan Limit or the restoration of interest subsidy; and (13) prohibit guaranty agencies from charging collection costs if a borrower enters into a repayment agreement within 60 days of the default notice.

Public Participation

On June 16, 2017, we published a notification in the **Federal Register** (82 FR 27640) announcing our intent to establish a negotiated rulemaking committee under section 492 of the HEA to revise the regulations on borrower defenses to repayment of Federal student loans and other matters, and on the authority of guaranty agencies in the FFEL Program to charge collection costs to defaulted borrowers under 34 CFR 682.410(b)(6). We also announced two public hearings at which interested parties could comment on the topics suggested by the Department and suggest additional topics for consideration for action by the negotiated rulemaking committee. The hearings were held on—

July 10, 2017, in Washington, DC; and

July 12, 2017, in Dallas, TX.

Transcripts from the public hearings are available at *www2.ed.gov/policy/highered/reg/hearulemaking/2017/index.html.*

We also invited parties unable to attend a public hearing to submit written comments on the proposed topics and to submit other topics for consideration. Written comments submitted in response to the June 16, 2017, **Federal Register** notification may be viewed through the Federal eRulemaking Portal at *www.regulations.gov,* within docket ID ED–2017–OPE–0076. Instructions for finding comments are also available on the site under ''How to Use *Regulations.gov*'' in the Help section.

On August 30, 2017, we published a notification in the **Federal Register** (82 FR 41194) requesting nominations for negotiators to serve on the negotiated rulemaking committee and setting a schedule for committee meetings.

Negotiated Rulemaking

Section 492 of the HEA, 20 U.S.C. 1098a, requires the Secretary to obtain public involvement in the development of proposed regulations affecting programs authorized by title IV of the HEA. After obtaining extensive input and recommendations from the public, including individuals and representatives of groups involved in the title IV, HEA programs, the Secretary in most cases must subject the proposed regulations to a negotiated rulemaking process. If negotiators reach consensus on the proposed regulations, the Department agrees to publish without alteration a defined group of regulations on which the negotiators reached consensus unless the Secretary reopens the process or provides a written explanation to the participants stating why the Secretary has decided to depart from the agreement reached during negotiations. Further information on the negotiated rulemaking process can be found at: *www2.ed.gov/policy/highered/reg/hearulemaking/hea08/neg-reg-faq.html.*

On August 30, 2017, the Department published a notification in the **Federal Register** (82 FR 41194) announcing its intention to establish two negotiated rulemaking committees and a subcommittee to prepare proposed regulations governing the Federal Student Aid programs authorized under title IV of the HEA. One negotiated rulemaking committee was established to propose regulations relating to gainful employment and the other to propose regulations pertaining to borrower defenses to repayment of Federal student loans, the definition of misrepresentation as it pertains to borrower defense, the program participation agreement for schools participating in the title IV programs, closed school and false certification loan discharges, financial responsibility and administrative capability, arbitration and class action lawsuits, revisions to regulations that will address whether and to what extent guaranty agencies may charge collection costs under 34 CFR 682.410(b)(6) to a defaulted borrower who enters into a loan rehabilitation or other repayment agreement within 60 days of being informed that the guaranty agency has paid a claim on the loan.

A subcommittee, which was composed of individuals with expertise in the applicable financial accounting and reporting standards set by the Financial Accounting Standards Board (FASB), was established to discuss whether and how the (FASB's) recent changes to the accounting standards for financial reporting affected financial reporting requirements for schools and to recommend appropriate regulatory changes to the negotiated rulemaking committee.

The notification set forth a schedule for the committee meetings and requested nominations for individual negotiators to serve on the negotiating committee and the subcommittee. The Department sought negotiators to represent the following groups: Students and former students; consumer advocacy organizations; legal assistance organizations that represent students and former students; groups representing U.S. military service members or veteran Federal student loan borrowers; financial aid administrators at postsecondary schools; general counsels/attorneys and compliance officers at postsecondary schools; chief financial officers (CFOs) and experienced business officers at postsecondary schools; State attorneys general and other appropriate State officials; State higher education executive officers; institutions of higher education eligible to receive Federal assistance under title III, parts A, B, and F, and title V of the HEA, which include Historically Black Colleges and Universities, Hispanic-Serving Institutions, American Indian Tribally Controlled Colleges and Universities, Alaska Native and Native Hawaiian-Serving Institutions, Predominantly Black Institutions, and other institutions with a substantial enrollment of needy students as defined in title III of the HEA; two-year public institutions of higher education; four-year public institutions of higher education; private, nonprofit institutions of higher education; private, proprietary institutions of higher education; FFEL Program lenders and loan servicers; FFEL Program guaranty agencies and guaranty agency servicers (including collection agencies); and accrediting agencies. The Department sought subcommittee members to represent the following constituencies who also have expertise in the applicable financial accounting and reporting standards set by the Financial Accounting Standards Board (FASB): Private, nonprofit institutions of higher education, with knowledge of the accounting standards and title IV financial responsibility

requirements for the private, nonprofit sector; private, proprietary institutions of higher education, with knowledge of the accounting standards and title IV financial responsibility requirements for the proprietary sector; accrediting agencies; chief financial officers (to include experienced business officers and bursars) at postsecondary institutions; associations or organizations that provide accounting guidance to auditors and institutions; certified public accountants or firms who conduct financial statement audits of title IV participating institutions; and FASB. The Department considered the nominations submitted by the public and chose negotiators who would represent the various constituencies.

The negotiating committee included the following members: Joseline Garcia, United States Students Association, and Stevaughn Bush, (alternate) Student, Howard University School of Law, representing students and former students.

Ashley Harrington, Center for Responsible Lending, and Suzanne Martindale (alternate), Consumers Union, representing consumer advocacy organizations.

Abby Shafroth, National Consumer Law Center, and Juliana Fredman, (alternate) Bay Area Legal Aid, representing legal assistance organizations that represent students.

Will Hubbard, Student Veterans of America, and Walter Ochinko (alternate), Veterans Education Success, representing U.S. military service members or veterans.

Valerie Sharp, Evangel University, and Kimberly Brown (alternate), Des Moines University, representing financial aid administrators.

Aaron Lacey, Partner, Thomas Coburn LLP, and Bryan Black, (alternate), Attorney, representing General Counsels/attorneys and compliance officers.

Kelli Hudson Perry, Rensselaer Polytechnic Institute, and Dawnelle Robinson (alternate), Roanoke Chowan Community College, representing CFOs and business officers.

John Ellis, State of Texas Office of the Attorney General, and Evan Daniels (alternate), Office of the Arizona Attorney General, representing State attorneys general and other appropriate State officials.

Robert Flanigan, Jr., Spelman College, and Lodriguez Murray (alternate), United Negro College Fund, representing minority serving institutions.

Dan Madzelan, American Council on Education, and Barmak Nassirian (alternate), American Association of State Colleges and Universities, representing two-year public institutions.

Alyssa Dobson, Slippery Rock University, and Kay Lewis (alternate), University of Washington, representing four-year public institutions.

Ashley Ann Reich, Liberty University, and Gregory Jones (alternate), Compass Rose Foundation, representing private, non-profit institutions.

Mike Busada, Ayers Career College, and Chris DeLuca (alternate), DeLuca Law LLC, representing private, proprietary institutions with enrollment of 450 students or fewer.

Michael Bottrill, SAE Institute North America, and Linda Rawles, (alternate) Rawles Law, representing private, proprietary institutions with enrollment of 451 students or more.

Wanda Hall, Edfinancial Services, and Colleen Slattery (alternate), MOHELA, representing FFEL Program lenders and loan servicers.

Jaye O'Connell, Vermont Student Assistance Corporation, and Sheldon Repp (alternate), National Council of Higher Education Resources, representing FFEL Program guaranty agencies and guaranty agency servicers.

Dr. Michale McComis, Accrediting Commission of Career Schools and Colleges, and Karen Peterson Solinski, (alternate), Higher Learning Commission, representing accreditors.

Annmarie Weisman, U.S. Department of Education, representing the Department.

The subcommittee included the following members:

John Palmucci, Maryland University of Integrative Health, representing private, non-profit institutions.

Jonathan Tarnow, Drinker Biddle & Reath LLP, representing private, proprietary institutions.

Dr. Julianne Marie Malveaux, Economic Education, and formerly of Bennett College, representing minority serving institutions.

Dale Larson, Dallas Theological Seminary, representing Accrediting agencies.

Dawnelle Robinson, Shaw University, representing CFOs, business officers, and bursars.

Susan M. Menditto, National Association of College and University Business Officers, representing organizations that provide accounting guidance to auditors and institutions.

Ronald E. Salluzzo, Attain, representing Certified public accountants or firms who conduct compliance audits and/or prepare financial statements of participating Title IV institutions.

Jeffrey Mechanick, the Financial Accounting Standards Board (FASB), representing FASB.

The negotiated rulemaking committee met to develop proposed regulations on November 13–15, 2017, January 8–11, 2018, and February 12–15, 2018. The subcommittee met in person on November 16–17, 2017, January 4–5, 2018, and by telephone on January 30, 2018.

At its first meeting, the negotiating committee reached agreement on its protocols and proposed agenda. The protocols provided, among other things, that the committee would operate by consensus. Consensus means that there must be no dissent by any member in order for the committee to have reached agreement. Under the protocols, if the committee reached a final consensus on all issues, the Department would use the consensus-based language in its proposed regulations. Furthermore, the Department would not alter the consensus-based language of its proposed regulations unless the Department reopened the negotiated rulemaking process or provided a written explanation to the committee members regarding why it decided to depart from that language.

During the first meeting, the negotiating committee agreed to negotiate an agenda of eight issues related to student financial aid. These eight issues were: Borrower defense to repayment standard; the process for applying for and considering borrower defense claims; financial responsibility and administrative capability; pre-dispute arbitration agreements, class action waivers, and internal dispute processes; closed school discharges; false certification discharges; guaranty agency collection fees; and subsidized usage period recalculations.

During committee meetings, the negotiators reviewed and discussed the Department's drafts of regulatory language and the committee members' alternative language and suggestions. At the final meeting on February 15, 2018, the committee did not reach consensus on the Department's proposed regulations. For that reason, and according to the committee's protocols, all parties who participated in or who were represented in the negotiated rulemaking, in addition to all members of the public, may comment freely on the proposed regulations. For more information on the negotiated rulemaking sessions, please visit: *www2.ed.gov/policy/highered/reg/hearulemaking/2017/borrowerdefense.html.* Transcripts and audio recordings of the negotiated rulemaking session are also available at:

www2.ed.gov/policy/highered/reg/hearulemaking/2017/borrowerdefense.html.

While transcripts have been made available by the Department to aid public understanding of the negotiated rulemaking proceedings, the transcripts have not been vetted or reviewed for accuracy or completeness and should not be considered as the Department's official transcription of the negotiated rulemaking proceedings.

Summary of Proposed Changes

The proposed regulations would—

- Rescind specified provisions of the 2016 final regulations, which have not yet become effective.
- Amend § 668.41 to require schools that require students to accept pre-dispute arbitration agreements or class action waivers as a condition of enrollment to disclose that information to students, prospective students, and the public in an easily accessible format;
- Amend § 668.91 to provide that the Secretary may accept other types of surety or financial protection in addition to letters of credit and that a hearing official must uphold the amount of financial protection required by the Secretary unless certain conditions are met;
- Amend § 668.94 to provide that a limitation on an institution's participation in the Title IV programs may include changing the institution's status from fully certified to provisionally certified;
- Amend § 668.171 to establish the actions or events that have or may have an adverse material effect on an institution's financial condition and revise appendices A and B of the financial responsibility regulations to conform with changes in accounting standards;
- Amend § 668.172 to address changes to the accounting standards regarding leases;
- Amend § 668.175 to expand the types of financial protection acceptable to the Secretary;
- Amend §§ 674.33, 682.402 and 685.214 to extend the window for a borrower to qualify for a closed school discharge and to specify that if a closing school provided a borrower the reasonable opportunity to complete his or her academic program through an orderly school closure or a teach-out plan and that is approved by the school's accrediting agency and, if applicable, the school's State authorizing agency, the borrower will not qualify for a closed school discharge;
- Amend §§ 682.202, 682.405, and 682.410 to prohibit guaranty agencies and FFEL Program lenders from capitalizing the outstanding interest on a FFEL loan when the borrower rehabilitates a defaulted FFEL loan;
- Amend § 682.405 to prohibit guaranty agencies and FFEL Program lenders from charging collections costs when a borrower enters into a repayment agreement within 60 days of the notice of default;
- Amend § 685.200 to specify that a loan discharge based on school closure, false certification, an unpaid refund, or a defense to repayment will lead to the elimination of or recalculation of the subsidized usage period that is associated with the loan or loans discharged;
- Amend § 685.206 to clarify that existing regulations with regard to borrower defenses to repayment apply to loans first disbursed prior to July 1, 2019; to establish a Federal standard for deciding borrower defenses to repayment pertaining to a loan first disbursed on or after July 1, 2019; to establish the procedures that the Department would use to determine the liability of a school for the amount of any loan discharges resulting from borrower defense claims pertaining to loans first disbursed on or after July 1, 2019; and to provide that the Secretary may initiate a proceeding to recover from an institution the amount of any loan discharged by the Secretary based on a defense to repayment within five years of the date of the final decision to discharge the loan.
- Amend § 685.212 to add borrower defense to repayment discharges to the discharge provisions listed in this section.
- Amend § 685.215 to provide that in cases when a Direct Loan borrower could not obtain an official transcript or diploma from high school and instead provided an attestation to the institution that the borrower was a high school graduate, the borrower will not qualify for a false certification discharge based on not having a high school diploma.
- Amend § 685.300 to require institutions to accept responsibility for the repayment of amounts discharged by the Secretary pursuant to the borrower defense to repayment, closed school discharge, false certification discharge, and unpaid refund discharge regulations.
- Amend § 685.304 to require institutions that use pre-dispute arbitration agreements or class action waivers to provide written, plain language descriptions of those agreements and to provide the student borrower with written information on how to use the school's internal dispute resolution process.
- Amend § 685.308 to require the repayment of funds and the purchase of loans by the school if the Secretary determines that the school is liable as a result of a successful claim for which the Secretary discharged a loan, in whole or in part, pursuant to §§ 685.206, 685.214, and 685.216.

Significant Proposed Regulations

We discuss substantive issues under the sections of the proposed regulations to which they pertain. Generally, we do not address proposed regulatory provisions that are technical or otherwise minor in effect.

In 2016, the Department conducted negotiated rulemaking and published the 2016 final regulations on the topic of borrower defenses to repayment and related issues, but those regulations have not yet gone into effect. On June 16, 2017, the Department published in the **Federal Register** a notification of the partial delay of effective dates under section 705 of the Administrative Procedure Act (5 U.S.C. 705) (82 FR 27621) (705 Notification), for certain provisions of the final regulations until a legal challenge by the California Association of Private Postsecondary Schools is resolved. *See* Complaint and Prayer for Declaratory and Injunctive Relief, *California Association of Private Postsecondary Schools* v. *DeVos*, Civil Action No. 1:17-cv-00999 (D.D.C. May 24, 2017). Subsequently, we published an interim final rule (82 FR 49114), which gave notice that after the 705 notification delayed implementation past July 1, 2017, pursuant to the Department's interpretation of the master calendar requirement, the earliest the regulation could go into effect was July 1, 2018. Then, on February 14, 2018, following a notice of proposed rulemaking, the Department published a final rule establishing July 1, 2019, as the effective date of the 2016 final regulations (83 FR 6458).

We now propose rescission of the 2016 final regulations that we delayed through previous notification. In this preamble, we describe the proposed changes to the regulations based on the currently effective regulations and not the delayed provisions of the 2016 final regulations. In light of the withdrawal (*i.e.* rescission) of the delayed provisions of the 2016 final regulations, this approach is required under 1 CFR part 21, which provides that each agency that drafts regulations must do so as an amendment to the Code of Federal Regulations. The currently effective regulations, not the delayed provisions of the 2016 final regulations, are the provisions codified in the Code of Federal Regulations. Thus, we are

amending the currently effective regulations, not the delayed provisions of the 2016 final regulations, in this NPRM. Throughout the ''Significant Proposed Regulations'' section of this NPRM, we describe our reasoning for the proposed rescissions in the context of the topics to which they pertain. For purposes of determining the budget impact of the regulation, we utilize the 2019 President's Budget Request, which assumed the implementation of the 2016 regulation.

Please note that the following two issues in the 2016 final regulations are being addressed through a separate rulemaking process focused on the Gainful Employment regulations process: The requirement that proprietary schools at which the median borrower has not repaid in full, or paid down by at least one dollar the outstanding balance of, the borrower's loans to provide a Department-issued plain language warning in promotional materials and advertisements; and the requirement for a school to disclose on its website and to prospective and enrolled students if it is required to provide financial protection, such as a letter of credit, to the Department. The Department felt that the Gainful Employment rulemaking was the appropriate place to propose and discuss eliminating these disclosures because the Gainful Employment negotiated rulemaking committee addressed other regulations on disclosures.

Thus, in this NPRM, we propose rescinding the revisions to or additions to the following regulations:

Section 668.14(b)(30), (31), and (32) Program participation agreement.

Section 668.41(h) and (i) Reporting and disclosure of information.

Section 668.71(c) Scope and special definitions.

Section 668.90(a)(3) Initial and final decisions.

Section 668.93(h), (i) and (j) Limitation.

Section 668.171 General.

Section 668.175(c), (d), (f), and (h) Alternative standards and requirements.

Part 668, subpart L, appendix C.

Section 674.33(g)(3) and (8) Repayment.

Section 682.202(b)(1) Permissible charges by lenders to borrowers.

Section 682.211(i)(7) Forbearance.

Section 682.402(d)(3), (d)(6)(ii)(B)(*1*) and (*2*), (d)(6)(ii)(F) introductory text, (d)(6)(ii)(F)(*5*), (d)(6)(ii)(G), (d)(6)(ii)(H) through (K), (d)(7)(ii) and (iii), (d)(8), and (e)(6)(iii) Death, disability, closed school, false certification, unpaid refunds, and bankruptcy payments.

Section 682.405(b)(4)(ii) Loan rehabilitation agreement.

Section 682.410(b)(4) and (b)(6)(viii) Fiscal, administrative, and enforcement requirements.

Section 685.200(f)(3)(v) and (f)(4)(iii) Borrower eligibility.

Section 685.205(b)(6) Forbearance.

Section 685.206(c) Borrower responsibilities and defenses.

Section 685.212(k) Discharge of a loan obligation.

Section 685.214(c)(2), (f)(4) through (7) Closed school discharge.

Section 685.215(a)(1), (c) introductory text, (c)(1) through (8), and (d) Discharge for false certification of student eligibility or unauthorized payment.

Section 685.222 Borrower defenses.

Part 685 subpart B, appendix A Examples of borrower relief.

Section 685.300(b)(11) and (12) and (d) through (i) Agreements between an eligible school and the Secretary for participation in the Direct Loan Program.

Section 685.308(a) Remedial actions.

Note: Section 668.90 has been redesignated as § 668.91 and § 668.93 has been redesignated as § 668.94 pursuant to the borrower defense procedural rule, published January 19, 2017 at 82 FR 6253 (the borrower defense procedural rule).

Borrower Defenses—General (§ 685.206)

Background: Section 455(h) of the HEA authorizes the Secretary to specify which acts or omissions of an institution of higher education a borrower may assert as a defense to the repayment of a Direct Loan. 20 U.S.C. 1087e(h). Under the Department's current regulations at § 685.206(c), a borrower may assert as a defense against repayment of a loan in response to a proceeding by the Department to collect on a Direct Loan, any act or omission of the school attended by the student directly and clearly related to the making of a Direct Loan for enrollment at the institution or the provision of educational services for which the loan was made that would give rise to a cause of action against the school under applicable State law (referred to in this document as the ''State law standard'').

The Department first promulgated the Direct Loan Program's borrower defense to repayment regulation December 1, 1994 (59 FR 61664, 61696), which became effective on July 1, 1995. The Department's intent was for this rule to be effective for the 1995–1996 academic year and then to develop a more extensive rule for both the Direct Loan and FFEL Loan programs through a negotiated rulemaking process. However, based on the recommendation of the non-Federal negotiators on a negotiated rulemaking committee convened in the spring of 1995 (60 FR 37768), the Secretary decided not to develop further regulations or to revise § 685.206(c).

Though the regulation has been in effect since 1995, it was rarely used prior to 2015, when the Department received applications from borrowers for loan relief in response to the Department's announcement (*see www.ed.gov/news/press-releases/fact-sheet-protecting-students-abusive-career-colleges* and *https://studentaid.ed.gov/sa/about/announcements/corinthian*) that it would consider affirmative borrower defense claims.

The current regulation does not set forth the process a borrower may use to assert an affirmative borrower defense claim. Therefore, the Department appointed a Special Master in June 2015 to create and oversee a process to provide debt relief for borrowers who sought Federal student loan discharges based on claims against the borrower's institution. Later, the Department's Federal Student Aid (FSA) office assumed responsibility for resolving these claims, and it continues to do so. This FSA process has proven to be burdensome to borrowers, given the time it takes to adjudicate each claim, and costly to taxpayers.

The Department is considering whether to allow only defensive claims or to continue the approach taken in its 2015 interpretation that allowed it to accept both defensive and affirmative claims. One regulatory alternative, specified in the proposed amendatory language, continues to provide a remedy to borrowers in a collections proceeding, as has been the case since the borrower defense to repayment regulation was promulgated in 1994, by permitting borrowers to assert defense to repayment during a proceeding by the Department to collect on a Direct Loan including, but not limited to, tax refund offset proceedings under 34 CFR 30.33, wage garnishment proceedings under section 488A of the HEA, salary offset proceedings for Federal employees under 34 CFR part 31, and consumer reporting proceedings under 31 U.S.C. 3711(f).

The other regulatory alternative, specified in the proposed amendatory language, would allow for both affirmative claims from borrowers not in a collections action and defensive claims. If we do accept affirmative claims, we would need to develop appropriate deterrents to frivolous claims. At a minimum, the Department

would revise the affirmative claim review process to provide institutions with a reasonable opportunity to see and respond to borrower claims and would require the borrower to sign a waiver that allows the institutions to provide the Department with any information from the borrower's education record that is relevant to the claim. The Department could also limit the period of time after a borrower leaves an institution during which a borrower could make an affirmative claim. Given the Department's long-standing requirement that institutions retain certain documents for only three years, the Department could limit claims to the three-year period following the borrower's departure from the institution to ensure that the institution would have access to records that could be relevant to their defense. The Department seeks public comment on ways to balance the need to serve borrowers with the need to limit unsubstantiated claims and provide an opportunity for the institution to provide evidence in its own defense.

Borrower Defense to Repayment—Assertion of Defenses to Repayment in Collection Proceedings and Federal Standard for Asserting a Borrower Defense to Repayment

Statute: Section 455(h) of the HEA authorizes the Secretary to specify in regulation which acts or omissions of an institution of higher education a borrower may assert as a defense to repayment of a Direct Loan.

Current Regulations: Section 685.206(c) establishes the conditions under which a Direct Loan borrower may assert a defense to repayment, the relief afforded by the Secretary in the event the defense is successful, and the Secretary's authority to recover from the school any loss that results from a defense to repayment discharge granted by the Department. Specifically, § 685.206(c)(1) provides that a borrower may assert a defense to repayment based upon any act or omission of the school that would give rise to a cause of action against the school under applicable State law. The borrower may raise such defense to repayment during a proceeding by the Department to collect on a Direct Loan, including, but not limited to, tax refund offset proceedings under 34 CFR 30.33, wage garnishment proceedings under section 488A of the HEA, salary offset proceedings for Federal employees under 34 CFR part 31, and consumer reporting proceedings under 31 U.S.C. 3711(f). Under the current regulations, since 2015, the Department has accepted affirmative claims, *i.e.,* those not in collection proceedings. Under 34 CFR 685.206(c)(2), if a borrower defense to repayment discharge is approved, the borrower is relieved of the obligation to pay all or part of the loan and associated costs and fees, and may be afforded such further relief as the Secretary determines is appropriate, including, among other things, reimbursement of amounts previously paid toward the loan.

Proposed Regulations: Proposed § 685.206(c) would specify that, with respect to Direct Loans disbursed prior to July 1, 2019, the State law standard would continue to apply. Proposed paragraph (c) maintains that a borrower defense to repayment of these loans may be asserted in proceedings including, but not limited to, tax refund offset proceedings, wage garnishment proceedings, salary offset proceedings for Federal employees, and consumer reporting agency reporting proceedings, but includes clarifications as to statutory and regulatory authorities for those specified proceedings.

Proposed § 685.206(d) would establish a new uniform standard not based upon applicable State law, also referred to here as the ''Federal standard'' for a borrower's defense to repayment discharge on a Direct Loan first disbursed on or after July 1, 2019. First, § 685.206(d)(1) would define terms applicable to the Federal standard, including the term ''borrower defense to repayment.'' Consistent with the Department's current interpretation that it is not appropriate for the taxpayer to face potential loss based on action by schools in matters unrelated to the Department's loan programs, this definition would provide that a borrower defense to repayment discharge must directly and clearly relate to the making of the Direct Loan, or the making of a loan that was repaid by a Direct Consolidation Loan, for enrollment at a school or the provision of educational services for which the loan was obtained. In addition, we clarify that for the purposes of this paragraph, ''borrower'' includes the student who attended the institution for whom Direct Loans (Parent PLUS) were obtained by a parent. Further, under this proposed definition, a ''borrower defense to repayment'' would be considered to include both a defense to repayment of amounts owed to the Secretary on a Direct Loan and reimbursement of payments previously made to the Secretary on the Direct Loan. Proposed § 685.206(d)(1) also would define the terms ''provision of educational services'' and ''school'' and ''institution.''

Parallel to the current regulation, the proposed regulations provide that for loans first disbursed on or after July 1, 2019, a borrower may assert a defense to repayment ''defensive'' claim as part of a proceeding related to certain actions by the Department to collect on a Direct Loan, including tax refund offset proceedings under 26 U.S.C. 6402(d), 31 U.S.C. 3716 and 3720A; wage garnishment proceedings under section 488A of the Act or under 31 U.S.C. 3720D and 34 CFR part 34; salary offset proceedings for Federal employees under 34 CFR part 31, 5 U.S.C. 5514, and 31 U.S.C. 3716; and consumer reporting agency reporting proceedings under 31 U.S.C. 3711(e). This language is reflected in proposed § 685.206(d)(2)—Alternative A.

The Department is also considering accepting ''affirmative'' claims from borrowers not in a collections action. Proposed regulatory language for this approach is set forth in § 685.206(d)(2)—Alternative B. Like Alternative A, Alternative B proposes to consider both affirmative and defensive claims under a preponderance of the evidence standard. But the Department seeks comment on whether claims under this regulatory alternative should have to be supported by clear and convincing evidence, rather than a preponderance of the evidence. Such a standard might be appropriate, as it is the standard used in most States for adjudicating fraud litigation and could deter some frivolous affirmative claims. *See* Restatement (Third) of Torts: Liab. for Econ. Harm section 9 TD No 2 (2014) (''The elements of a tort claim ordinarily must be proven by a preponderance of the evidence, but most courts have required clear and convincing evidence to establish some or all of the elements of fraud.'')

The Department is interested in comments regarding the benefits or risks of these proposals. The Department also seeks public comments regarding other mechanisms that could be utilized to discourage the submission of frivolous claims, which are costly for the Department and institutions to adjudicate. Such mechanisms could include limiting the period of time after a borrower leaves an institution during which a defense to repayment claim can be submitted (such as imposing a 3 year limit on borrower defense to repayment claims to align with the Department's 3 year record retention requirement).

Under this proposed regulation, the Department would develop a claim review process for either (or both) defensive or affirmative claims that would provide institutions with a reasonable opportunity to see and

respond to borrower claims. The Department proposes, for example, to require the borrower to sign a waiver that allows the institution to provide the Department with any information from the borrower's education records that is relevant to the claim. The Department also proposes to require borrowers to submit information about whether, for reasons other than the education received, the borrower has been removed from a job due to on-the-job-performance, disqualified from work in the field for which the borrower trained, or worked less than full-time in the chosen field. Such circumstances would not disqualify a borrower from a successful defense to repayment, but might be relevant to determining whether the asserted financial harm was in fact caused by an alleged misrepresentation.

The proposed regulations also would remind borrowers submitting affirmative or defensive claims that if the borrower receives a 100 percent discharge for the loan, the institution has the right to withhold an official transcript for the borrower, as has always been the case in instances in which the borrower has been awarded student loan discharge through false certification, closed school or defense to repayment discharge.

The Department also welcomes comments regarding the process the Department might use to collect evidence from borrowers and schools, to evaluate the merits of a borrower's defense to repayment claim, and to render decisions on claims that are submitted affirmatively.

Under proposed § 685.206(d)(4), a borrower defense to repayment related to a loan that was repaid by a Direct Consolidation Loan disbursed on or after July 1, 2019, would be evaluated under the proposed Federal standard. Although this approach may result in different treatment of some borrowers who took out loans before this NPRM, such differences in treatment would arise only if the borrower chose to take out a new Direct Consolidation Loan after July 1, 2019. This is consistent with the longstanding treatment of consolidation loans as new loans. The Department is interested in comments as to whether this structure would likely lead borrowers to engage in, or borrower advocates to encourage, strategic default for the sole purpose of asserting a defense to repayment. Proposed § 685.206(d)(5) includes two alternatives relating to affirmative and defensive claims.

Section 685.206(d)(5)(i) and (ii)—Alternative A provides that the Secretary will approve the borrower's defense to repayment claim if a preponderance of the evidence establishes that the school at which the borrower was enrolled made a misrepresentation, upon which the borrower reasonably relied under the circumstances in deciding to obtain a Direct Loan (or a loan repaid by a Direct Consolidation Loan) for the student to enroll in a program at the school which resulted in financial harm to the borrower. The proposed regulations in § 685.206(d)(5) would define misrepresentation as a statement, act, or omission by the eligible institution to the borrower that is (i) false, misleading, or deceptive, (ii) made with knowledge of its false, misleading, or deceptive nature or with a reckless disregard for the truth, and (iii) directly and clearly related to the making of a Direct Loan for enrollment at the school or to the provision of educational services for which the loan was made. Proposed section 685.206(d)(5)(i) and (ii)—Alternative B contains the same language with respect to defensive claims and extends the proposed standard to affirmative claims.

Proposed § 685.206(d)(5)(iii) sets forth that the Secretary may consider additional information when evaluating a claim. Proposed § 685.206(d)(5)(iv) would provide additional information about what may constitute a preponderance of the evidence of a misrepresentation and evidence of financial harm. The Department is interested in comments as to whether it should require clear and convincing evidence of misrepresentation and financial harm (as opposed to a preponderance of the evidence of misrepresentation and financial harm) in the event it continues to consider affirmative claims.

Proposed § 685.206(d)(6) would clarify that a school's violation of an eligibility or compliance requirement in the HEA or the Department's implementing regulations is not a basis for a borrower defense to repayment unless that conduct would, by itself, establish a basis for a defense to repayment. Proposed § 685.206(d)(6) also lists other circumstances that would not suffice to establish a defense to repayment under the proposed Federal standard.

Reasons: During the public hearings and negotiated rulemaking sessions, the Department heard from representatives from a broad range of constituencies on what they thought was an appropriate basis for a borrower defense to repayment. At the negotiated rulemaking sessions, negotiators expressed a shared desire to develop a regulation that would provide for fair treatment of borrowers who had been harmed by an act or omission of a school, but differed widely in their views of how this might be achieved. The Department began negotiations by asking whether we should establish a Federal standard for evaluating future borrower defense to repayment applications.

Defense to Repayment—Assertion of Borrower Defenses

As part of the discussions of a Federal standard, negotiators debated whether borrowers should be allowed to assert defenses to repayment affirmatively—in other words, at any point of time regardless of whether the borrower's loan is in default and the subject of Department collection proceedings—or only defensively, during such collection proceedings. Many negotiators were in favor of permitting borrowers to pursue affirmative claims to allow borrowers an opportunity to rectify the harm stemming from an act or omission of a school. One negotiator noted that the current regulation implies that a borrower raises a defense to repayment in response to collection activities and asked what, if any, discretion the Department might have to interpret the regulation more broadly. Another negotiator asserted that she understood that the Department did not interpret the current regulation to limit claims to borrowers who are in default and that it had allowed affirmative applications to be submitted by borrowers.

From 1994 to 2015, the Department's regulation—as per earlier negotiated rulemaking—provided defense to repayment loan discharge opportunities only to borrowers who were in a collection proceedings. As a matter of practice, starting in 2015 and later codified in the 2016 regulations, the Department has (primarily in response to the closure of Corinthian Colleges, Inc.) accepted borrower defenses to repayment requests asserted affirmatively outside of the collection proceedings specifically listed in the existing regulation.

We are now considering that for loans first disbursed on or after July 1, 2019, the Department return to the pre-2015 interpretation such that borrowers may only submit applications in connection with one of the specific collection proceedings listed in current § 685.206(c). The language of both the statute and existing regulations on borrower defenses is consistent with this approach, and the Department believes it may better balance the competing interests of borrowers and taxpayers. Under this approach, the Department would view the assertion of

defenses to repayment as a last resort for borrowers, with disputes between borrowers and schools primarily resolved by those parties in the first instance. The proposal to allow borrowers to assert defenses to repayment during the enumerated Department collection proceedings, and not as affirmative claims at any point in time, aligns with the Department's 20 year prior practice and protects taxpayers from liabilities that should be leveraged first against the institutions that committed acts or omissions covered by the defense to repayment provision.

Section 455(h) of the HEA provides that ''a borrower may assert . . . a *defense* to repayment of a loan made under [the Direct Loan Program],'' on the basis of an act or omission of a school, as specified by the Secretary. 20 U.S.C. 1087e(h) (emphasis added). The current regulations implementing the statutory provision reflect the Department's understanding at the time of the rule's promulgation in 1994 that the statute directs the Department to provide borrowers with a *defense* to repayment, as part of certain Department collection actions. *See* 34 CFR 685.206(c)(1) (''In any proceeding to collect on a Direct Loan, the borrower may assert [ ] a *defense* to repayment . . . These proceedings include, but are not limited to, the following . . .'' (emphasis added)). The proceedings referenced in the regulation only occur after a borrower defaults on a loan.

The Department processed a small number of defense to repayment claims from borrowers in a collections proceeding under the existing regulation from 1994 through 2015. In response to the closure of Corinthian Colleges, Inc. (CCI) in 2015, however, the Department changed its position and began to accept borrowers' requests for the type of relief (loan discharges and certain further relief) provided under 34 CFR 685.206(c), even before the borrower defaulted on a loan—or, in other words, the Department allowed borrowers to affirmatively assert borrower defense claims. As a result, the Department was flooded with tens of thousands of borrower defense claims before it had promulgated new regulations that officially notified the public of this new interpretation or established a mechanism or structure under which to adjudicate the large volume of claims.

After further consideration of the history and regulatory provisions governing borrower defenses, the Department believes that it may be appropriate to provide in the proposed regulations that, for loans first disbursed after the proposed rules' anticipated effective date of July 1, 2019, borrowers may request a loan discharge and related relief under the proposed Federal misrepresentation standard for such requests only by asserting such defense in a proceeding to collect on the loan by the Department (*i.e.,* a tax refund offset proceeding, a wage garnishment proceeding, a salary offset proceeding for a Federal employee, or a consumer reporting agency reporting proceeding).

As noted above, this proposal is squarely within the Department's authority under section 455(h) of the HEA to ''specify in regulations which acts or omissions of an institution of higher education a borrower may assert as a *defense* to repayment'' of a Direct Loan. 20 U.S.C. 1087e(h) (emphasis added). It is also consistent with the Department's direction that students should use processes already in place at schools, as well as at accrediting agencies and State authorizing agencies, to resolve issues relating to the services provided by the institution as quickly as possible following any incident, rather than delaying corrective action and shifting the financial burden to the taxpayer.

This differs from the approach taken in the 2016 final regulations. In those regulations, the Department took the approach it had adopted in 2015 to allow affirmative defense to repayment claims and accordingly would have removed language referencing the Department's collection proceedings as the forum for a borrower's assertion of a defense to repayment. The Department continues to consider whether to accept affirmative claims from borrowers, as opposed to only accepting defensive claims from borrowers during a specified collection proceeding. However, the Department believes that if it were to allow affirmative claims, it would need to also consider appropriate deterrents to frivolous claims.

The Department is concerned that in the event of affirmative claims, it is relatively easy for a borrower to submit an application for loan relief, even if the borrower has suffered no harm, on the chance that perhaps some amount of loan forgiveness will be awarded. Although the barriers to submitting a claim are low for borrowers, the collective burden of numerous unjustified claims could be significant for both the Department and institutions. This could delay our efforts to review and provide loan relief to borrowers who have been genuinely harmed. The Department seeks comment on how it could continue to accept and review affirmative claims, but at the same time discourage borrowers from submitting unjustified claims. One idea is to increase the evidentiary standard to ''clear and convincing'' for affirmative claims. The Department seeks comment on whether or not this evidentiary standard would be appropriate to balance the need to serve borrowers who have been harmed and the need to reduce the number of unjustified claims students might otherwise submit. If such a standard is warranted, the Department also seeks comment about whether it should continue to evaluate defensive claims under the preponderance of the evidence standard and on the rationale for having two different evidentiary standards.

The Department believes that, even if it continues to accept affirmative claims, it must also accept defensive claims so both students in repayment and students in collections have access to remedies for instances of fraud.

Defense to Repayment—Federal Standard (Provision of Educational Services and Relationship With the Loan)

The language we propose in this NPRM clarifies that the misrepresentation of a school forming the basis of a borrower defense to repayment discharge must directly and clearly relate to the making of a Direct Loan for enrollment at the school or the provision of educational services for which the loan was made. This language reflects the Department's consistent position, as explained in a Notice of Interpretation issued in 1995 (60 FR 37769) and adopted in the 2016 final regulations (81 FR 76080 (revised 34 CFR 685.206(c)(1)), 76083 (new 34 CFR 685.222(a)(5))), that the Department will acknowledge a borrower defense to repayment only if it directly relates to the loan or to the school's provision of educational services for which the loan was provided.

Some non-Federal negotiators requested that the regulation define the term ''provision of educational services'' and include a reference to educational resources. Another non-Federal negotiator noted that the Department has made its understanding of this term ''provision of educational services'' clear in the regulatory history for the borrower defense regulation and that there are well-developed bodies of State law that explain this term.

The Department agrees that the term ''provision of educational services'' is open to interpretation and, in proposed § 685.206(d), we define that term as ''the educational resources provided by the institution that are required by an accreditation agency or a state licensing

or authorizing agency for the completion of the student's educational program.'' We thus intend for a misrepresentation relating to the ''provision of educational services'' to be clearly and directly related to the borrower's program of study. We also intend misrepresentation to include items such as the nature of the school's educational program or related resources required by an accreditor or licensing authority, the nature of the school's financial charges, the advertised outcomes (including job placement rates, licensure pass rates, and graduation rates) of prior graduates of the school's educational program, an institution's published rankings or selectivity statistics, the eligibility of graduates of the educational program for licensure or certification, the State agency authorization or approval of the school or educational program, or an accreditor approval of the school or educational program.

Defense to Repayment—Consolidation Loans

The Department proposes that for a Direct Consolidation Loan first issued on or after the anticipated effective date of these regulations, a borrower may assert a defense to repayment under the proposed Federal standard (discussed below). Under the Department's existing regulation at 34 CFR 685.220, a borrower may consolidate certain specified loans into a Direct Consolidation Loan. Generally, the Department views a consolidation loan as a new loan, distinct from the underlying loans that were paid in full by the proceeds of the Direct Consolidation Loan. The Department's borrower defense authority is part of the Direct Loan Program, *see* 20 U.S.C. 1087e(h) (''[A] borrower may assert . . . a defense to repayment of a loan made under this part [as to the Direct Loan Program]'') and Direct Consolidation Loans are made under the Direct Loan Program. As a result, the Department's existing practice is to provide relief under the Direct Loan authority if the underlying loans have been consolidated under the Direct Loan Program into a Direct Consolidation Loan. Or, if consolidation is being considered depending on the outcome of any preliminary analysis of whether relief might be available under 34 CFR 685.206(c), relief is not actually provided until the borrower's loans have been consolidated into a Direct Consolidation Loan.

The Department's proposal clarifies the Department's position and the standard that it proposes to use to evaluate a Direct Consolidation Loan borrower's defense to repayment claim. The Department will consider a misrepresentation that the borrower reasonably relied upon under the circumstances in deciding to obtain the underlying loan repaid by the Direct Consolidation Loan, for the student to enroll or continue enrollment in a program at an institution.

The Department's standard is designed to provide borrowers with relief for the misrepresentations made with either knowledge of their false, misleading, or deceptive nature, or with a reckless disregard for the truth. Where misconduct of such nature has been demonstrated, the Department believes it is appropriate to provide borrowers with relief, regardless of whether the underlying loan is a Direct Loan. However, given that the Department's borrower defense authority is part of the Direct Loan Program, *see* 20 U.S.C. 1087e(h) (''[A] borrower may assert . . . a defense to repayment of a loan made under this part [as to the Direct Loan Program]''), the Department will only consider providing such relief if the underlying loans were themselves Direct Loans or have been consolidated under the Direct Loan Program, into a Direct Consolidation Loan. If a defense to repayment was approved on a Direct Consolidation Loan, borrowers would receive a discharge of the remaining balance on their Direct Consolidation Loan in an amount proportionate to the amount of the underlying loan at issue and would receive proportionate reimbursements of any payments made to the Secretary on the underlying loan or the Direct Consolidation Loan. *See Hiatt* v. *Indiana State Student Assistance Comm. (In re Hiatt),* 36 F.3d. 21, 24 (7th Cir., 1994) and *In re McBurney,* 357 B.R. 536, 538 (9th Cir BAP, 2006), supporting the consideration of consolidation loans as new loans.

Under the Department's proposal, the standard that would be applied to determine if a defense to repayment has been established is the Federal standard for Direct Consolidation Loans first disbursed after July 1, 2019. The 2016 final regulations would have similarly applied a Federal standard to some underlying loans that were *not* Direct Loans, but it would have done so based upon the underlying loans' date of first disbursement. Thus, under the 2016 final regulations, the same claim might have required the application of different standards to different underlying loans, if the borrower had both underlying Direct Loans and loans that are not Direct Loans. The Department believes that the language it proposes in this NPRM is more consistent with the Department's longstanding policy regarding the treatment of consolidated loans, would be more easily understood, would create less confusion for schools and borrowers, and would be easier to administer for the Department. Further, as a consolidation loan is a new loan, the Department believes it is appropriate to apply the date of first disbursement of that loan to determine what standard would apply. The Department understands that this approach may deter some borrowers who might otherwise wish to consolidate their loans but do not wish to be subject to the proposed standard and associated time limits. But the Department believes that this concern is outweighed by the benefits of this standard. In all events, as under the existing regulations, a borrower would be able to choose consolidation if he or she determines it is the right option for the borrower. The Department invites comment on this approach.

Defense to Repayment—Federal Standard (Misrepresentation)

In this rulemaking, the Department is proposing an exclusively Federal standard not based in State law for loans disbursed after July 1, 2019, for ease of administration and to provide fair, equitable treatment for all borrowers regardless of the State in which the school is located or the student was in residence while enrolled or while in repayment. That Federal standard differs somewhat from the ''substantial misrepresentation'' standard adopted in the 2016 final regulations and drawn from more general enforcement contexts. 81 FR 75939–75940. It also differs somewhat from the proposal that the Department offered during negotiations, in that it relies solely on misrepresentation as the basis for discharge, rather than also allowing final judgments to serve as a basis for discharge. As discussed in more detail below, the Department believes that the standard it proposes will provide more equitable treatment for borrowers and ease of administration for the Department.

During discussions relating to the Federal standard for borrower defense to repayment applications, negotiators disagreed about whether to establish a Federal standard at all. Some negotiators expressed opposition, arguing that protecting consumers and ensuring the educational quality of schools licensed to operate by the State are the responsibilities of the States. Other negotiators noted that a Federal standard not based in State law could disadvantage borrowers. Many States'

consumer protection laws might be more favorable to borrowers than the Federal standard proposed by the Department (discussed immediately below). These negotiators also noted that the proposed Departmental process to adjudicate claims under a Federal standard would not provide borrowers with the benefit of a discovery process like the one that exists in judicial proceedings. Still, many negotiators supported establishing a Federal standard, arguing that doing so would provide clarity, uniformity of borrower treatment, and ease of administration. Some negotiators stated that the Department should adopt a structure under which a Federal standard would serve as a minimum standard, but with the Department also evaluating whether a borrower defense claim would receive more favorable treatment under applicable State law and then applying the more favorable standard to the borrower defense claim.

The Department is persuaded that an exclusively Federal standard for borrower defense to repayment applications is appropriate. The Department's primary reason for proposing a Federal standard for borrower defenses to repayment is that Direct Loans are Federal assets and the benefits of such loans should be established by Federal law. In addition, the Department believes that using a Federal standard will reduce the burden on borrowers and the Department. Applying a State law-based standard means that borrowers have to determine which State law applies to their claim and the Department has to review that determination. Moreover, borrowers in some States may have access to more favorable law than borrowers in other States for the same Federal defense to repayment. In contrast, applying a Federal standard will eliminate the issue of what law applies and ensure that all borrowers' claims are evaluated under the same rules.

The Department's proposed Federal standard is a modified version of the proposal it offered at the negotiated rulemaking sessions. The Department's proposal during negotiations would have included two different bases for a borrower to assert a defense to repayment for loans first disbursed on or after July 1, 2019: (1) A final, definitive judgment by a State or Federal court of competent jurisdiction, rendered in a contested proceeding, where the borrower was awarded monetary damages against the institution relating to the student's enrollment at the subject institution or the provision of educational services for which the loan was obtained, and (2) generally, a misrepresentation by the school made with intent to deceive, knowledge of the falsity of the misrepresentation, or a reckless disregard for the truth, and that resulted in financial harm to the borrower. In this NPRM, the Department now proposes a modified version of the second basis for relief—a misrepresentation standard, as discussed in depth below.

With regard to the misrepresentation standard, negotiators disagreed on the appropriate definition of ''misrepresentation'' and whether the borrower should be required to prove the school's intent, knowledge of falsity, or reckless disregard for the truth. Some negotiators argued that it would be difficult for a borrower to prove that a school had acted with the requisite intent or had knowledge of the falsity of the misrepresentation, and that it would also be difficult for a borrower to demonstrate that the school had engaged in a level of misconduct that would amount to a ''reckless disregard for the truth.'' These negotiators argued in favor of a standard that would enable borrowers to avail themselves of the full range of States' consumer protection laws that prohibit certain unfair and deceptive conduct (commonly known as ''unfair and deceptive trade acts and practices'' or ''UDAP'' laws). Some negotiators argued the Department should not approve borrower defenses and also hold a school liable for losses from approvals of misrepresentation-based defenses to repayment, if the school had committed an inadvertent mistake or if the misrepresentation had been made by an employee acting without the school's knowledge or against the school's direction.

The 2016 final regulations provided that a borrower may assert a borrower defense for a ''substantial misrepresentation'' as defined in the Department's regulation at 34 CFR 668.71, if the school, any of its representatives, or any institution, organization, or person with whom the school has an agreement for specified services made such a substantial misrepresentation that the borrower reasonably relied on to the borrower's detriment in deciding to attend, or continue attending, the school or in deciding to take out a Direct Loan. *See* 81 FR 76083 (text for 34 CFR 685.222(d)). The 2016 final regulations also included a non-exclusive list of circumstances for a Department official to consider in determining whether the borrower's reliance was reasonable. Under those regulations, a borrower would be able to assert such a borrower defense to recover funds previously collected by the Secretary not later than six years after the borrower discovered, or reasonably could have discovered, the substantial misrepresentation. The borrower would also be able to assert a defense to any outstanding amounts owed on the loan at any time.

The ''substantial misrepresentation'' definition was drawn from § 668.71, which permits the Department to bring an enforcement action for a substantial misrepresentation in the form of a suspension, limitation, termination, or fine action. The section generally defines a misrepresentation as any false, erroneous, or misleading statement made by a school, and it defines a misleading statement to include any orally or visually made statement, or one that is made in writing or by other means, that has the likelihood or tendency to deceive. It then defines a ''substantial misrepresentation'' as any misrepresentation on which the person to whom it was made could reasonably be expected to rely, or has relied, to that person's detriment. The 2016 final regulations amended the language of § 668.71 to explicitly note that an omission of information can amount to a misrepresentation. 81 FR 76072 (text of language added to 34 CFR 668.71). As stated above, while a substantial misrepresentation under current § 668.71 includes misrepresentations that a person had relied upon or could reasonably have been expected to rely upon, for the purposes of borrower defense to repayment under the 2016 final regulations, a substantial misrepresentation would have been found only if the person had, indeed, reasonably relied upon the misrepresentation to his or her detriment.

In this NPRM, the Department proposes a different Federal standard for defenses to repayment based upon misrepresentations by an institution to the borrower. Under the proposed standard, a misrepresentation is a statement, act, or omission by an eligible institution to a borrower upon which the borrower reasonably relies that is false, misleading, deceptive, and made with knowledge of its false, misleading, or deceptive nature or with reckless disregard for the truth and directly and clearly related to the making of a Direct Loan, or a loan repaid by a Direct Consolidation Loan, for enrollment at the school or to the provision of educational services for which the loan was made. The vast majority of the borrower defense claims filed since 2015 have alleged that the school at issue made statements to the borrower that amount to misrepresentations under State law. As

a result, we believe it is appropriate to base the Federal standard upon a school's misrepresentations. We have removed breach of contract or State law judgment as a standard for borrower defense relief since breach of contract or a State law judgment may be for actions or events not directly related to the educational services provided by the institution, and therefore do not qualify for relief under borrower defense to repayment. That said, a State law judgment could serve as evidence provided by a borrower in filing a borrower defense to repayment application.

Nothing in this proposed regulation attempts to prevent a borrower from taking action against an institution of higher education based on State law. However, for the purpose of evaluating a borrower's defense to repayment claim, only the new Federal standard will be considered.

The proposed standard takes the same position as in the 2016 final regulations that certain persons and institutions affiliated with a school may make misrepresentations leading to a borrower defense to repayment under circumstances generally understood to render those misrepresentations attributable to the school.

In the 2016 final regulations, the Department declined to include a requirement that the borrower prove that the school had acted with intent in making the misrepresentation. In the preamble to those regulations, the Department also specifically declined to include any requirement that the Department find that the school had knowledge of the misrepresentation. 81 FR 75947. The Department reasoned, in 2016, that it is more reasonable and fair to have an institution be responsible for the harm caused to borrowers as a result of a misrepresentation, even if such a misrepresentation is the result of innocent or inadvertent mistakes. *Id.* at 75947–75948.

As was the case in the 2016 final regulations, the Department does not propose that a defense to repayment be approved only when a school can be shown to have made a misrepresentation with the intent to induce the reliance of the borrower on the misrepresentation. The Department agrees with negotiators that it is unlikely that a borrower would have evidence to demonstrate that an institution had acted with intent to deceive. But given its responsibility to the Federal taxpayer, the Department believes that defense to repayment should be granted only where a preponderance of the evidence shows that a school has made a misrepresentation with either knowledge of its falsity or with a reckless disregard of the truth. The Department's proposal includes a non-exhaustive list of evidence that may indicate that such a misrepresentation took place. The Department believes that this standard strikes a balance between protecting borrowers by establishing a standard of evidence that is reasonable for a borrower to meet and protecting the Federal taxpayer by requiring a level of evidence that ensures misrepresentation actually took place and the student relied upon that misrepresentation and suffered harm.

Like the 2016 final regulations, the Department's proposed misrepresentation standard also covers omissions. The Department believes that an omission of information that makes a statement false, misleading, or deceptive can cause injury to borrowers and can serve as the basis for a defense to repayment. As it did in the 2016 final regulations, the Department recognizes that the reasonableness of a borrower's reliance on the misrepresentation may depend upon the circumstances, and its proposed rule thus states that the Department will look at whether a borrower reasonably relied upon the misrepresentation ''under the circumstances.''

Under the proposed alternative regulations, which would return to the practice of allowing borrower defense to repayment applications only in response to Department collection proceedings, the proposed standard differs from the time limitations imposed under the 2016 final regulations. Those regulations imposed a six-year limitation period on a borrower's ability to raise a defense to repayment claim for amounts previously collected. Under the proposed standard, a borrower may be able to assert a defense to repayment at any time during the repayment period, once the loan is in collections, regardless of whether the collection proceeding is one year or many years after a borrower's discovery of the misrepresentation. The proposal does not impose a limit on the borrower's ability to recover amounts previously collected by the Department.

The Department considered an alternative approach in which the borrower would have only three years following the end of enrollment at the institution to assert a defense to repayment claim. This three-year limit corresponds to the three-year record retention policy imposed by the Department. It is unlikely that it would take a borrower more than three years to realize that he or she was harmed by misrepresentations upon which the borrower relied to make an enrollment decision. However, since collection proceedings can be initiated at any time during the repayment period, the current proposal similarly provides borrowers with the opportunity to assert a defense to repayment during a collection proceeding, regardless of how many years after enrollment that proceeding is commenced. In the event that the Department is persuaded by public comments provided in response to this NPRM to continue accepting affirmative claims, the Department proposes to implement a three-year limit on filing claims after the end of the borrower's enrollment at the institution accused of misrepresentation.

The proposed standard also differs from the 2016 final regulations in that it does not include breach of contract or a State law judgment as a standard for defense to repayment. Although those standards are utilized by the Department in enforcement actions, and breach of contract or a State law judgment could be used as evidence to substantiate a borrower defense claim, breach of contract or a State law judgment, alone, does not automatically qualify a borrower for borrower defense to repayment relief since these may pertain to actions or activities other than the institution's provision of educational services.

Some negotiators noted that consumer protection laws governing misrepresentations are generally the province of the States, but the Department's proposed Federal standard would not invade that province. The proposed Federal standard would not prevent a borrower from pursuing a claim against a school based on a violation of State law. It simply would not provide for that claim to be the basis of a borrower defense to repayment claim. Thus, it would leave such State law claims to be pursued through arbitration, State courts, or other administrative bodies responsible for adjudicating them.

Other negotiators expressed concern that changes to a financial aid award letter not be construed as misrepresentations, and the Department agrees that such changes ordinarily would not qualify as misrepresentations. For example, if a financial aid award letter changes as a result of a change in the borrower's financial circumstances, the Department would not consider the change to form the basis of a borrower defense to repayment claim under our proposed regulations.

Borrower Defense—Judgments and Breach of Contract

During the negotiations, the Department discussed using a non-default, contested Federal or State court judgment issued by a court of competent jurisdiction, as a possible basis for borrower defense claims. Negotiators expressed support generally for a judgment-based standard as one basis for a claim, but some negotiators expressed concern that lawsuits based on the acts or omissions of a school have often been concluded by default judgments that did not result from a contested proceeding or by settlement. Some negotiators also expressed the concern that borrowers may not have the resources to bring such lawsuits or that the schools may require borrowers to execute agreements that would prevent such lawsuits. They urged that the Department accept judgments obtained by government entities, such as State Attorneys General. However, since Direct Loans are Federal assets, only the Federal government has the authority to relieve a borrower of his or her repayment obligation. Therefore, although a State law judgment could serve as evidence to support a borrower defense to repayment claim, the judgment alone would not be sufficient to grant automatic relief.

The Department had included non-default, favorable contested judgments as a basis for a borrower defense claim for loans first disbursed after the anticipated effective date of the 2016 final regulations. In the preamble to those regulations, the Department stated that while it does not anticipate such judgments to be common, such a standard would allow the Department to continue to recognize State law causes of action, without putting the burden on the Department to interpret and apply States' laws. 81 FR 75941–75942. However, this does not alleviate the inequities that can result if, as a result of differences in State laws, two borrowers who have suffered equal harm as the result of the same misrepresentation receive different treatment. Therefore, in this regulation we propose a single Federal standard that would ensure equal treatment of borrowers regardless of where they live or their school is located.

The Department acknowledges negotiators' concerns that some court cases do not result in contested, non-default judgments, such as where the institution chooses to settle pending litigation or an arbitration proceeding and satisfies the claim pursuant to a settlement agreement or consent judgment, or where an insurer for the institution satisfies the claim. But the Department believes this concern is less pressing for these regulations, which do not propose a judgment-based standard for a defense to repayment claims. The Department also acknowledges that private parties often settle disputes among themselves without court action. The Department believes that it is preferable for a school (or its insurer, if such coverage exists) to satisfy a student borrower's meritorious claims of misrepresentation against it and to provide appropriate relief directly to the student borrower for the school's own actions where it is merited. A borrower who receives a favorable decision in such a dispute but believes he or she still has not received the relief to which he or she is entitled may submit the record of that dispute process and decision as evidence in support of the defense to repayment claim with the Department. As part of its adjudication of a defense to repayment, and if the evidence is directly and clearly related to the loan or to the school's provision of education services for which the loan was provided, the Department may also consider as evidence findings of fact by a court of competent jurisdiction or arbitrator, admissions of fact by the school made in a court of competent jurisdiction or arbitration, and court orders.

During the negotiated rulemaking sessions, one negotiator proposed including breaches of contract as a basis for borrower defense claims. In 2016, the Department included breach of contract as a basis for borrower defense in recognition of lawsuits borrowers have brought alleging breaches of contract. 81 FR 39341. But the majority of the defense to repayment applications before the Secretary do not allege breaches of contract, and the Department believes it is appropriate in these proposed regulations to tailor the standard to the types of claims being alleged by borrowers. Moreover, breach of contract, as described in the 2016 regulations, would cover conduct beyond the scope of defense to repayment since breach of contract is not limited to the provision of education services. If the conduct underlying a breach of contract would satisfy the proposed requirements for a misrepresentation, a borrower may assert a defense to repayment for that misrepresentation during a collection proceeding. Or, prior to those proceedings, a borrower may pursue more expedient relief through a school's internal dispute process, arbitration, or other legal proceeding.

While the Department is proposing a new Federal standard based in misrepresentation for loans first disbursed on or after the anticipated effective date of the proposed regulations, July 1, 2019, we are not proposing any changes to the existing State law standard (or, as noted above, the context in which a defense to repayment may be requested) for loans first disbursed before the anticipated effective date of these regulations. Rather, for loans made on or before July 1, 2019, the Department proposes to keep the State law-based standard in the currently effective regulations. In the event that a borrower enters into a consolidation loan, the date on which the loan was consolidated (prior to or after July 1, 2019) determines whether the Department will review a defense to repayment claim based on a State law standard or the proposed Federal standard.

Borrower Defense—Evidentiary Standard for Asserting a Borrower Defense

During the negotiated rulemaking sessions, negotiators were divided on the evidentiary standard that should be applied to borrower defense to repayment claims adjudicated by the Department under a Federal standard. There were extensive discussions regarding the meaning of, and differences between, the terms ''clear and convincing evidence'' and ''preponderance of the evidence.'' Some negotiators argued that the evidentiary standard should use terms that are consistent with legal terminology and precedent. Other negotiators advocated using an evidentiary standard that is not based on legal terminology and might be clearer to individual borrowers. In addition, several negotiators argued in favor of an evidentiary standard based on ''clear and convincing evidence;'' others argued that a ''preponderance of the evidence'' standard would be fairer to borrowers, since it would not require a high level of evidence that borrowers would be unlikely to be able to provide. One negotiator noted that preponderance of the evidence is the typical standard that applies in civil cases. Negotiators representing consumer advocates asserted that the Department's proposal to apply a preponderance of the evidence standard that requires corroboration of the borrower's attestation would be harder to satisfy than a simpler preponderance of the evidence standard.

We preliminarily agree with negotiators that, given the types of evidence borrowers are likely to have in their possession, a preponderance of the evidence standard is appropriate. The Department is accordingly proposing an

evidentiary standard that requires the borrower to establish by a preponderance of the evidence that the school at which the borrower enrolled made a statement, act, or omission directly and clearly related to enrollment at the school or the provision of educational services upon which the borrower reasonably relied under the circumstances in deciding to obtain a Direct Loan to enroll or continue enrollment in a program at the school that resulted in financial harm to the borrower.

As we noted in the 2016 final regulations, the Department uses a preponderance of the evidence standard in other proceedings regarding borrower debt issues. See 34 CFR 34.14(b), (c) (administrative wage garnishment); 34 CFR 31.7(e) (Federal salary offset). We believe that this evidentiary standard strikes a balance between ensuring that borrowers who have been harmed are not subject to an overly burdensome evidentiary standard and protecting the Federal government, taxpayers, and institutions from unsubstantiated claims.

Proposed § 685.206(d)(5)(ii)—Alternative A would provide that the Secretary will find that the preponderance of the evidence supports the approval of a borrower defense to repayment discharge when the borrower's attestation is supported by sufficient evidence provided by the borrower or otherwise in the possession of the Secretary. The Secretary will permit the institution to review and respond to this evidence and will consider the school's response. Alternative B for this section would extend this standard to affirmative claims as well.

Borrower Defense—Financial Harm

Consistent with its proposal during the negotiated rulemaking sessions, the Department proposes that a misrepresentation may serve as a basis for a borrower defense to repayment only if the misrepresentation resulted in financial harm to the borrower. During discussions of this issue, some negotiators argued that the act of taking a Federal student loan should be sufficient evidence of financial harm to the borrower. These negotiators suggested that, absent the misrepresentation, the borrower may have opted to not take a Federal student loan.

The Department does not agree that taking a Federal student loan, by itself, is sufficient evidence of financial harm to the borrower in the context of a borrower defense to repayment. Borrowers consider a variety of factors in choosing a school or program, including not just cost, but also other attributes of the school, such as its facilities, convenience, and the opportunity for the student to enroll in his or her program of choice (which may be unavailable to the student at other institutions). The borrower has the opportunity to compare schools' and programs' relative costs and other factors before committing to borrow and repay a Federal student loan, and the borrower has the opportunity to leave an institution should it not provide educational opportunities or experiences commensurate with the borrower's expectations. Therefore, even in the event of misrepresentation, the borrower may not be successful in receiving loan relief under the defense to repayment regulation if that misrepresentation was not the basis for the borrower's enrollment decision or it did not cause subsequent financial harm.

Moreover, the Master Promissory Note signed by the borrower describes the borrower's obligation to repay the full amount of the loan even if the student borrower (or the student for whom a PLUS loan was obtained) does not complete the program, does not complete the program within the regular time for program completion, is unable to obtain employment upon completion, or is otherwise dissatisfied with or does not receive the educational or other services that the student borrower purchased from the school. The foregoing information is provided to borrowers again during entrance counseling.

As discussed earlier, some negotiators were concerned that a borrower might allege misrepresentation on the part of the school based solely on a change in the borrower's financial aid award due to changes in financial circumstances or the availability of outside aid, such as vocational rehabilitation funding. The Department does not view such changes to necessarily be evidence of a misrepresentation on the part of the school. Instead, the proposed regulations specify that financial harm may be established if, for example, there were a significant difference between the actual amount or nature of the tuition and fees charged by the school for which the Direct Loan was obtained and the amount or nature of the tuition and fees that the school represented to the borrower the school would charge or was charging. Similarly, financial harm might be established if an institution awarded sizeable grants or scholarships to attract a student to an institution, but then failed to continue such support throughout the program (except in cases in which the student failed to meet the requirements of the scholarship or grant), because the student could have made the decision to enroll based on the reasonable belief that scholarship or grant support would continue. Such misrepresentation could potentially form the basis of a defense to repayment claim.

Some negotiators advocated including opportunity costs or the quality of education as evidence of financial harm. However, the Department believes these assertions of financial harm are too difficult to quantify to be used for that purpose.

Under the 2016 final regulations, a borrower was required to show that he or she had reasonably relied upon the misrepresentation to his or her detriment. 81 FR 76083 (text of 34 CFR 685.222(d)(1)). The use of the word ''detriment'' echoed the definition for substantial misrepresentation under the Department's regulation for its enforcement activities for a school's misrepresentation under 34 CFR 668.71, which was expressly cross-referenced by the 2016 final regulations' borrower defense to repayment standard. While the 2016 final regulations did not include a definition for ''detriment,'' in the preamble, the Department noted that generally the term refers to any loss, harm, or injury suffered by a person or property. 81 FR 75951. Further, the Department stated that there was no quantum or minimum amount of detriment required for borrower defense under the substantial misrepresentation standard and a school's failure to provide some element or quality of a program that had been promised may be such a detriment. *Id.*

Under the proposed Federal standard, a borrower would be required to demonstrate that the borrower had suffered financial harm as a result of the misrepresentation by the school, and does not use the word ''detriment.'' As the Department is not proposing to align the Department's enforcement regulation at 34 CFR 668.71 for misrepresentation to the borrower defense to repayment standard, we do not believe it is necessary to use the same term in the proposed regulation. Further, in light of the Department's interest in balancing the need to protect both borrowers and Federal taxpayers, the Department believes it is appropriate to require that financial harm, in the form of a monetary loss as a result of the misrepresentation, be present for a borrower defense to repayment to be approved. As with the 2016 final regulations, however, the Department does not believe it is necessary for a borrower to demonstrate

a specific level of financial harm, other than the presence of such harm, to be eligible for relief under the proposed standard.

Borrower Defense—Filing Deadline for Asserting a Borrower Defense Claim

During the negotiated rulemaking sessions, negotiators discussed whether to impose time limits on a borrower's ability to assert a borrower defense to repayment and possible time periods for such limits. Some negotiators expressed concern that the imposition of a limitation period would bar otherwise valid borrower defenses to repayment, even when the loan(s) in question remained collectible under Federal law.

The proposed regulations do not impose a statute of limitations on the filing of a borrower defense to repayment claim. However, a borrower must comply with the filing deadlines established for the different proceedings in which a borrower defense claim may be raised. For example, when the Department intends to garnish a borrower's wages, the borrower is sent a notice of the Department's intention to initiate wage garnishment and is provided 30 days to request a hearing to dispute that action. A borrower could raise a defense to repayment claim during that 30-day timeframe, but would not be able to raise a claim after that period has elapsed.

With our regulatory proposal to accept defense to repayment claims during the enumerated collection proceedings, as opposed to the regulatory proposal to accept both defensive and affirmative claims, we do not propose to incorporate the timeframes for submission of borrower defense to repayment claims that were included in the 2016 final regulations. As discussed previously, the 2016 final regulations established time limits for borrowers' claims regarding recovery of amounts previously collected, but allowed defenses of repayment for amounts owed to be brought at any time. This NPRM instead enables borrowers to assert claims during collection proceedings, which can occur at any time during the repayment period. Borrowers can accordingly raise their defenses whenever such proceedings are instituted, but must comply with the existing filing deadlines for raising defenses in those collections proceedings. The Department proposes adopting the existing filing deadlines for defensive claims both because amending those deadlines was beyond the scope of the negotiated rulemaking and because harmony of deadlines will reduce confusion for borrowers.

The filing deadlines for the various proceedings in which a defensive borrower defense claim may be raised are reflected in the chart below:

Collection action	Number of days[3] for borrower response
Tax Refund Offset proceedings under 34 CFR 30.33	65
Salary Offset proceedings for Federal employees under 34 CFR part 31	65
Wage Garnishment proceedings under section 488A of the HEA	30
Consumer Reporting proceedings under 31 U.S.C. 3711(f)	30

Similar to our approach to timeframes in this NPRM, for suspension of collections, we follow the existing processes in the applicable collection proceeding. For example, with regard to wage garnishment proceedings under section 488A of the HEA, the accompanying regulations at 34 CFR 32.10 state that the wage deductions do not begin until a written decision has been issued, if the borrower has requested a pre-offset hearing to review the existence of amount of the debt. Thus, if a borrower defense claim has been raised in the context of a wage garnishment proceeding, collections would be suspended until a written decision on the wage garnishment has been issued. The 2016 final regulations also included suspension of collection for defaulted loans during a pending borrower defense claim.

If the Department were to accept affirmative claims as well as defensive claims, the Department proposes to impose a three-year time limit on borrowers to file such claims based on regulations that require institutions to retain administrative records for three years, while allowing defensive claims to be asserted at any time in response to collection proceedings. The Department welcomes comments on other approaches to set up a window for submitting affirmative claims. Since institutions would likely need access to records to defend themselves against inaccurate claims, it would make sense to require that affirmative borrower defense claims must be made within the first three years after a student leaves an institution. We recognize that in the case of defensive claims, it is likely that the institution would no longer have access to certain records, but the Department must balance that concern with the need to provide borrowers an opportunity to make a defense to repayment claim during already established opportunities for the borrower to challenge collection of the loan.

[3] The days listed may vary depending on the particular circumstances of each borrower's situation.

Borrower Defense—Exclusions

As discussed above, the Department's consistent position since 1995 has been that the Department will acknowledge a borrower defense to repayment only if it directly relates to the loan or to the school's provision of educational services for which the loan was provided. 60 FR 37769. As a result, the Department has not considered personal injury tort claims or allegations of sexual or racial harassment to be grounds for alleging a defense to repayment. In these regulations, the Department proposes making this limit explicit and provides a non-exhaustive list of circumstances that would not constitute, in and of themselves, borrower defenses to repayment that are directly related to the borrower's loan or the provision of educational services. This list also includes slander or defamation, property damage, and allegations about the general quality of the student's education or the reasonableness of an educator's conduct in providing educational services. The Department believes such a list will provide clarity and guidance for borrowers and schools in applying the proposed defense to repayment regulation.

The proposed regulations further state that a violation of the HEA does not by itself establish a defense to repayment, unless the underlying conduct also meets the Federal standard under the regulations. This has been the Department's consistent position since 1995. *See* 60 FR 37769; 81 FR 76053 (text of 34 CFR 685.222(a)(3) (defense to repayment regulation does not provide a private right of action for a borrower nor create any new Federal right)).

For all of these reasons, we are proposing to adopt the regulations described above and to rescind the Federal standard provisions of the 2016 final regulations.

Borrower Defense Adjudication Process (§§ 685.206, 685.212)

Statute: Section 455(h) of the HEA authorizes the Secretary to specify in regulation which acts or omissions of a school a borrower may assert as a defense to repayment of a Direct Loan.

Current Regulations: Section 685.206(c) provides that borrowers may

assert a borrower defense to repayment during proceedings which are available to the borrower when the Department initiates certain collection actions on a Direct Loan.

Section 685.212 establishes the conditions under which the Department discharges a borrower's obligation to repay a loan, or a portion of a loan, under various discharge or forgiveness provisions of the HEA, including closed school discharges, false certification discharges, and public service loan forgiveness.

Proposed Regulations: Proposed § 685.206(d)(2) and (3) describes the process by which a borrower would file a borrower defense to repayment application for a loan disbursed on or after July 1, 2019. Proposed § 685.206(d)(2) would specify that a borrower may assert a borrower defense to repayment in any of the enumerated proceedings to collect on a Direct Loan. Proposed § 685.206(d)(3) would specify that the borrower must raise a defense to repayment within the specified timeframe included in the notification to the borrower of the Department's action to collect on a defaulted student loan. The borrower would submit a completed borrower defense to repayment application to the Department on a form approved by the Secretary and signed under penalty of perjury. The borrower must also submit any evidence supporting the defense to repayment within the specified timeframe included in the Department's directions to the borrower.

Proposed § 685.206(d)(7) provides that the school against which the borrower alleges misrepresentation in a defense to repayment will be notified of the pending application and allowed to submit a response and evidence within the specified timeframe included in the notice.

Proposed § 685.206(d)(8) provides the items the Secretary may consider in resolving a borrower defense to repayment claim and that, following such consideration, the Secretary will issue a written decision informing both the borrower and the school of the relief, if any, that the borrower will receive.

Proposed § 685.206(d)(9) would provide that the Secretary would decide the amount of financial relief provided to the borrower upon the determination of successful borrower defense to repayment. This section also would provide that the amount of relief awarded to a borrower during the borrower defense process would be reduced by any amounts that the borrower obtained from the school or other sources for claims related to the justification of the defense to repayment, as reported pursuant to proposed § 685.206(d)(3).

Proposed § 685.206(d)(10) provides that the determination of a borrower defense by the Department is final and not subject to appeal.

Proposed § 685.212(k)(1) would add borrower defense discharges to the discharge provisions listed in § 685.212.

Reasons: During negotiated rulemaking, some negotiators were in favor of the Department providing borrowers with a non-adversarial process through which to seek resolution, with others asserting that in such a process, the Department should rely primarily on the borrower's attestation, submitted under penalty of perjury, and that corroborating evidence could come from the Department's own records. Other negotiators advocated for a more extensive process for resolving borrower defenses to repayment, and asserted that an unsubstantiated assertion of wrongdoing by a borrower should not be sufficient to justify the discharge of a borrower's Federal student loans or to impose a financial liability upon the school for the relief provided to the borrower.

The 2016 final regulations established separate adjudication processes for borrower defense to repayment applications submitted by individuals and those to be considered as a group. Generally, for the individual application process, the 2016 final regulations established that a borrower would submit an application on a form approved by the Secretary and provide any supporting evidence or other information or documentation reasonably requested by the Secretary. A Department official would then take appropriate action to put the borrower in loan forbearance, if not declined by the borrower, or, in the case of a defaulted loan, in stopped collection status. Next, the Department official would conduct a fact-finding process, during which the Department would notify the school of the defense to repayment application and consider the application and any supporting evidence provided by the borrower. According to the 2016 regulations, the Department official would consider any additional information found in the Department's records, or obtained by the Department. If requested by the borrower, the Department would identify relevant records to the borrower and provide such records upon reasonable request. At the end of the process, the Department official would issue a written decision. Although the written decision would be the final decision of the Department, the borrower could request reconsideration, upon the identification of ''new evidence,'' or relevant evidence not previously provided by the borrower or identified in the written decision. 81 FR 76083–76084 (text of 34 CFR 685.222(e)).

The process proposed by the Secretary in this NPRM would require that the borrower submit an application to the Department along with any supporting evidence. Whereas the 2016 final regulations did not explicitly provide an opportunity for schools to submit evidence and information in response to the borrower defense claim, this NPRM proposes to provide schools with an opportunity to provide a response and supporting evidence. Given the fact-specific nature of misrepresentation claims, the Department believes that it is appropriate to obtain as much evidence as possible from all sources, including from the school alleged to have made the misrepresentation. The Department would not, however, rely upon Department records or other information obtained by the Secretary, unless the school had an opportunity to review and respond to such evidence. The Department believes that the proposed process will assist it in making fair and accurate decisions, while providing borrowers and schools with due process protections.

As discussed in the section titled ''Defense to Repayment—Federal Standard for Asserting a Defense to Repayment,'' the Department is proposing that borrowers who have defaulted on a Direct Loan may raise a defense to repayment of loans first disbursed on or after July 1, 2019, on the basis of the proposed Federal misrepresentation standard, in response to a notice of the Department's intent to engage in certain collection actions. The Department's existing regulations as to those collection actions provide certain processes and protections for borrowers, which the Department is not proposing to change and would apply to borrower defense to repayment applications made during the course of those proceedings.

As is the case for defense to repayment claims under the existing regulation and the 2016 final regulations, the Department proposes that a decision made in the adjudication process be final as to the merits of the defense to repayment and any relief to be provided as a result. In this way, borrowers will not be subject to the additional wait that an appeal period may cause and will receive more expedient relief. We address the issue of reconsideration later in this section.

In the 2016 final regulations, the Department established a process for evaluating defense to repayment applications, regardless of the substantive standard that would be applied to the defense to repayment. Because the Department is now proposing that, for loans first disbursed on or after the anticipated effective date of these regulations (July 1, 2019), defenses to repayment applications be made only during the specified collection proceedings. The Department will continue to apply the State law standard for loans made prior to July 1, 2019. The Department proposes only clarifying updates to the statutory and regulatory cross-references for the collection proceedings listed for defenses to repayment for pre-effective date loans, and otherwise retains the existing language of current 34 CFR 685.206(c) as to such defenses to repayment applications. We also propose to rescind the process for adjudication of borrower defense to repayment portions of the 2016 final regulations.

The Department seeks public comment regarding potential processes that could be used to adjudicate affirmative claims, should the Department accept affirmative claims for some period after a borrower ends enrollment at an institution. The Department preliminarily believes that such a process must include an opportunity for the institution to receive a copy of the borrower's claim and a signed waiver allowing the institution to share relevant portions of the borrower's education record with the Department, and provide sufficient time for the institution to provide a response and any supporting evidence of its own to the Secretary. In order to assist the Department's assessment of the harm a potential misrepresentation caused a borrower, the borrower, in submitting a defense to repayment claim, might also be required to submit information about whether, for reasons other than the education received, the borrower has been removed from a job due to on-the-job-performance, disqualified from work in the field for which the borrower trained, or working less than full-time in the chosen field. In addition, the Secretary proposes to include a provision emphasizing to borrowers submitting affirmative or defensive claims that if the borrower receives a 100 percent discharge for the loan, the institution has the right to withhold an official transcript for the borrower, to avoid any confusion or surprise that would result from such withholding. Finally, the regulations make clear that the Secretary will also review both the borrower's claim and the institution's response in making a defense to repayment decision.

Additional Borrower Defense to Repayment Application Process Proposals

At the negotiated rulemaking sessions, the Department proposed that the regulations could allow borrowers to ask the Secretary to reconsider a denial of a defense to repayment, if the reconsideration claim was supported by newly discovered evidence. The negotiating committee discussed variations on this reconsideration process idea, in which either the school or the borrower could submit additional evidence to the Department. Negotiators also proposed that the regulations include an early dispute resolution process, whereby the Department or another party would mediate borrower defense disputes between a borrower and the school, to attempt to resolve the dispute without the need for the parties to go through the Department's full borrower defense adjudication process.

Under our proposed process for adjudicating defenses to repayment, a defense to repayment would be submitted in response to the Department's collection actions on a defaulted loan on a form approved by Secretary, and the Department's Federal Student Aid office will make a decision on the defense to repayment based on the submissions from the borrower and the school, if any. The borrower and the school will each be afforded the opportunity to see and respond to evidence provided by the other.

The reconsideration process proposed by some members of the negotiated rulemaking committee would involve either the borrower or the school submitting additional, newly discovered, evidence to the Department. Under the process and standard included in these proposed regulations, the Department expects to receive and consider all relevant evidence from the borrower and the institution during its consideration of the borrower's defense. Therefore, we do not believe that an appeal process or a process for reconsideration will be needed, nor is one included in these proposed regulations.

With regard to the proposed early dispute resolution process, the Department does not believe such a process is appropriate within the proposed regulations governing borrower defense. A borrower and a school may pursue voluntary resolution of a claim by the borrower at any time, without the involvement of the Department. A borrower may also pursue relief through his or her state consumer protection agency.

Group Process

A group of negotiators proposed that the Department establish a process for considering groups of borrower defenses to repayment claims. They argued that groups of borrowers who were all subject to the same act or omission by a school should have their defenses considered together as a group. These negotiators also asserted that a group process in these cases would be more efficient and would result in more equitable treatment of similarly situated borrowers.

The 2016 final regulations provided for a group process. Specifically, the Secretary could initiate, upon consideration of factors including, but not limited to, common facts and claims, fiscal impact, and the promotion of compliance by the school or other title IV, HEA program participant, a process to determine whether a group of borrowers has a legitimate borrower defense claim. Those regulations provided for the Secretary to identify groups comprised of borrowers who individually filed applications, as well as borrowers who did not file applications, should those borrowers have common facts and claims. 81 FR 76084. The Department further differentiated the processes based upon whether the subject school was open or closed. 81 FR 76085.

The Department does not include a group process, whether the school in question is open or closed, in these proposed regulations. Because relief through a borrower's defense to repayment claim is based not just on evidence of misrepresentation, but also evidence that the borrower reasonably relied on the misrepresentation in deciding to enroll or continue enrollment in the institution, and was harmed by the misrepresentation, the Department must consider each borrower's claim independently. The Department recognizes that a group of borrowers with defaulted loans who are each subject to a proceeding to collect on a Direct loan may assert misrepresentation on the part of the same school based on the same facts and circumstances, such as when the student borrowers were enrolled in a program that the school advertised to the public as being fully accredited by a specific programmatic accrediting agency when, in fact, it was not so accredited. The Department may, at its discretion, determine it is more efficient to establish facts regarding claims of misrepresentation put forth by a group

of borrowers. However, in approving an individual defense, the Secretary would still need to determine that the borrower made a decision based on the misrepresentation, that the borrower was harmed by the misrepresentation, and to what, if any, amount of or type of relief the borrower is entitled. To make that determination, it will be necessary to have a completed application from each individual borrower, and to examine the facts and circumstances of each borrower's individual situation. In addition, it would be inappropriate to subject borrowers who did not individually submit defense to repayment claims to the possible collateral consequences of debt relief, including potentially having their transcript withheld.

Relief

Proposed § 685.206(d)(9) would provide that the Secretary would decide the amount of financial relief provided to the borrower upon the determination of an approved defense to repayment discharge. As part of this determination, the amount of relief awarded to a borrower during the defense to repayment process would be reduced by any amounts that the borrower received from other sources based on a claim by the borrower that relates to the same loan and the same misrepresentation by the school as the defense to repayment. The rule would prevent a double recovery for the same injury at the expense of the Federal taxpayer.

As noted in the preamble to the 2016 final regulations, the Department has a responsibility to protect the interests of Federal taxpayers as well as borrowers. As a result, we continue to believe that establishing a legal presumption of full relief would not be appropriate. *See, e.g.,* 81 FR 75973–75974. While the Department's other loan discharge processes for closed school discharges, 34 CFR 685.214; false certification, 34 CFR 685.215; and unpaid refunds, 34 CFR 685.216, do provide for full loan discharges and recovery of funds paid on subject loans, the factual premises for such discharges are clearly established in statute and are relatively straightforward. In contrast, we anticipate that determinations for borrower defense claims will involve more complicated issues of law and fact since students may have been told different things by different representatives of an institution or may have heard the same statements differently. In many instances, borrower defense claims assert that an admissions representative made certain claims or promises, and yet without a recording of the actual conversation, it is hard to know precisely what was said, the degree to which the borrower relied on that information to make an enrollment decision, and the harm that came from the decision.

In the NPRM for the 2016 final regulations, the Department proposed certain methodologies for calculating relief, 81 FR 39420, but ultimately did not include those in light of their confusing nature, 81 FR 75976. Instead, the Department stated that it would consider factors such as the value of the education provided by the school and the student's cost of attendance, as well as conceptual, non-binding examples for substantial misrepresentation claims. *See* 81 FR 76086–76087. The Department proposes to allow for partial relief, based on the degree of harm suffered by the borrower. Given the complexity of such determinations, however, the Department invites comments on this proposal and on methods for calculating partial relief in connection with defenses to repayment. We also propose to rescind the application provisions of the 2016 final regulations.

Recovery From The School (§§ 685.206 and 685.308)

Statute: Section 455(h) of the HEA authorizes the Secretary to specify in regulation which acts or omissions of an institution of higher education a borrower may assert as a defense to repayment of a Direct Loan.

Current Regulations: Section 685.206(c)(3) states that the Department may initiate an appropriate proceeding to require a school whose act or omission resulted in a successful borrower defense to repayment to require the school to pay the Department the amount of the loan to which the defense applies. It specifies that this proceeding may not be initiated after the period of record retention required in § 685.309(c), unless the school received notice of the borrower's defense during that period.

Proposed Regulations: Proposed § 685.206(d)(13) would clarify that, for borrower defense to repayment discharges granted under the new Federal standard, the Secretary may initiate, within five years of the date of the final determination of the borrower's defense to repayment application, an appropriate proceeding to require a school whose misrepresentation resulted in an approved borrower defense to repayment discharge to pay the Department the amount of the discharged loan. The recovery proceeding would be conducted in accordance with 34 CFR part 668 subpart G.

Proposed § 685.206(d)(11) would require that a borrower who has received a defense to repayment loan discharge reasonably to cooperate with the Secretary in any proceeding to recover funds from the school. The Secretary may revoke relief granted to a borrower who does not fulfill this obligation. Proposed § 685.206(d)(12) would require a borrower whose defense to repayment is successful to transfer to the Secretary any right to recovery against third parties of any amounts discharged by the Department, based on the borrower's defense to repayment.

Conforming changes would be made by proposed §§ 685.300 and 685.308 related to the agreements signed by schools to participate in the Direct Loan Program and to remedial actions that the Department may take to require repayment of funds from schools in various circumstances, respectively.

Reasons: Proposed § 685.206(d)(13) would establish that the Secretary may initiate a recovery proceeding to require the school whose act or omission resulted in the borrower's successful defense to repayment discharge of a Direct Loan to pay to the Secretary the amount discharged. The Department proposes the subpart G hearing as a mechanism for recovery of funds from schools resulting from a borrower defense to repayment discharge. These proceedings are well established in regulation and familiar to schools. The subpart G hearing offers due process to schools, with an opportunity for a preconference hearing via telephone, an informal meeting, or a paper process; submission of evidence; and a hearing. The burden of proof rests with the Department, and the school has an opportunity to appeal the decision of the hearing official to the Secretary.

Proposed § 685.206(d)(11) would help to ensure that the Department receives the borrower's cooperation, if needed, in any proceeding against the school. It is similar to the requirements applicable to other loan cancellation provisions. Cooperation includes providing testimony regarding any representation made by the borrower to support a successful borrower defense to repayment, and producing, within timeframes established by the Secretary, any documentation reasonably available to the borrower with respect to those representations and any sworn statement required by the Secretary with respect to those representations and documents.

In the preamble to the 2016 final regulations, 81 FR 75929–75932, the Department explained that it has the legal authority to recover liabilities from

schools related to approved borrower defenses to repayment. The Department continues to maintain that it has this authority under its statutory and existing regulatory framework as part of its responsibility to administer the Direct Loan Program for the reasons stated in the preamble to those regulations. We note that this has been the Department's consistent position on borrower defenses to repayment, as is reflected in the existing borrower defense to repayment regulation at 34 CFR 685.206(c)(3).

Consistent with the Department's longstanding view, we propose in these regulations to add language to 34 CFR 685.300 regarding Program Participation Agreements schools must sign to participate in the Direct Loan Program. This language would clarify that schools are responsible to the Department for the amounts of the loans underlying approved borrower defense claims, as well as those for other Direct Loan discharges (closed school discharges, false certification discharges, and unpaid refund discharges) approved under the Department's other regulations. The Department also proposes to amend 34 CFR 685.308 to make corresponding changes clarifying that the Department may take remedial actions to recover such losses. The Department also proposes to rescind the recovery from schools provisions of the 2016 final regulations.

Statute of Limitations for Recovering Funds From Schools (§§ 685.206 and 685.308)

The negotiators discussed whether to impose a time limit on the Department's ability to recover losses for the amount of an approved borrower defense to repayment from a school. Negotiators noted that current § 685.206(c)(3) imposes a three-year limit on the Secretary's ability to initiate an action based on the period for the retention of records described in § 685.309(c). This three-year limit is derived from §§ 668.24 and 685.309(c), which describe the requirement to retain ''program records''—records of the determination of eligibility for Federal student financial assistance and the management of Federal funds provided to the school. Section 668.24(e)(2) provides that the school must keep records of borrower eligibility and other records of its ''participation'' in the Direct Loan Program for three years after the last award year in which the student attended the school. In these proposed regulations, we maintain this time limit for recovery actions on approved borrower defense to repayment claims for loans first disbursed before July 1, 2019.

We propose to extend that time limit to five years from the date of the Department's final determination on the borrower's defense to repayment for loans first disbursed after July 1, 2019. Although, as explained above, the Department does not view liabilities from borrower defense to repayment as fines, penalties, or forfeitures, a five-year limitation period is used in other contexts by the Federal government, such as in enforcement actions. *See* 28 U.S.C. 2462. Further, given that the Department does not have a basis for recovery against a school until a borrower defense to repayment has been approved, we believe that the five years should run from the final determination of a borrower's defense to repayment claim, instead of from the last award year the borrower attended school. Therefore, we propose in these regulations that for loans first disbursed on or after July 1, 2019, the Secretary will provide notice to the school of the defense to repayment application and will not initiate such a proceeding more than five years after the date of the final determination of the borrower's defense to repayment. We also propose to rescind the statute of limitations provisions of the 2016 final regulations.

Pre-Dispute Arbitration Agreements and Internal Dispute Processes (§§ 668.41 and 685.304)

Statute: Section 485(a) of the HEA identifies information that participating schools must provide to prospective and enrolled students. Sections 485(b) and (l) of the HEA establish counseling requirements for borrowers of Federal student loans. Section 454(a) of the HEA authorizes the Secretary to specify in regulation the requirements for school participation in the Direct Loan program.

Current Regulations: Section 668.41 describes the information a school must report and disclose to prospective and enrolled students. Section 668.41(a) defines terms used in the regulation. Section 685.304 describes the required entrance counseling that schools must provide to Federal Direct Loan borrowers prior to making the first disbursement of a Federal Direct student loan.

Proposed Regulations: We propose a new § 668.41(h), which would require schools that use pre-dispute arbitration agreements or class action waivers as a condition of enrollment to disclose that information in writing in an easily accessible format to students, prospective students, and the public. We propose to add definitions to paragraph (h)(2) for the terms ''class action,'' ''class action waiver,'' and ''pre-dispute arbitration agreement.'' We propose to define ''class action'' to mean a lawsuit or an arbitration proceeding in which one or more parties seeks class treatment pursuant to Federal Rule of Civil Procedure 23 or any State process analogous to Federal Rule of Civil Procedure 23. We propose to define ''class action waiver'' as any agreement or part of an agreement between a school and a student that relates to the provision of educational services for which the student received title IV funding and prevents an individual from filing or participating in a class action that pertains to those services. We propose to define ''pre-dispute arbitration agreement'' as any agreement or part of an agreement between a school and a student requiring arbitration of any future dispute between the parties relating to the making of a Direct Loan or provision of educational services for which the student received title IV funding.

We also propose to make other revisions to § 668.41: revising paragraph (a) to amend the definition of ''undergraduate students'' to specify that such students are those enrolled in a program ''at or'' below the baccalaureate ''level,'' and revising paragraph (c) to add cross-references to new § 668.41(h).

Proposed revisions to § 685.304 would require schools that require borrowers to accept pre-dispute arbitration agreements or class action waivers as a condition of enrollment to (1) clearly, and in plain language, provide written explanation to the borrower of the nature and application of the pre-dispute arbitration agreement and/or class action waiver, and (2) provide to the borrower written information on the availability of the school's internal dispute resolution process.

Reasons: Current regulations do not address the use of pre-dispute arbitration agreements or class action waivers in enrollment agreements between schools and students or in other documents that must be signed by the student as a condition of enrollment.

In 2016, the Department issued regulations that prohibited a school participating in the Direct Loan Program from enforcing class action waivers or pre-dispute arbitration agreements against borrowers with Direct Loans for claims that may form the basis of a borrower defense to repayment claim. The 2016 final regulations required participating schools to ''forgo reliance on any pre-dispute agreement with a student that waives the student's right

to participate in a class action against the school related to a borrower defense claim.'' 81 FR at 75927, 76088. However, the 2016 regulations did permit a borrower to enter into a voluntary post-dispute arbitration agreement with a school to arbitrate a borrower defense claim. For these voluntary post-dispute arbitrations, the Department required institutions to submit copies of the arbitral filings, responses, awards, and certain other documents to the Secretary within 60 days of the filing or receipt by the school, as applicable. The Department also required schools to submit certain judicial records of lawsuits filed as to claims related to borrower defense to repayment.

Since issuance of the 2016 final regulations and subsequent delay of their effective date, schools have been allowed to continue enforcing pre-dispute arbitration agreements, and the Department has heard from students, advocates representing students, and the public about this practice. Many of these groups told the Department that the implications of class-action waivers or pre-dispute arbitration agreements can be unclear to students when they enroll at a school. These groups urged the Department to take steps to provide increased protection for student loan borrowers. Other negotiators argued that students are and can be well-served by the arbitration process, which they contend can be a more efficient, timely, and cost-effective option for dispute resolution.

The Department is aware of court decisions holding that prohibitions on pre-dispute arbitration agreements and class action waivers violate the Federal Arbitration Act (FAA). The FAA ''establishes a liberal federal policy favoring arbitration agreements'' that applies ''unless the FAA's mandate has been overridden by a contrary congressional command.'' *CompuCredit Corp.* v. *Greenwood,* 565 U.S. 95, 98 (2012). This policy protects the right of parties to set dispute resolution procedures by contract.

In the 2016 regulations, the Department took the position that the HEA gives the Department broad authority to impose conditions on schools that wish to participate in a Federal benefit program and that regulation of the use of pre-dispute arbitration agreements and class action waivers was necessary to ''protect the interests of the United States and promote the purposes'' of the Direct Loan Program under section 454(a)(6) of the HEA, 20 U.S.C. 1087d(a)(6). We recognize, as explained in the preamble to the 2016 final regulations, that pre-dispute arbitration agreements and class action waivers may, in some circumstances, not be well understood by consumers or facilitate the Department's awareness of potential issues faced by students at a school. However, our reweighing of the issue and subsequent legal developments have led us to believe that the Department should take a position more in line with the strong Federal policy favoring arbitration.

We believe that arbitration offers a number of potential advantages in this context. Arbitration may, for example, be more accessible to borrowers since it does not require legal counsel and can be carried out more quickly than a legal process that may drag on for years. It may also allow an institution to more quickly identify and stop bad practices to ensure that other students are not harmed. It may also allow borrowers to obtain greater relief than they would in a consumer class action case where attorneys often benefit most. And it may reduce the expense of litigation that a university would otherwise pass on to students in the form of higher tuition and fees. Arbitration also eases burdens on the overtaxed U.S. court system.

Our reexamination of the legal landscape also weighs in favor of the Department's proposal not to disrupt pre-dispute arbitration agreements or class-action waivers. In particular, the U.S. Supreme Court recently held that the FAA governs, unless Congress ''manifests a clear intention'' to displace it, and that arbitration agreements ''must be enforced as written.'' *Epic Systems Corp.* v. *Lewis,* 584 U.S.—, 2018 WL 2292444 at 17 (May 21, 2018). Thus, in *Epic Systems Corp* v. *Lewis,* the Court declined to afford deference to the National Labor Relations Board's reading of the National Labor Relations Act (NRLA) to trump FAA policy—even though an agency's interpretation of its own statute normally receives deference. *Id.* Nothing in the NLRA manifested Congress's clear intention to displace the FAA, and the FAA accordingly controlled.

Epic Systems is consistent with the Supreme Court's earlier decision holding that a prohibition on class arbitration waivers in consumer contracts violates the FAA, *AT&T Mobility LLC* v. *Concepcion,* 563 U.S. 333, 347–51 (2011). We believe that the Supreme Court's recent reaffirmation of the Federal policy in favor of arbitration may warrant a different approach to these regulations.

That belief is further supported by recent congressional action. Specifically, Congress passed, and the President signed, a joint resolution disapproving a final rule published by the Bureau of Consumer Financial Protection (BCFP) that would have regulated pre-dispute arbitration agreements in contracts for specified consumer financial products and services. That proposed rule was informed by the same extensive study conducted by the BCFP on the impact of such agreements that the Department relied on in its rationale for the pre-dispute arbitration and class action waiver provisions in the 2016 final regulations. In light of Congress' clear action, the Department believes a change in its position to align with the strong Federal policy in favor of arbitration is appropriate.

The Department thus proposes to revise its treatment of pre-dispute arbitration agreements and class action waivers. It is not currently proposing to ban such agreements or waivers. And given the burden to the Department of reviewing such records, the Department is also not proposing that institutions be required to report information about arbitration awards or judicial proceedings to the Secretary. However, the Department acknowledges negotiators' concerns that borrowers and students may not understand the implications of arbitration agreements and class action waivers that may be included in their agreements with the school.

The Department agrees that it is important that students understand what a pre-dispute arbitration agreement or class action waiver means, so that students can elect to enroll at an institution that does not include such provisions if the student so desires. Also, it is important for a student who attends an institution that requires arbitration to know how to access and utilize arbitration, thus the requirement that schools relying upon mandatory arbitration provide plain language instruction on both the meaning of this restriction and the ways a student can access it. Thus, the Department is proposing regulatory changes to promote greater transparency by schools that require students to enter into such agreements as a condition of enrollment, to allow borrowers the opportunity to make an informed choice as to whether to enroll in such schools.

During the negotiated rulemaking sessions, the Department proposed including in the regulations a requirement that schools including pre-dispute arbitration agreements or class action waivers in their enrollment agreements clearly disclose that information to prospective and continuing students, and educate borrowers during loan entrance

counseling about pre-dispute arbitration agreements, class action waivers, and the schools' internal dispute processes. Negotiators expressed two distinct points of view about the value of arbitration: Some believed that an internal dispute resolution process or arbitration proceeding serves the best interests of students, schools, and taxpayers. They noted that the Department, as well as accreditors, direct students with complaints to first attempt to resolve those complaints with the school. And some of those negotiators also asserted that arbitration can be quicker and less expensive than a court proceeding, provide meaningful relief to the student at the school's (rather than the Federal taxpayers') expense, and allow schools to resolve issues with students outside of the courts. In contrast, other negotiators expressed concerns that requiring students to use an internal dispute resolution process or arbitration, or prohibiting students from joining class action lawsuits, was more likely to suppress students' meritorious claims against their schools.

Negotiators also differed as to the benefits of increased transparency about such agreements. Some negotiators supported the Department's proposal, asserting that it would enable prospective and continuing students to make an informed choice before taking out a Federal student loan to enroll or continue enrollment at a school that required these agreements. They also noted that, if these processes are beneficial to students, as asserted by some schools, this would be an additional reason for highlighting them in the enrollment and student loan application processes. One negotiator expressed concern that the Department's initial proposed language was too broad and could apply to arbitration agreements unrelated to the school's provision of educational services, such as arbitration agreements relating to the use of campus parking facilities or other student services.

After hearing from the negotiators, and for the foregoing reasons, the Department has concluded that it is better to require schools to disclose the existence of pre-dispute arbitration agreements and class action waivers, rather than, as was done in 2016, outright ban these practices. We acknowledge one negotiator's concern about the Department's initial proposed language and have altered the proposed definition of ''pre-dispute arbitration agreement'' to make clear that the requirement applies only to agreements requiring arbitration of any future disputes between the parties relating to the making of a Direct Loan or the provision of educational services for which the student received title IV funding. The Department believes that it would be burdensome to schools and the Department to require submission of arbitration documentation (which also may contain confidential information) and are not proposing to include this requirement here. We therefore propose to rescind our 2016 final regulations that banned pre-dispute arbitration agreements and class action waivers, as well as the requirement that schools using arbitration submit specific documentation to the Department.

Closed School Discharges (§§ 674.33, 682.402, and 685.214)

Statute: Sections 437(c) and 464(g)(1) of the HEA provide for the discharge of a borrower's liability to repay a FFEL Loan or a Perkins Loan if the student is unable to complete the program in which the student was enrolled due to the closure of the school. The same discharge is available to Direct Loan borrowers under section 455(a) of the HEA.

Current Regulations: Sections 674.33(g), 682.402(d), and 685.214 describe the qualifications and procedures in the Perkins, FFEL, and Direct Loan Programs for a borrower to receive a closed school discharge. Under §§ 674.33(g)(4), 682.402(d)(3), and 685.214(c), a Perkins, FFEL, or Direct Loan borrower, respectively, must submit a written request and supporting sworn statement, under penalty of perjury, to apply for a closed school discharge. Sections 674.33(g)(4)(i)(B), 682.402(d), and 685.214 provide that, to qualify for a closed school discharge a student must have been enrolled in the school at the time it closed or must have withdrawn from the school not more than 120 days before the school closed. The regulations also provide that the Secretary may extend the 120-day window under exceptional circumstances. Sections 674.33(g)(4)(i)(C), 682.402(d)(3)(ii)(C), and 685.214(c)(1)(i)(C) provide that a borrower may qualify for a closed school discharge if the borrower did not complete, and is not in the process of completing, the program of study through a teach-out at another school.

Proposed Regulations: Proposed revisions to §§ 674.33(g)(4), 682.402(d)(3) and (d)(6)(ii)(G) and (H), and 685.214(c) would replace the requirement that, to apply for a closed school loan discharge, the borrower submit a sworn statement with a requirement that the borrower submit a completed application signed under penalty of perjury.

Proposed revisions to §§ 674.33(g), 682.402(d), and 685.214(c) would extend the window for a borrower to qualify for a closed school discharge based on withdrawal from a closed school without completion of a program from 120 days before the school closed to 180 days, and would modify some of the examples of ''exceptional circumstances'' under which the Secretary may extend the proposed 180-day period.

Proposed §§ 674.33(g)(4)(i)(D), 682.402(d)(3)(iii), and 685.214(c)(1)(ii) would state that if a closing school provided an opportunity to a borrower to complete the program of study while the school was still open by allowing students to complete their program of study before shutting down through an orderly closure (referred to by accreditors as a teach-out) approved by the school's accrediting agency and, if applicable, the school's State authorizing agency, the borrower would not qualify for a closed school discharge.

Proposed revisions to § 682.402(d)(6)(ii)(F) would require a guaranty agency that denies a closed school discharge request to inform the borrower of the opportunity to request a review of the guaranty agency's decision by the Secretary and explain how the borrower may request that review. Proposed § 682.402(d)(6)(ii)(J) would describe the responsibilities of the guaranty agency and the Secretary if the borrower requests a review.

Reasons:

Application Process

The current regulations refer to a borrower submitting a sworn statement made under penalty of perjury, but borrowers now apply for closed school discharges by filing a Federal closed school discharge application. This application includes several certifications that the borrower must make under penalty of perjury. The closed school discharge application takes the place of the sworn statement that was formerly required, and several of our proposed revisions to the regulations reflect that change.

In the 2016 regulations, the Department included provisions that provided automatic closed school discharges for borrowers who have not re-enrolled in a Title IV-eligible institution within three years of their schools' closures. See, *e.g.,* 81 FR at 76038.

During the 2017–2018 negotiations, some negotiators proposed that the Department also provide for an automatic closed school discharge in certain circumstances. The negotiators

proposed that a borrower who attended a closed school and who did not re-enroll within one year, or, alternatively, three years, of the school closing be granted a closed school discharge without being required to submit an application.

In these regulations, we are not proposing an automatic closed school discharge. Under existing §§ 674.33(g)(3)(ii), 682.402(d)(8), and 685.214(c)(2), the Department may grant a closed school discharge without an application if the Secretary determines, based on information in the Secretary's (or, in the case of a FFEL loan, the guaranty agency's) possession that the borrower qualifies for the discharge. Thus, the Secretary already has the authority to grant a discharge without an application in appropriate cases at her discretion, and, therefore, we do not believe that it is necessary to establish in the proposed regulations a requirement that the Secretary grant automatic closed school discharges. In addition, because an institution (or the entity maintaining records from a closed school) might withhold official transcripts of borrowers who received a defense to repayment of closed school discharge, automatic discharges could have collateral consequences for students who did not opt-in.

Furthermore, through these proposed regulations, the Department is encouraging schools that are closing to go through an orderly closure, which includes offering appropriate teach-outs to their students. Under the proposed regulations, students who decline to participate in an appropriate teach-out, when made available by the institution and approved by the accreditor (and, if applicable, State authorizing entities) are not eligible for a closed school discharge. An application will be useful, and in some cases necessary, for the Department to determine whether the student was provided with an appropriate opportunity to complete a teach-out. For these reasons, we are proposing to rescind the regulations concerning automatic closed school discharge that were part of the 2016 final regulations.

Extending the Window To Qualify for a Closed School Discharge From 120 Days to 180 Days

The HEA provides that a borrower may receive a closed school discharge if the borrower ''is unable to complete the program in which the student is enrolled due to the closure of the institution,'' (sections 454(g)(1) and 437(c)(1)) but does not establish a period prior to the closure of the school that a borrower may withdraw and still qualify for a closed school discharge. The Department has nevertheless long interpreted the statute to allow discharge for students who withdraw a short time before a school closure, recognizing that a precipitous closure may be preceded by degradation in academic quality or student services. In 2013, the Department expanded the window for eligibility for a closed school loan discharge from 90 to 120 days, meaning that students who withdraw from the school within 120 days of the school's closure are eligible for closed school loan discharge.

In the 2016 final regulations, the Department determined that the 120-day look-back period to qualify for closed school discharge in current regulations is sufficient. The Department noted that under current regulations in § 685.214(c)(1)(B), it has the authority to extend the look-back period due to ''exceptional circumstances.'' At that time, we believed that this provision provided appropriate flexibility to the Department in cases where it may be necessary to extend the look-back period. *See* 81 FR at 76040.

However, during the 2017–2018 negotiated rulemaking sessions, the Department proposed to extend the window for a borrower to qualify for a closed school discharge from 120 days to 150 days, and most negotiators supported that proposal. Some negotiators expressed concerns that extending the window to 150 days would significantly increase the number of borrowers who could qualify for a closed school discharge, even if those borrowers could have graduated before the school closed. They also noted that closed school discharges apply to locations of a school that are closed, not just to schools that have closed entirely, and many large universities have campuses at different locations that they may choose to close in a responsible, planned manner. One negotiator noted that schools often engage in short-term partnerships with private entities to provide instruction at specific off-campus locations. Even though such programs may be intended to last for only a short term to address a specific need in the community, students attending the school at these locations could qualify for closed school discharges. In the view of these negotiators, extending the window for eligibility for a closed school discharge could have the effect of discouraging innovation and creativity by schools involving other locations.

Some negotiators expressed concern that a longer window could lead to strategic behavior on the part of borrowers. For example, if a borrower is aware that a school will be closing, the borrower could continue to attend the school and take out more loans, with the intention of getting the loans discharged once the school closes. These borrowers may be unaware that the institution might withhold official transcripts from students who receive closed school discharges. Since a longer window under which a borrower could qualify for a closed school discharge would also increase the opportunity for a borrower to complete the program in a school that is planning to close, these negotiators argued that a borrower should not qualify for a closed school discharge if the borrower could have completed the program before the school closure date.

Other negotiators did not agree that borrowers should be ineligible for a closed school discharge if they could have completed the program at the school prior to its closure. They pointed out that schools that close precipitously may show symptoms of failing months before the actual closure date. These negotiators stated that they have seen evidence of degradation in their interactions with such schools as teachers and administrative staff members leave and the quality of services provided by the school deteriorates. In the view of these negotiators, borrowers at such schools should qualify for a closed school discharge, even if they could have stayed at the failing school and completed their program before the school officially closed its doors.

Some of these negotiators proposed extending the window for a closed school discharge to a year, since, in their view, a school that closes may have problems well in advance of the actual closure date. The negotiators pointed out that a school that only planned to open a location temporarily, or that engaged in a planned, responsible closure of a location, could stop accepting new students at the location, and commit to allowing the current students to complete their studies at the location before shutting down—in other words, conduct an orderly closure under an approved teach-out plan—to avoid a dramatic expansion of the borrowers entitled to closed-school discharge under this longer look-back period.

Other negotiators objected strongly to the proposal to extend the window to a full year. They stated that this would put schools in the position of having to track every student who may have withdrawn or transferred during that one-year period until those students completed a program at another school, creating a ''quagmire'' for schools.

Based on the feedback we received and the Department's recent experience with precipitous school closures, the Department is proposing to extend the period to 180 days—60 days longer than provided in the current regulations. We believe that 180 days makes the most sense because it takes into account the situation in which, as a result of the summer break during which time many institutions offer few or no classes, a student who withdraws one semester prior to a school's precipitous closure could have withdrawn as many as 180 days earlier.

Exceptional Circumstances

The Department proposes clarifications and modifications to §§ 674.33(g)(4)(i)(B), 682.402(d), and 685.214 that provide examples of ''exceptional circumstances'' under which the Secretary may extend the period of time to provide a closed school discharge. For example, we propose replacing the reference in the existing regulations to the ''loss of accreditation'' with language referring to ''revocation or withdrawal by an accrediting agency of the school's institutional accreditation.''

Generally, the negotiating committee approved of these changes. One negotiator proposed adding an additional exceptional circumstance: The school's discontinuation of the student's program of study. However, other negotiators noted that the closed school discharge is intended for closed school situations, not situations in which a school terminates an academic program. These negotiators believed that adding a reference to the discontinuation of a student's academic program in the ''extenuating circumstances'' provision would be inconsistent with the statutory intent of the closed school discharge. Because the closed school discharge regulations are intended to address the closure of an entire school or branch campus, as opposed to discontinuation of a specific program offered at such a location, we agree with these negotiators. Therefore, we have declined to include this additional exceptional circumstance in the proposed regulations.

Teach-Out Plans, Orderly Closures and Transfer of Credits

Under these proposed regulations, we are proposing that students who are provided an opportunity to complete their program through a teach-out plan or an orderly closure approved by the school's accreditor and, if applicable, the school's State authorizing agency would not have the right to receive a closed school discharge as long as the school upheld the conditions of the teach-out plan or orderly closure. We believe that closing schools should be encouraged to offer accreditor-approved and, if applicable, State authorizer-approved teach-out plans and orderly closures to allow students the reasonable opportunity to complete the academic programs, either at another location after the school has closed, or by continuing to offer classes to students until they have completed their program of study before the school officially closes.

One negotiator noted that while closing schools may conduct orderly closures or offer teach-out plans, a borrower can choose not to participate in an orderly closure or a teach-out plan. This negotiator argued that a borrower should not qualify for a closed school discharge if he or she could have completed the program through an orderly closure or through a teach-out plan, but chose not to do so. In this negotiator's view, the law is written to encourage borrowers in closed school situations to complete their programs under the approved teach-out plan or through an orderly closure and not to receive closed school discharges.

We agree that borrowers who have a reasonable opportunity to complete their academic programs through an orderly closure or a teach-out plan should not qualify for a closed school discharge, if the orderly closure or the teach-out plan has been approved by the school's accrediting agency and, if applicable, the school's State authorizing agency. In such cases, the closure of the school did not render the student unable to complete the program in which the student was enrolled. Borrowers who attend closing schools may be better served by completing their programs, either at the school or at another school through a teach-out plan, than by having their loans forgiven and being required to start their education over at another institution. Students should be encouraged to complete their academic program, not to have their loans discharged. And schools should be encouraged to provide their students with an opportunity to do so. It is for this reason that accreditors are required to review and approve a school's teach-out plan if the institution is at risk for closure.

Department Review of Guaranty Agency Denial of a Closed School Discharge Request

In the Perkins Loan and Direct Loan Programs, closed school discharge determinations are made by the Department. The Department is the loan holder for all Direct Loans and becomes the loan holder for Perkins Loans held by a school that closes. In the FFEL Program, closed school discharge determinations are generally made by the guaranty agency. The current FFEL Program regulations do not specifically provide an opportunity for a review of the guaranty agency's determination of a borrower's eligibility for a closed school discharge. Proposed § 682.402(d)(6)(ii)(F) would provide an opportunity for the borrower to receive Departmental review of closed school discharge claims which have been denied by the guaranty agency to provide a more complete review of the claims, comparable to that provided for false certification discharge claims.

A negotiator pointed out that existing regulations allow the Department to review closed school discharge application denials for Direct Loan borrowers. This proposal is intended to establish parity between the FFEL and Direct Loan programs with regard to the review of closed school discharge applications.

Additional Closed School Discharge Proposals

The negotiated rulemaking committee also discussed several additional proposed revisions to the closed school discharge regulations.

Some negotiators proposed adding a provision specifying that a borrower who graduated prior to the school's closure could not qualify for a closed school discharge. The Department does not need to add such a provision. A borrower who graduates prior to the closure of a school is already ineligible for closed school discharge because the student has completed his or her program of study and received a credential.

One negotiator proposed narrowing the scope of the closed school discharge by disqualifying a borrower from a closed school discharge if the borrower completed a ''comparable program'' of study at another school. Another negotiator suggested defining ''comparable program'' as meaning a program of equal or greater value or quality, based on academic outcomes, graduation rates, and default rates. Another negotiator recommended determining ''comparable program'' based on the Classification of Instructional Programs (CIP) code plus credential level. However, other negotiators expressed concerns that this proposal might push borrowers into programs in which they originally did not intend to enroll. They expressed concern that a student may be pushed into a program that is not really ''comparable'' to the borrower's original

program. A student may enroll in the program because there is nothing else comparable nearby, although the better option for the student would have been to apply for the closed school discharge. Other negotiators questioned the value of adding the ''comparable program'' language at all. One negotiator suggested that, since a borrower can transfer credits to another program, there is no need to explicitly use or define the term ''comparable program'' in the regulations.

Given the uncertain statutory authority for, or effect of adding the ''comparable program'' language suggested by the negotiator, the Department declines to propose including such a provision in the regulations.

False Certification Discharges (§ 685.215)

Statute: Section 437(c) of the HEA provides for the discharge of a borrower's liability to repay a FFEL Loan if the student's eligibility to borrow was falsely certified by the school. The false certification discharge provisions also apply to Direct Loans, under the parallel terms, conditions, and benefits provision in section 455(a) of the HEA. Section 484(d) of the HEA specifies the requirements that a student who does not have a high school diploma or a recognized equivalent of a high school diploma must meet to qualify for a title IV, HEA loan.

Current Regulations: Section 685.215(a)(1)(i) provides that a Direct Loan borrower may qualify for a false certification discharge if the school certified the eligibility of a borrower who was admitted on the basis of the ability to benefit, but the borrower did not in fact meet the eligibility requirements in 34 CFR part 668 and section 484(d) of the HEA, as applicable. Section 685.215(c) and (d) describes the qualifications and procedures for receiving a false certification discharge.

Proposed Regulations: The proposed changes to § 685.215(a)(1)(i) would eliminate the reference to ''ability to benefit'' and specify that a borrower qualifies for a false certification discharge if the borrower reported not having a high school diploma or its equivalent and did not satisfy the alternative to graduation from high school requirements in 34 CFR part 668 and section 484(d) of the HEA. Thus, under proposed § 685.215(a)(1)(i), if a school certified the eligibility of a borrower who is not a high school graduate (and does not meet the applicable alternative to high school graduation requirements) at the time the loan was disbursed, the borrower would qualify for a false certification discharge.

Proposed § 685.215(c) and (d) would update the procedures for applying for a false certification discharge. Proposed § 685.215(c)(1) would describe the requirements a borrower must meet to qualify for a discharge based on a false certification of high school graduation status. Proposed § 685.215(c)(1)(ii) would specify that a borrower who was unable to obtain an official transcript or diploma from his or her high school and, in place of a high school transcript or diploma, submitted a written attestation that the borrower had a high school diploma, does not qualify for a false certification discharge if the borrower actually did not have a high school diploma. The attestation would have to be provided under penalty of perjury.

Reasons:

Application Process

Current § 685.215(c) requires the borrower to submit a ''written request and a sworn statement'' to apply for a false certification discharge. We propose replacing this language with a requirement that the borrower submit an application for discharge on ''a form approved by the Secretary, signed under penalty of perjury,'' to bring the regulations up to date with the current process. Borrowers applying for false certification discharges now submit a Federal false certification discharge application. This application includes several certifications that the borrower must make under penalty of perjury. The false certification discharge application takes the place of the sworn statement that was formerly required.

False Certification of a Borrower Without a High School Diploma or Equivalent

We propose removing the ''ability to benefit'' language from § 685.215(a)(1)(i) because there is no longer a statutory basis for certifying the eligibility of non-high school graduates based on an ''ability to benefit.'' Section 484(d) of the HEA establishes different standards under which a non-high school graduate may qualify for title IV aid. We believe that it is preferable to refer to section 484(d) of the HEA by cross-reference, rather than to incorporate the statutory language in the regulations. Under this approach, the regulatory language will incorporate any current or future alternatives to the high school graduation requirements specified in section 484(d) of the HEA.

Some of the non-Federal negotiators noted that a borrower may provide false information to the school the borrower is applying to attend regarding their high school graduation status. The negotiators asserted that, unless the school investigates the borrower's claim that he or she is a high school graduate—for instance by requesting transcripts, which are harder to falsify than a diploma—the school may unknowingly falsely certify the borrower's eligibility. One negotiator proposed adding language specifying that, for a borrower to qualify for a false certification discharge, the school must be unable to provide to the Department clear and convincing evidence that the student provided the school with evidence of their high school graduation status. The negotiator pointed out that in some instances—for example with homeschooled students—the school basically only has a representation from the student that the student is a high school graduate. Under this proposal, the borrower would have to demonstrate that the school knowingly certified the eligibility of the borrower even though the borrower did not meet the high school graduation requirements.

There was strong disagreement between the negotiators over whether the school must ''knowingly'' falsely certify the high school graduation status of a borrower for the borrower to qualify for a false certification discharge. Some negotiators noted that it is the school's responsibility to determine the borrower's eligibility. If the school does not, and certifies eligibility anyway, the borrower's eligibility may have been falsely certified, and the borrower should qualify for the discharge. Other negotiators felt that a mistaken certification of eligibility should not qualify a borrower for a false certification discharge. One negotiator pointed out that, regardless of whether the school knew if the borrower was a high school graduate, if the school certified a non-high school graduate's eligibility, the borrower's eligibility would still have been falsely certified, and the borrower would still qualify for a false certification discharge. Other negotiators expressed concern with this proposal, noting that borrowers would have a difficult time proving that the school ''knowingly'' falsified the borrower's eligibility.

Under current regulations, a school may be responsible for the repayment of funds related to a false certification discharge due to a school's ''negligent or willful false certification'' (34 CFR 685.308(a)(2)). It would be inconsistent with these requirements to require that a school would have to ''knowingly'' falsely certify a borrower's eligibility for the borrower to qualify for a false certification discharge. However, the

Department believes that schools should be able to rely on an attestation from a borrower that the borrower earned a high school diploma in cases when the borrower is unable to obtain an official transcript or diploma from the high school. Therefore, we are proposing regulatory language that would provide that when a borrower provides an institution an attestation of their high school graduation status for purposes of admission to the institution, they may not subsequently qualify for a false certification discharge based on not having a high school diploma. Moreover, if the institution has confirmed with a State authority that the school was approved by that State to issue high school diplomas at the time of the borrower's graduation from that school, the institution must collect evidence that a student has a bona fide diploma from the school. The school has no additional obligation to collect transcripts or other information in order to certify the student.

A negotiator noted that the current regulations specify that the borrower qualifies for a false certification discharge if the borrower did not have a high school diploma or recognized equivalent at the time the loan was originated. The negotiator pointed out that the loan can be originated but the funds might not be disbursed and suggested that the date of disbursement might be the appropriate date rather than the date of origination. In addition, a borrower could be a senior in high school at the time the loan was originated, with the expectation that the borrower will have graduated high school at the time of enrollment. While a loan can be originated months before a borrower enrolls in a school, it is not disbursed until the student is enrolled.

The Department agrees that using disbursement date rather than origination date would be a more accurate indicator that a school falsely certified a borrower's high school graduation status, and has made that change in the proposed language.

One negotiator suggested amending the regulations to specify that a borrower must have a ''valid high school diploma.'' The negotiator believed that this addition would protect schools from companies that create false diplomas for potential student loan borrowers. Although the 2016 final regulations did not use the phrase ''valid high school diploma,'' those regulations added language to 34 CFR 685.215 intended to state more explicitly that a school's certification of eligibility for a borrower who is not a high school graduate, and who does not meet the alternative to high school graduate requirements, is grounds for a false certification discharge. As explained in the preamble to the NPRM for the 2016 final regulations, the added language was meant to address the problem of schools encouraging students to obtain false high school diplomas to qualify for Direct Loans. *See* 81 FR 39377. Upon further review however, the Department believes that the existing language of 34 CFR 685.215, with its proposed updates for changes in the Department's statutory authority as noted above, already covers such circumstances. The Department accordingly does not propose including such additional language in the regulations proposed in this NPRM, and proposes to rescind these provisions of the 2016 final regulations. A school still falsely certifies a borrower's eligibility if it is aware that a student does not have a high school diploma and encourages the student to obtain a false diploma. The addition of the word ''valid'' to the requirement that a borrower have a high school diploma would not have any meaningful effect, as an ''invalid'' high school diploma would not be a ''high school diploma'' for the purposes of this regulation.

In the 2016 final regulations, the Department also added language to clarify a provision in existing 34 CFR 685.215 that a borrower may receive a false certification discharge of a Direct Loan if the school certified the eligibility of a student who, because of a physical or mental condition, age, criminal record, or other reason accepted by the Secretary, would not meet the requirements for employment in the student's State of residence in the occupation for which the training program for which the loan was provided was intended—or in other words, certified the student despite the fact that the student had a disqualifying status. 34 CFR 685.215(a)(1)(iii). Upon further review, however, the Department believes that the changes in the 2016 final regulations did not alter the operation of the existing regulation as to disqualifying conditions in any meaningful way, and as a result does not propose such added language in these regulations. We, therefore, propose to rescind this provision of the 2016 final regulations.

Finally, in the 2016 final regulations, the Department added that the Department may consider evidence that a school had falsified the Satisfactory Academic Progress (SAP) of its students to determine whether to discharge a borrower's loan without an application from the borrower. 81 FR 76082 (text of 34 CFR 685.215(c)(8)). Existing 34 CFR 685.215 already provides that the Department may discharge a borrower's Direct Loan by reason of false certification without an application. Evaluation of an institution's implementation of their SAP policy is already part of an FSA program review, so there is already a mechanism in place to identify inappropriate activities in implementing an institution's SAP policy. Therefore, the Department declines to include such a provision in the regulations proposed in this NPRM and proposes rescinding this provision of the 2016 final regulations.

Financial Responsibility (§ 668.171 General)

Statute: Section 487(c)(1) of the HEA authorizes the Secretary to establish reasonable standards of financial responsibility. Section 498(a) of the HEA provides that, for purposes of qualifying an institution to participate in the title IV, HEA programs, the Secretary must determine the legal authority of the institution to operate within a State, its accreditation status, and its administrative capability and financial responsibility.

Section 498(c)(1) of the HEA authorizes the Secretary to establish ratios and other criteria for determining whether an institution has the financial responsibility required to (1) provide the services described in its official publications, (2) provide the administrative resources necessary to comply with title IV, HEA requirements, and (3) meet all of its financial obligations, including but not limited to refunds of institutional charges and repayments to the Secretary for liabilities and debts incurred for programs administered by the Secretary.

Current Regulations: The current regulations in § 668.171(a) mirror the statutory requirements that to begin and to continue to participate in the title IV, HEA programs, an institution must demonstrate that it is financially responsible. The Secretary determines whether an institution is financially responsible based on its ability to provide the services described in its official publications, properly administer the title IV, HEA programs, and meet all of its financial obligations.

The Secretary determines that a private non-profit or proprietary institution is financially responsible if it satisfies the ratio requirements and other criteria specified in the general standards under § 668.171(b) and appendix A or B to subpart L of the General Provisions regulations. Under those standards, an institution:

- Must have a composite score of at least 1.5, based on its Equity, Primary Reserve, and Net Income ratios;

• Must have sufficient cash reserves to make required refunds;

• Must be current in its debt payments. An institution is not current in its debt payment if it is in violation of any loan agreement or fails to make a payment for 120 days on a debt obligation and a creditor has filed suit to recover funds under that obligation; and

• Must be meeting all of its financial obligations, including but not limited to refunds it is required to make under its refund policy or under § 668.22, and repayments to the Secretary for debts and liabilities arising from the institution's participation in the title IV, HEA programs.

Proposed Regulations: We propose to restructure § 668.171, in part, by amending paragraph (b) and adding new paragraphs (c) and (d) that provide that an institution does not or may not be able to meet its financial or administrative obligations if it is subject to one or more of the following actions or events:

Mandatory triggering events:

• *Liabilities from borrower defenses to repayment or final judgments or determinations.* After the end of the fiscal year for which the Secretary has most recently calculated an institution's composite score, the institution incurs a liability arising from borrower defense to repayment discharges granted by the Secretary, or a final judgment or determination from an administrative or judicial action or proceeding initiated by a Federal or State entity and as a result of that liability, the institution's recalculated composite score is less than 1.0, as determined by the Secretary under proposed paragraph (e) of this section.

• *Withdrawal of owner's equity.* For a proprietary institution whose composite score is less than 1.5, there is a withdrawal of owner's equity from the institution by any means, including by declaring a dividend (unless the withdrawal is a transfer to an entity included in the affiliated entity group on whose basis the institution's composite score was calculated), and as a result of that withdrawal, the institution's recalculated composite score is less than 1.0, as determined by the Secretary under proposed paragraph (e) of this section.

• *SEC and Exchange Actions for publicly traded institutions.* The SEC issues an order suspending or revoking the registration of the institution's securities pursuant to section 12(j) of the Securities and Exchange Act of 1934 (the ''Exchange Act'') or suspends trading on the institution's securities on any national securities exchange pursuant to section 12(k) of the Exchange Act or the national securities exchange on which the institution's securities are traded delists, either voluntarily or involuntarily, the institution's securities pursuant to the rules of the relevant national securities exchange.

Discretionary triggering events:

• *Accrediting agency actions.* The institution is issued a show-cause order that if not satisfied, would lead the accreditor to withdraw, revoke or suspend institutional accreditation.

• *Loan agreement violations.* The institution violated a provision or requirement in a security or loan agreement with a creditor, and as provided under the terms of that security or loan agreement, a monetary or nonmonetary default or delinquency event occurs, or other events occur, that trigger, or enable the creditor to require or impose on the institution, an increase in collateral, a change in contractual obligations, an increase in interest rates or payments, or other sanctions, penalties, or fees.

• The institution is cited by a State licensing or authorizing agency for violating a State or agency requirement and notified that its licensure or authorization will be withdrawn or terminated if the institution does not take the steps necessary to come into compliance with those requirements.

• *90/10 Revenue Requirement.* For its most recently completed fiscal year, a proprietary institution did not derive at least 10 percent of its revenue from sources other than title IV, HEA program funds, as provided under § 668.28(c).

• *Cohort default rate (CDR).* The institution's two most recent official cohort default rates are 30 percent or greater, as determined under 34 CFR part 668, subpart N, unless the institution files a challenge, request for adjustment, or appeal under that subpart with respect to its rates for one or both of those fiscal years, and that challenge, request, or appeal remains pending, results in reducing below 30 percent the official cohort default rate for either or both years, or precludes the rates from either or both years from resulting in a loss of eligibility or provisional certification.

Also, we propose to add a new paragraph (e) under which the Secretary would recalculate an institution's most recent composite score for a mandatory triggering event under proposed paragraph (c)(1) by recognizing as an expense the actual amount of the liability incurred by an institution or by accounting for the withdrawal of owner's equity. Specifically, the Secretary would use the audited financial statements from which the institution's most recent composite score was calculated and would account for that expense or withdrawal by:

• For the actual liabilities incurred by a proprietary institution, (1) increasing expenses and decreasing adjusted equity by that amount for the primary reserve ratio, (2) decreasing modified equity by that amount for the equity ratio, and (3) decreasing income before taxes by that amount for the net income ratio.

• For the withdrawal of owner's equity, (1) decreasing adjusted equity by the amount for the primary reserve ratio, and (2) decreasing modified equity by that amount for the equity ratio.

• For the actual liabilities incurred by a non-profit institution, (1) increasing expenses and decreasing expendable net assets by that amount for the primary reserve ratio, (2) decreasing modified net assets by that amount for the equity ratio, and (3) decreasing change in net assets without donor restrictions by that amount for the net income ratio.

In addition, we propose to add a new paragraph (f) under which an institution would be required to notify the Secretary no later than 45 days after the end of its fiscal year if it did not satisfy the 90/10 revenue requirement, and notify the Secretary no later than 10 days after any other mandatory or discretionary triggering event occurs. In that notice, or in response to a preliminary determination by the Secretary that the institution is not financially responsible based on one or more of those actions or events, the institution could:

• Demonstrate that the reported withdrawal of owner's equity was used exclusively to meet tax liabilities of the institution or its owners for income derived from the institution;

• Show that the mandatory or discretionary event has been resolved, or demonstrate that the institution has insurance that will cover all or part of the liabilities that arise from final judgments or determinations; or

• Provide information about the conditions or circumstances that precipitated that triggering event that demonstrates that the action or event has not or will not have a material adverse effect on the institution.

• Show that the creditor waived a violation of a loan agreement and if applicable, identify any conditions or changes to the loan agreement that the creditor imposed in exchange for granting the waiver.

Finally, the Secretary would consider the information provided by the institution in determining whether to issue a final determination that the

institution is not financially responsible.

Reasons: Under the current process, for the most part, the Department determines annually whether an institution is financially responsible based on its audited financial statements, which are submitted to the Department six to nine months after the end of the institution's fiscal year. Under these proposed regulations, we may determine at the time that certain actions or events occur that the institution is not financially responsible. We address the significance of an action or event that occurs after the close of an audited period (or, in other words, between audit cycles), to assess in a more timely manner whether the institution, regardless of its composite score, satisfies the statutory requirements that it is able to provide the services described in its publications and statements, to provide the administrative resources necessary to comply with title IV, HEA requirements, and to meet all of its financial obligations. In doing so, we propose to expand the range of events that could make an institution not financially responsible, from the provisions under § 668.171(b)(3) relating to whether an institution is current in its debt payments, to other events that may pose a material adverse risk to the financial viability of the institution. In cases where the Department determines that an event poses a material adverse risk, this approach would enable us to address that risk contemporaneously by taking the steps necessary to protect the Federal interest.

Mandatory Triggering Events

With regard to liabilities arising from defenses to repayment discharges adjudicated by the Secretary or an administrative or judicial action or proceeding initiated by a Federal or State entity, we would assess the risk by determining whether the payment of those liabilities would cause the institution's composite score to fall below 1.0. As noted above, the actual amount of the liability would be treated as an expense and the Department would recalculate the institution's most recent composite score using that amount. Assuming that an institution's composite score is 1.0 or higher, if its recalculated composite score does not fall below 1.0, we would conclude that the institution has the resources to pay those liabilities and continue operations. In cases where the institution's recalculated score is less than 1.0, we would conclude that the payment of those liabilities would have a material adverse effect on its operations that warrants additional oversight and financial protection.

During negotiated rulemaking, several non-Federal negotiators argued that including liabilities arising from judicial or administrative actions initiated by a Federal or State entity may cause small or not material changes from an accounting perspective, and reporting those liabilities to the Department would be burdensome and of little value. They suggested that an institution should report only those liabilities that are material, as determined by the institution or its accountant. While we agree that reporting all liabilities from actions resulting in final judgments or determinations may not be necessary, we are concerned that the subjective nature of materiality evaluations could result in an institution not reporting an otherwise significant action. We believe that a better, more objective, approach would be to evaluate the impact of the liability on the institution's composite score, regardless of the amount or materiality of the liability.

The withdrawal of owner's equity is currently an event that an institution reports to the Department under the provisions of the zone alternative in § 668.175(d). An institution participates under the zone alternative if its composite score is between 1.0 and 1.5. We proposed at negotiated rulemaking to relocate this provision to the general standards of financial responsibility under § 668.171. Under those general standards, this provision would still be a reportable event, but only in cases where an institution's financial condition is already precarious and any withdrawal of funds from the institution would further jeopardize its ability to continue as a going concern. In this NPRM, we propose to account for the withdrawal of owner's equity by decreasing adjusted equity and modified equity in recalculating the institution's composite score. Doing so would enable the Department to quantify objectively the impact of the withdrawal.

For publicly-traded institutions, we believe that the SEC or stock exchange-related issues listed in the proposed regulations are actions which would jeopardize the institution's ability to meet its financial obligations or continue as a going concern.

When the SEC suspends trading on the institution's stock, the SEC does not make this warning public or announce that it is considering a suspension until it determines that the suspension is required to protect investors and the public interest.[4] In that event, the SEC posts the suspension and the grounds for the suspension on its website. Therefore, under the reporting requirements in proposed § 668.171(e), the institution would be required to notify the Department within 10 days of receiving notification from the SEC that the institution is being suspended. The SEC may decide to, for example, suspend trading on the institution's stock based on (1) a lack of current, accurate, or adequate information about the institution, for example when the institution is not current in filing its periodic reports; (2) questions about the accuracy of publicly available information, including information in institutional press releases and reports and information about the institution's current operational status, financial condition, or business transactions; or (3) questions about trading in the stock, including trading by insiders, potential market manipulation, and the ability to clear and settle transactions in the stock.[5] Because an action by the SEC to suspend trading in, or delist, an institution's stock directly impairs an institution's ability to raise funds—creditors may call in loans or the institution's credit rating may be downgraded—the Department needs to be informed of those actions in a timely manner.

With regard to compliance with stock exchange requirements, the major exchanges typically require institutions whose stock is listed to satisfy certain minimum requirements such as stock price, number of shareholders, and the level of shareholder's equity.[6] Among other things, if a stock falls below the minimum price, the institution fails to provide timely reports of its performance and operations in its Form 10–Q or 10–K filings with the SEC, or other requirements are not met, the exchange may delist the institution's stock. Delisting is generally regarded as the first step toward a Chapter 11 bankruptcy. However, before the exchange initiates a process to delist the stock, the exchange notifies the institution and may, as applicable, give the institution several days to respond

[4] See SEC Investor Bulletin: Trading Suspensions, available at *www.sec.gov/answers/tradingsuspension.htm.*

[5] Id.

[6] See, *e.g.,* New York Stock Exchange Rule 801.00: Suspension and Delisting: Securities admitted to the list may be suspended from dealings or removed from the list at any time that a company falls below certain quantitative and qualitative continued listing criteria. When a company falls below any criterion, the Exchange will review the appropriateness of continued listing.

Available at *nysemanual.nyse.com/lcm/sections/lcmsections/chp_1_9/default.asp.*

with a plan of the actions it intends to take to come into compliance with exchange requirements.

With respect to an institution's failure to timely file a required annual or quarterly report with the SEC, we noted previously in this discussion that the late filing of, or failure to file, a required SEC report may precipitate an adverse action by the SEC or a stock exchange. Or, a late filing may limit the institution's ability to conduct certain types of registered securities offerings. In addition, capital markets tend to react negatively in response to late filings. All told, the consequences of late SEC filing may impact the institution's capital position and its financial responsibility for title IV purposes.

With regard to the proposed provision regarding an institution that voluntarily delists its stock; we note that this action would typically relate to a change in ownership that would be subject to Department review. However, even if that action does not trigger a change in ownership, we believe the shift from equity to private financing is a significant event warranting review.

Discretionary Triggering Events

During negotiated rulemaking, the Department proposed several actions or events, all of which were discretionary, that would likely have a material adverse effect on an institution's financial condition. Some of the non-Federal negotiators noted that the 2016 final regulations contained a wider range of triggering events, some mandatory and some discretionary, and urged the Department to adopt that framework and those triggering events in this NPRM to better protect taxpayers. As previously discussed, we are proposing in this NPRM only mandatory triggering events whose consequences are known and quantified (*e.g.,* the actual liabilities incurred from defense to repayment discharge) and objectively assessed through the composite score methodology, or whose consequences pose a severe and imminent risk (*e.g.,* SEC or stock exchange actions) to the Federal interest that warrant financial protection.

This approach differs from that in the 2016 final regulations. Those regulations included as mandatory triggering events (1) events whose consequences were speculative (*e.g.,* estimating the dollar value of a pending lawsuit or pending defense to repayment claims, or evaluating the effects of fluctuations in title IV funding levels), (2) events more suited to accreditor action or increased oversight by the Department (*e.g.,* high drop-out rates and unspecified State violations that may have no bearing on an institution's financial condition or ability to operate in the State), and (3) results of a test (*e.g.,* a financial stress test) whose future development and application was unspecified. Upon further review, we believe these triggering events are inappropriate and would have unnecessarily required institutions to provide a letter of credit or other financial protection. But we propose to include some of the 2016 triggers as discretionary events- certain accrediting agency actions, violations of loan agreements, State licensure and authorization violations, and high cohort default rates. We are also proposing to rescind the mandatory triggering event provisions of the 2016 final regulations.

When an accrediting agency issues an institutional accreditation show-cause order, such action may call into question the institution's continued ability to operate as an accredited institution. As a discretionary trigger, we would work with the institution and the accreditor to determine whether that action has or will have a material adverse effect on the institution's condition or its ability to continue as a going concern before determining whether the institution is financially responsible.

The Department also intends to modify the provisions currently in § 668.171(b)(3) to address violations of loan agreements as a discretionary triggering event. That section currently provides that an institution is not current in debt payments if a loan agreement violation is noted in its audited financial statements or it is more than 120 days delinquent in making a payment and a creditor has filed suit. The Department intends to replace that rule with a discretionary trigger that looks more holistically at the nature and outcome of loan violations. Doing so removes the constraints of relying on disclosures in annual audits or the filing of a lawsuit, and is more in keeping with our goal of assessing potential financial issues contemporaneously. As noted in the proposed provision, a violation of a loan agreement can precipitate a number of consequences that may have a material adverse effect on an institution's ability to meet its financial obligations. For example, the creditor may decide to waive the violation entirely or waive it in exchange for other concessions. In any case, as a discretionary trigger, the Department would work with the institution to determine whether the violation has or could have material financial consequences before determining whether the institution is financially responsible.

The Department similarly plans a more targeted approach to violations of State authorization or licensing requirements. Unlike the 2016 final regulations where an institution would report to the Department any violation of a State authorization or licensing requirement, we propose to consider only those violations that, if unresolved, could lead to termination of the institution's ability to continue to provide educational programs or otherwise continue to operate in the State. Therefore, we propose to rescind these mandatory reporting provisions of the 2016 final regulations.

The Department also proposes to treat the 90/10 revenue requirement as a discretionary triggering event. A proprietary institution that fails the requirement for one fiscal year is in danger of losing its eligibility to participate in the title IV, HEA programs if it fails again in the subsequent fiscal year. Along the same lines, an institution whose cohort default rate is 30% or more for two consecutive years is in danger of losing its title IV loan eligibility if its default rate is 30% or more in the subsequent year. In either case, that risk of lost eligibility may require the Department to seek financial protection from the institution. While the 2016 final regulations would have required an affected institution to provide a letter of credit or other financial protection immediately, the Department believes it is more appropriate for the Department to review the institution's efforts to remedy or mitigate the reasons for its failure, to evaluate the institution's potential and plan to teach-out students if closure appears inevitable, and to assess the extent to which there were anomalous or mitigating circumstances leading to its failure, before determining whether the institution is financially responsible.

In response to requests by the non-Federal negotiators that a process be created to allow an institution to provide information about an action or event to the Department before the Department issues a final determination, we suggested such a process during the negotiations and propose that same process in these regulations. Under that process, an institution has the opportunity to provide information for reportable events twice—once when it notifies the Department that the event occurred and then, if it has additional information, whenever the Department makes a preliminary determination that the event would have a material adverse impact on the institution. For the

reporting requirements in proposed paragraph (f), we adopt the timeframe currently in § 668.28 for notifying the Department of 90/10 failures. For all other events addressed in these proposed regulations, we believe 10 days provides sufficient time for institutions to report those events and for the Department to take action, if needed.

Financial Ratios (§ 668.172)

Statute: Section 498(c)(1) of the HEA authorizes the Secretary to establish ratios and other criteria for determining whether an institution has the financial responsibility required to (1) provide the services described in its official publications; (2) provide the administrative resources necessary to comply with title IV, HEA requirements; and (3) meet all of its financial obligations, including but not limited to refunds of institutional charges and repayments to the Secretary for liabilities and debts incurred for programs administered by the Secretary.

Current Regulations: Section 668.172 defines the Primary Reserve, Equity, and Net Income ratios that comprise the composite score and Appendices A and B illustrate how the composite score is calculated using sample financial statements from proprietary and private non-profit institutions.

Proposed Changes: The Secretary proposes to calculate a composite score in accordance with new standards issued by the Financial Standards Accounting Board (FASB) in Accounting Standards Update (ASU) 2016–02, ASC 842 (Leases). However, the Department will need to update the composite score calculation to take into account this dramatic change in FASB standards, which it cannot do immediately. As a result, for 6 years following the implementation of the new FASB standards, or following the publication of new composite score formula regulations to take into account the FASB change, whichever is shorter, institutions that fail the composite score based on the new FASB standards, but would have had a passing composite score under the former FASB standards (with regard to leases), may request the calculation of an alternative composite score based on additional data provided by the institution to the Department to enable it to calculate an alternative composite score excluding operating leases. The Department will use the higher of those two composite scores to determine whether the institution is financially responsible.

Reasons: The new FASB reporting requirements could negatively impact an institution's composite score even though the underlying financial condition of the institution has not changed. Based on changes FASB announced in February, 2016 in ASU–2016–2, operating leases longer than 12 months will be recorded under GAAP as separate liabilities and right-of-use assets. Consequently, adding operating leases to the Balance Sheet (for proprietary institutions) or to the Statement of Financial Position (for non-profit institutions) could decrease the Equity Ratio if the right-of-use assets in the Modified Assets category significantly increased compared to Modified Equity or Modified Net Assets, resulting in a lower composite score. With that in mind, some of the non-Federal negotiators argued that, due to the long-term nature of some leases, the Department should allow an institution some time to change its business model regarding leases before applying the new FASB standards to its existing leases for purposes of calculating the composite score. We agreed, and in the final session of negotiated rulemaking proposed a six year transition period during which existing leases would be treated under the previous FASB guidance.

However, upon further review, we believe that a transition period would only partially defer and not adequately address the consequences of the accounting changes and how those changes are reflected in the composite score. While we recognize that schools must adhere to the new FASB reporting requirements, which will be reflected in their audited statements, we believe that including assets and liabilities associated with those transactions in the composite score, where no lease-related assets or liabilities are currently included, could encourage some institutions to make changes in their business model that have negative consequences for students. To mitigate a negative impact of the new lease reporting requirements on their composite score, institutions may enter into shorter term but higher cost leases instead of continuing in or entering into longer term leases which typically have better terms, such as lower monthly lease rates and more cost-effective lease improvements. Shorter, more expensive leases may raise costs for institutions, and therefore students, and could result in more frequent campus relocations or closures that may interfere with students' ability to complete their programs and raise the risk to taxpayers of increased numbers of closed school student loan discharges. We believe that it is undesirable to put an institution in a position where it could incur increased costs from short-term leases or where the institution would have to relocate or close because it could not negotiate or renew a favorable lease agreement without jeopardizing its composite score. In some instances, even if the school is able to relocate to another comparable facility, the State authorizing body or the accreditor may not approve that relocation if the new facility is more than a certain geographic distance or travel time away from the original campus, if it is on a different public transportation line or if it lacks comparable access via public transportation. In such a case, the campus move is treated as a campus closure, which requires the institution to either teach-out the closing campus or suffer the financial losses associated with closed school loan discharges. The higher costs of short-term leases or relocation costs, or both, would likely be passed on to students. Unfortunately, the composite score currently has no mechanism for automatic updates in the event of changes in accounting standards.

For these reasons, and because the impact of the upcoming FASB lease requirements is unknown, we believe it is necessary to update the composite score regulations to take into account this and other FASB changes. Future negotiated rulemaking will be required to update the composite score regulations, so until such time as revised composite score regulations are established, or for six years after implementation of the new FASB standards (for leases), the Department will allow institutions the option to continue calculating the composite score under current GAAP standards. Therefore, the Department proposes an approach under which we will calculate a composite score for all institutions under the new FASB requirements when they take effect since all audited financial statements will be based on the new requirements, but we will allow institutions to provide additional data to support the calculation of an alternative composite score under current GAAP standards (GAAP prior ASU–2016–2 implementation), and in such a case, to use the higher of the two composite scores to evaluate financial responsibility, for the next six years or until revised composite score regulations are promulgated, which ever period is shortest.

Appendix A to Subpart L, Part 668

Statute: Section 498(c)(1) of the HEA authorizes the Secretary to establish ratios and other criteria for determining whether an institution has the financial responsibility required to (1) provide

the services described in its official publications, (2) provide the administrative resources necessary to comply with title IV, HEA requirements, and (3) meet all of its financial obligations, including but not limited to refunds of institutional charges and repayments to the Secretary for liabilities and debts incurred for programs administered by the Secretary.

Current Regulations: As provided under § 668.172(a), appendix A to subpart L contains three sections that illustrate how the composite score is calculated for a proprietary institution. Section 1 sets forth the ratios and defines the ratio terms. Section 2 provides a model Balance Sheet and Statement of Income and Retained Earnings with numbered line entries and shows the numbered entries that are used to calculate each of the financial ratios. Section 3 takes the calculated ratios from Section 2 and applies strength factors and weights associated with each ratio to derive a blended, or composite, score that the Secretary uses to determine, in part, whether the institution is financially responsible.

Proposed Changes: The Secretary proposes revising these three sections by amending the first section to reflect changes in accounting standards and to make other clarifying changes that the Secretary believes will improve compliance with the financial responsibility standards. We propose to add a new section 2 that would provide a Supplemental Schedule which schools would be required to provide as part of their annual financial statement audit submission. Proposed section 2 would be titled, ''Section 2: Financial Responsibility Supplemental Schedule Requirement and Example.'' Proposed Section 3 would combine sections 2 and 3 from the current regulations, and would be titled, ''Example Financial Statements and Composite Score Calculation.''

Appendix A, Section 1

For a proprietary institution, the Secretary proposes to revise the numerator, Adjusted Equity, and the denominator, Total Expenses, of the Primary Reserve Ratio.

Changes to Adjusted Equity:

As currently defined, Adjusted Equity includes ''post-employment and retirement liabilities'' and ''all debt obtained for long-term purposes.'' The Secretary proposes changing these terms to ''post-employment and defined benefit pension liabilities'' and ''all debt obtained for long-term purposes, not to exceed property, plant and equipment (PP&E),'' respectively. In addition, the Secretary proposes to clarify the term ''unsecured related party receivables'' by referencing the related entity disclosure requirements under § 668.23(d). With regard to determining the value of PP&E, which is currently the amount net of accumulated depreciation, the Secretary proposes to include construction in progress and lease right-of-use assets.

As noted above, we propose to amend the current definition of ''debt obtained for long-term purposes'', which currently includes the short-term portion of the debt, up to the amount of PP&E. Specifically, we are proposing to change the meaning of the term ''debt obtained for long-term purposes'', to include lease liabilities for lease right-of-use assets and the short-term portion of the debt, up to the amount of net PP&E. However, if an institution wishes to include the debt as part of the total debt obtained for long-term purposes, including debt obtained through long-term lines of credit, the institution would have to provide a disclosure in the financial statements that the debt, including lines of credit, exceeds twelve months and was used to fund capitalized assets (*i.e.,* PP&E or capitalized expenditures per Generally Accepted Accounting Principles (GAAP)). The disclosure for the debt would include the issue date, term, nature of capitalized amounts and amounts capitalized. The debt obtained for long-term purposes would be limited to those amounts disclosed in the financial statements that were used to fund capitalized assets. Any other debt amount, including long-term lines of credit used to fund operations, would be excluded from debt obtained for long-term purposes.

Changes to Total Expenses:

Currently, the regulations provide that the term ''Total Expenses'' excludes income tax, discontinued operations, extraordinary losses or change in accounting principle. The Department proposes to change that term to ''Total Expenses and Losses'' and define the proposed term as: All expenses and losses, (excludes income tax, discontinued operations not classified as an operating expense or change in accounting principle), less any losses on investments, post-employment and defined benefit pension plans and annuities. Any losses on investments would be the net loss for the investments and Total Expenses and Losses would include the nonservice component of net periodic pension and other post-employment plan expenses.

Net Income Ratio

The Department proposes to modify the numerator of the Net Income ratio, ''Income before Taxes,'' and the denominator, ''Total Revenues.''

Currently, ''Income before Taxes'' is taken directly from the institution's audited financial statements. The Department proposes to define ''Income before Taxes'' to include all revenues, gains, expenses and losses incurred by the institution during the accounting period. Income before taxes would not include income taxes, discontinued operations not classified as an operating expense or changes in accounting principle.

With regard to the denominator, we propose to change the term ''Total Revenues'' to ''Total Revenues and Gains.''

We note that while the current regulations define the term ''Total Pretax Revenues'' (total operating revenues + non-operating revenues and gains, where investments gains should be recorded net of investment losses), that term was erroneously published and we should have used the term Total Revenues. The Secretary proposes to correct that error and define the term, ''Total Revenues and Gains'' as all revenues and gains not including positive income tax amounts, discontinued operations not classified as an operating gain, or change in accounting principle (investment gains would be recorded net of investment losses).

Reasons: The proposed changes are intended to reflect current accounting standards, particularly Accounting Standards Update (ASU) 2016–2 Leases (Topic 842), and clarify how the composite score is calculated.

When implemented, ASU 2016–2 will require all non-profit and proprietary institutions to recognize the assets and liabilities that arise from leases. In accordance with FASB Concepts Statement No. 6, Elements of Financial Statements, all leases create an asset and a liability as of the date of the Statement of Financial Position, or Balance Sheet, and therefore, an institution must recognize those lease assets and lease liabilities as of that date. This is a change compared to the previous GAAP approach, which did not require lease assets and lease liabilities to be recognized for most leases.

Under this ASU, a proprietary institution is required to recognize in its Balance Sheet a liability for the value of the lease agreement (the lease liability) and a right-of-use asset representing its right to use the underlying asset for lease terms longer than one fiscal year. The principal difference from previous accounting guidance is that the lease assets and lease liabilities arising from

operating leases will now be recognized in the Balance Sheet.

The Subcommittee asked the Department to consider including defined benefit pension plan liabilities as a retirement liability that would be added back to Adjusted Equity. The Subcommittee stated that changes in accounting practice that now require defined pension plan liabilities to be on the face of the financial statements, as well as, the required insurance for pension liabilities and the timing of when the liability would be payable, all indicate that defined benefit plan liabilities should not reduce Adjusted Equity. In addition, the Subcommittee argued that all other retirement liabilities are already included in post-employment liabilities and rather than having post-employment and retirement liabilities for expendable net assets it would be clearer to the community to use post-employment and defined benefit pension plan liabilities. The Department agreed that the Subcommittee proposals would clarify how defined benefit pension plan liabilities will be treated for purposes of Adjusted Equity.

In the preamble to the notification of final regulations published in the **Federal Register** on November 25, 1997 (62 FR 62867) (1997 Regulations), the Department was clear that the expenses included in the Primary Reserve Ratio included losses; however the appendix did not include language concerning losses. Since the inception of the composite score as a measure of a school's financial health, the Department has included losses as part of the denominator for the Primary Reserve Ratio. The proposed changes to the denominator for the Primary Reserve Ratio reflect changes in the accounting terminology and clarify what has consistently been the Department's practice. With regard to losses, the Subcommittee suggested that there were some losses that should not be reflected in the Primary Reserve Ratio. The Subcommittee proposed that the Primary Reserve Ratio not include any losses from post-employment and defined benefit pension plans and annuities. The Department agreed.

As a result of ASU 2016–2, the Department proposes including the right-of-use asset from leases as part of PP&E (which is a component of Adjusted Equity in the Primary Reserve ratio). The Subcommittee recommended that the Department include construction in progress in PP&E for the purpose of calculating the Primary Reserve ratio. The Subcommittee members pointed out that by its very nature, construction in progress could not be considered an expendable asset because it cannot be easily converted to cash or cash equivalents when an institution is in financial difficulty. The Department agreed and proposes here to include construction in progress with PP&E.

Initially, the Subcommittee's discussion about how to treat debt obtained for long-term purposes in calculating the composite score, focused around the change in accounting for leases under ASU 2016–2. Under ASU 2016–2 the liability for leases is not considered debt for accounting purposes. The Subcommittee noted that although the lease liability was not debt, the liability was clearly associated with PP&E and argued that it should be included as debt obtained for long-term purposes for the composite score. This discussion then expanded to consider the various types of debt and liabilities that the Department encounters in evaluating financial statements and computing the composite score. In 2017, both the Government Accountability Office (GAO) and the Department's Office of Inspector General (OIG) issued audit reports that found that the Department was not doing enough to limit manipulation of the composite score to protect students from institutions that could be in danger of financial difficulty (''Education Should Address Oversight and Communication Gaps in Its Monitoring of the Financial Condition of Schools'' (GAO–17–555)[7] and ''Federal Student Aid's Processes for Identifying At-Risk Title IV Schools and Mitigating Potential Harm to Students and Taxpayers'' (ED–OIG A09Q0001)[8]). The Department is aware that some institutions use debt, including long-term lines of credit, to improve their composite scores without actually using the debt for long-term purposes. The use of debt to improve the composite score, including long-term lines of credit, can be difficult to identify from examining an institution's audited financial statements. When the composite score was originally developed, the Department's intention was that the long-term debt would be added back for purposes of the calculation of the expendable net assets was the amount of debt that was used for the purchase of capitalized assets. We question the viability of an institution that uses debt, including long-term lines of credit, for current operations as opposed to long-term purposes. Consequently, the amount of long-term debt that is added back for expendable net assets should have some relationship to PP&E—and therefore should not be included in debt obtained for long-term purposes if it is not used for the purchase of capitalized assets.

The Subcommittee specifically discussed the treatment of long-term lines of credit with regard to debt obtained for long-term purposes and agreed with the Department's proposed treatment of long-term lines of credit. The Department proposes extending this treatment to all debt not used for long-term purposes to further reduce or mitigate manipulation of the composite score.

In the preamble to the 1997 Regulations, the Department was clear that the calculation of expenses for the Primary Reserve Ratio included losses; however, the Appendices to subpart L did not include language concerning losses. Since the inception of the composite score, the Department has included losses as part of the denominator for the Primary Reserve Ratio. The proposed changes to the denominator for the Primary Reserve Ratio reflect changes in the accounting terminology and clarify what has consistently been the Department's practice. With regard to losses, the Subcommittee suggested that there were some losses that should not be reflected in the Primary Reserve Ratio. The Subcommittee proposed that the Primary Reserve Ratio should not include any losses on investments, post-employment and defined benefit pension plans and annuities. The Department agreed and has reflected this change in the proposed regulations.

The Department proposes to add a reference to the disclosure requirement for unsecured related party transactions under § 668.23(d). For both proprietary and non-profit schools, related party receivables or other related assets are excluded from the composite score calculation if the amount is not secured and perfected at the date of the financial statements. The Related Party disclosure should provide enough detail about the relationship, transaction(s) and any conditions for the Department to be able to make a determination on whether the related party receivable or other related assets are properly secured for inclusion in the composite score calculation.

Appendices A and B, Section 2

Proposed changes: Under proposed Section 2 for appendices A and B, proprietary and non-profit institutions would be required to submit a Supplemental Schedule as part of their audited financial statements. The Supplemental Schedule would contain

[7] Available at: *www.gao.gov/products/GAO-17-555.*

[8] Available at: *www2.ed.gov/about/offices/list/oig/auditreports/fy2017/a09q0001.pdf.*

all of the financial elements required to calculate the composite score and a corresponding or related reference to the Statement of Financial Position, Statement of Activities, Schedule of Natural to Functional Expenses, Balance Sheet, Income Statement, or Notes to the Financial Statements. The amount entered in the Supplemental Schedule for each element would tie directly to a line item, be part of a line item, tie directly to a note, or be part of a note in the financial statements. In addition, the audit opinion letter would contain a paragraph referencing the auditor's additional analysis of the *Supplemental Schedule.*

Reasons: As a result of the FASB updates, some elements needed to calculate the composite score would no longer be readily available in the audited financial statements, particularly for non-profit institutions. The Subcommittee suggested using a Supplemental Schedule as a means to address this issue. Moreover, by referencing the financial statements, the Supplemental Schedule would increase transparency in how the composite score is calculated for both institutions and the Department. The Subcommittee requested and received advice from auditors and accountants that the burden stemming from the Supplemental Schedule would be minimal. The Subcommittee believed, and we agree, that any burden is outweighed by the need for the information and the increase in transparency.

Appendices A and B, Section 3

Proposed changes: Proposed Section 3 would combine, conceptually, Sections 2 and 3 of the current appendices. While we do not propose to modify the current strength factors and weights for each, proposed Section 3 would be updated to reflect changes in terminology based on the changes in accounting standards and modifications to the item amounts used in the example financial statements.

Reasons: We propose to revise current Section 3 of appendices A and B to conform with the proposed changes to Sections 1 and 2 of those appendices.

Appendix B to Subpart L, Section 1

Statute: Section 498(c)(1) of the HEA authorizes the Secretary to establish ratios and other criteria for determining whether an institution has the financial responsibility required to (1) provide the services described in its official publications, (2) provide the administrative resources necessary to comply with title IV, HEA requirements, and (3) meet all of its financial obligations, including but not limited to refunds of institutional charges and repayments to the Secretary for liabilities and debts incurred in programs administered by the Secretary.

Current Regulations: Appendix B to subpart L contains three sections that illustrate how the composite score is calculated for a non-profit institution. Specifically, Section 1 sets forth the ratios and defines the ratio terms. Section 2 provides a model Statement of Activities and Balance Sheet with numbered line entries and shows the numbered entries that are used to calculate each of the financial ratios. Section 3 takes the calculated ratios from Section 2 and applies strength factors and weights associated with each ratio to derive a blended, or composite, score that the Secretary uses to determine, in part, whether the institution is financially responsible.

Proposed Changes: We propose to revise appendix B by amending the definitions of terms used in Section 1 to reflect changes in accounting standards and other changes that the Secretary believes would clarify how the composite score is calculated. We previously noted in the discussion for appendix A the proposed changes to Sections 2 and 3 of appendix B.

Appendix B, Section 1

The Department proposes to modify the definition of the terms ''Expendable Net Assets'' and ''Total Expenses'' as those terms are used in calculating the Primary Reserve Ratio. Under the current regulations, the ''Expendable Net Assets'' are:

(unrestricted net assets) + (temporarily restricted net assets) − (annuities, term endowments and life income funds that are temporarily restricted) − (intangible assets) − (net property, plant and equipment) * + (post-employment and retirement liabilities) + (all debt obtained for long-term purposes) ** − (unsecured related-party receivables).

*The value of property, plant and equipment is net of accumulated appreciation, including capitalized lease assets.

** The value of all debt obtained for long-term purposes includes the short-term portion of the debt, up to the amount of net property, plant and equipment.

The Department proposes to revise the definition of ''Expendable Net Assets'' to be:

(Net assets without donor restrictions) + (net assets with donor restrictions) − (net assets with donor restrictions: Restricted in perpetuity) * − (annuities, term endowments and life income funds with donor restrictions) ** − (intangible assets) − (net property, plant and equipment) *** + (post-employment and defined benefits pension plan liabilities) + (all long-term debt obtained for long-term purposes, not to exceed total net property, plant and equipment) **** − (unsecured related party transactions) *****.

* Net assets with donor restrictions: Restricted in perpetuity is subtracted from total net assets. The amount of net assets with donor restrictions: Restricted in perpetuity is disclosed as a line item, part of line item, in a note, or part of a note in the financial statements.

** Annuities, term endowments and life income funds with donor restrictions are subtracted from total net assets. The amount of annuities, term endowments and life income funds with donor restrictions is disclosed in as a line item, part of line item, in a note, or part of a note in the financial statements.

*** The value of property, plant and equipment includes construction in progress and lease right-of-use assets and is net of accumulated depreciation/amortization.

**** All Debt obtained for long-term purposes, not to exceed total net property, plant and equipment includes lease liabilities for lease right-of-use assets and the short-term portion of the debt, up to the amount of net property, plant and equipment. If an institution wishes to include the debt, including debt obtained through long-term lines of credit in total debt obtained for long-term purposes, the institution must include a disclosure in the financial statements that the debt, including lines of credit exceeds twelve months and was used to fund capitalized assets (*i.e.,* property, plant and equipment or capitalized expenditures per Generally Accepted Accounting Principles (GAAP)). The disclosures that must be presented for any debt to be included in expendable net assets include the issue date, term, nature of capitalized amounts and amounts capitalized. Institutions that do not include debt in total debt obtained for long-term purposes, including long-term lines of credit, do not need to provide any additional disclosures other than those required by GAAP. The debt obtained for long-term purposes will be limited to only those amounts disclosed in the financial statements that were used to fund capitalized assets. Any debt amount including long-term lines of credit used to fund operations must be excluded from debt obtained for long-term purposes.

***** Unsecured related party receivables as required at 34 CFR 668.23(d).

Under the current regulations, the term ''Total Expenses'' is defined as ''Total unrestricted expenses taken directly from the audited financial statements.'' We propose to change the term to ''Total Expenses without Donor Restrictions and Losses without Donor Restrictions.'' In addition, the Department proposes to define the new term ''Total Expenses without Donor Restrictions and Losses without Donor Restrictions'' as all expenses and losses without donor restrictions from the Statement of Activities less any losses

without donor restrictions on investments, post-employment and defined benefit pension plans, and annuities. (For institutions that have defined benefit pension and other post-employment plans, total expenses include the nonservice component of net periodic pension and other post-employment plan expenses and these expenses will be classified as non-operating. Consequently such expenses will be labeled non-operating or included with ''other changes – non-operating changes in net assets without donor restrictions'' when the Statement of Activities includes an operating measure).

The numerator of the Equity Ratio, Modified Net Assets, is currently defined as ''(total assets) – (intangible assets) – (unsecured related-party receivables).'' We propose to change the definition of Modified Net Assets to ''(net assets without donor restrictions) + (net assets with donor restrictions) – (intangible assets) – (unsecured related party receivables)''.

For the Net Income Ratio, the current regulations specify that the amounts for both the numerator, ''Change in Unrestricted Net Assets,'' and the denominator, ''Total Unrestricted Revenue'', are taken directly from the audited financial statements. We propose to rename the numerator as ''Change in Net Assets without Donor Restrictions,'' and the denominator as ''Total Revenue without Donor Restriction and Gains without Donor Restrictions.'' In addition, the Department proposes that the denominator, Total Revenue, would include amounts released from restriction plus total gains. The Department notes that with regard to gains, investment returns are reported as a net amount (interest, dividends, unrealized and realized gains and losses net of external and direct internal investment expense). Institutions that separately report investment spending as operating revenue (*e.g.* spending from funds functioning as endowment) and remaining net investment return as a non-operating item, will need to aggregate these two amounts to determine if there is a net investment gain or a net investment loss (net investment gains are included with total gains).

Reasons: The proposed changes are intended to reflect current accounting standards and clarify how the composite score is calculated. Many of the proposed changes stem from significant changes to the accounting standards, primarily ASU 2016–2 Leases (Topic 842) and 2016–14 Not-for-Profit Entities (Topic 958), ASU 2016–2 and ASU 2016–14 respectively.

When implemented, ASU 2016–2 will require all non-profit and proprietary institutions to recognize the assets and liabilities that arise from leases. In accordance with FASB Concepts Statement No. 6, Elements of Financial Statements, all leases create an asset and a liability as of the Statement of Financial Position, or Balance Sheet, date and, therefore, an institution must recognize those lease assets and lease liabilities as of that date.

A non-profit institution must recognize in the Statement of Financial Position a liability for the value of the lease agreement (the lease liability) and a right-of-use asset representing its right to use the underlying asset for the lease term. The principal difference from previous guidance is that the lease assets and lease liabilities arising from operating leases should be recognized in the Statement of Financial Position.

Under ASU 2016–14, a non-profit institution must present on the face of the Statement of Financial Position amounts for two classes of net assets at the end of the period, rather than for the currently required three classes. That is, the institution will report amounts for net assets with donor restrictions and net assets without donor restrictions, as well as the currently required amount for total net assets. Temporarily restricted net assets, which were previously reported, will be eliminated as a class of net assets. A non-profit institution must also present on the face of the Statement of Activities the amount of the change in each of the two classes of net assets rather than the currently required three net asset classes, as well as report the currently required amount of the change in total net assets for the period. These changes were made as a result of complexities arising from using the three classes of net assets which focus on the absence or presence of donor imposed restrictions and whether those restrictions are temporary or permanent.

ASU 2016–14 eliminated the use of the term ''temporarily restricted net assets'' because of difficulties with classifying assets as temporarily restricted. On its face, under this ASU, assets with donor restrictions would not be considered expendable net assets. In discussions with the Subcommittee, the Department agreed that there are some elements of assets with donor restrictions that could be considered expendable. An example of this would be an endowment where the corpus is permanently restricted by the donor, but the earnings from the endowment can be used to pay salaries. The Subcommittee put forward that the primary element of assets with donor restrictions that is not expendable is ''net assets with donor restrictions: restricted in perpetuity.'' Subtracting ''net assets with donor restrictions: restricted in perpetuity'' from net assets with donor restrictions plus net assets without donor restrictions roughly approximates the amount that would have been included in the composite score using unrestricted net assets and temporarily restricted net assets. Likewise, using the amounts from annuities, term endowments and life income funds with donor restrictions, approximates the amount of annuities, term endowments and life income funds that are temporarily restricted that would have been used prior to the proposed change.

The Subcommittee asked the Department to consider including defined benefit pension plan liabilities as a retirement liability that would be added back to expendable net assets. The Subcommittee stated that changes in accounting practice that now require defined pension plan liabilities to be on the face of the financial statements, as well as the required insurance for pension liabilities and the timing of when the liability would be payable, all indicate that defined benefit plan liabilities should not reduce expendable net assets. In addition, the Subcommittee argued that all other retirement liabilities are already included in post-employment liabilities, and rather than having post-employment and retirement liabilities for expendable net assets, it would be clearer to the community to use post-employment and defined benefit pension plan liabilities. The Department agreed that the Subcommittee proposals would clarify how defined benefit pension plan liabilities will be treated for expendable net assets.

As a result of ASU 2016–2, the Department proposes including the right-of-use asset from leases as part of PP&E (which is a component of Expendable Net Assets in the Primary Reserve ratio). During the general discussions with the Subcommittee about PP&E, the Subcommittee recommended that the Department should include construction in progress in PP&E for purposes of calculating the Primary Reserve ratio. The Subcommittee pointed out that by its very nature, construction in progress could not be considered an expendable asset because it cannot be easily converted to cash or cash equivalents when an institution is in financial difficulty. The Department agreed and

proposes here to include construction in progress with PP&E.

Initially, the discussion in the Subcommittee surrounding how to treat debt obtained for long-term purposes in calculating the composite score, focused around the change in accounting for leases under ASU 2016–2. Under ASU 2016–2 the liability for leases is not considered debt for accounting purposes. The Subcommittee noted that although the lease liability was not debt, the liability was clearly associated with PP&E and argued that it should be included as debt obtained for long-term purposes in the composite score calculation. This discussion then expanded to consider the various types of debt and liabilities that the Department encounters in evaluating financial statements and computing the composite score. As noted above, in 2017, both GAO and OIG issued audit reports that found that the Department was not doing enough to limit manipulation of the composite score to protect students from institutions that could be in danger of financial difficulty. The Department is aware that some institutions use debt, including long-term lines of credit, to improve their composite scores without actually using the debt for long-term purposes. The use of debt to improve the composite score, including long-term lines of credit, can be difficult to identify from examining an institution's audited financial statements. When the composite score was originally developed, the long-term debt that was intended to be added back for purposes of expendable net assets was the amount of debt that was used for the purchase of capitalized assets. We question the viability of an institution that uses debt, including long-term lines of credit, for current operations as opposed to long-term purposes. Consequently, the amount of long-term debt that is added back for expendable net assets should have some relationship to PP&E—and therefore should not be included in debt obtained for long-term purposes if it is not used for the purchase of capitalized assets.

The Subcommittee specifically discussed the treatment of long-term lines of credit with regard to debt obtained for long-term purposes and agreed with the Department's proposed treatment of long-term lines of credit. The Department proposes extending this treatment to all debt not used for long-term purposes to further reduce or mitigate manipulation of the composite score.

In the preamble to the 1997 Regulations, the Department was clear that expenses for the Primary Reserve Ratio included losses; however, the Appendices to subpart L did not include language concerning losses. Since the inception of the composite score, the Department has included losses as part of the denominator for the Primary Reserve Ratio. The proposed changes to the denominator for the Primary Reserve Ratio reflect changes in the accounting terminology and clarify what has consistently been the Department's practice. With regard to losses, the Subcommittee suggested that there were some losses that should not be reflected in the Primary Reserve Ratio. The Subcommittee proposed that the Primary Reserve Ratio should not include any losses without donor restrictions on investments, post-employment and defined benefit pension plans and annuities. The Department agreed.

All of the proposed changes to the Equity Ratio are based solely on changes in accounting terminology as a result of ASU 2016–14.

The change to the numerator for the Net Income Ratio is based solely on changes in accounting terminology as a result of ASU 2016–14. The proposed changes to the denominator are based on changes in accounting terminology and Department practice concerning gains. In the preamble to the 1997 Regulations, the Department was clear that revenue for the Net Income Ratio included gains; however the Appendices to subpart L did not include language concerning gains. Since the inception of the composite score, the Department has included gains as part of the denominator for the Net Income Ratio.

The Department proposes to add a reference to the regulatory disclosure requirement for unsecured related party transactions under § 668.23(d). While the Department believes that this reference promotes clarity, Subcommittee members representing the non-profit sector expressed concern that certain aspects of related party transactions unique to the non-profit sector required more thorough explanation. The Department agreed, and provides additional information below.

For both proprietary and non-profit institutions, related party receivables or other related assets are excluded from the composite score if the amount is not secured and perfected as of the date of the financial statements. The Related Party disclosure should provide enough detail about the relationship, transaction(s) and any conditions for the Department to be able to make a determination on whether the related party receivable or other related assets are properly secured for inclusion in the composite score.

For non-profit schools, related party contributions receivables from board members would be allowed to be included in secured related party receivables if there was no additional relationship or transactions with the board member or his/her family or related entities and there were no additional conditions associated with the contribution if disclosed in the related party disclosure.

Alternative Standards and Requirements (§ 668.175)

Statute: Section 498(c)(3) of the HEA provides that if an institution fails the composite score or other criteria established by the Secretary to determine whether the institution is financially responsible, the Secretary must determine that the institution is financially responsible if it provides third-party financial guarantees, such as performance bonds or letters of credit payable to the Secretary, for an amount that is not less than one-half of the annual potential liabilities of the institution to the Secretary for title IV, HEA funds, including liabilities for loan obligations discharged pursuant to section 437 of the HEA, and to students for refunds of institutional charges, including required refunds of title IV, HEA funds.

Current Regulations: As provided in § 668.175, an institution that is not financially responsible under the general standards in § 668.171 may begin or continue to participate in the title IV, HEA programs only by qualifying under an alternative standard.

Under the zone alternative in § 668.175(d), a participating institution that is not financially responsible solely because its composite score is less than 1.5 may participate as a financially responsible institution for no more than three consecutive years, but the Secretary requires the institution to (1) make disbursements to students under the heightened cash monitoring or reimbursement payment methods described in § 668.162, and (2) provide timely information regarding any adverse oversight or financial event, including any withdrawal of owner's equity from the institution. In addition, the Secretary may require the institution to (1) submit its financial statement and compliance audits earlier than the date specified in § 668.23(a)(4), or (2) provide information about its current operations and future plans.

Under the provisional certification alternative in § 668.175(f), an institution that is not financially responsible

because it does not meet the general standards in § 668.171(b), or because of an audit opinion in § 668.171(d) or a condition of past performance in § 668.174(a), may participate under a provisional certification for no more than three consecutive years, if the institution (1) provides an irrevocable letter of credit, for an amount determined by the Secretary that is not less than 10 percent of the title IV, HEA program funds the institution received during its most recently completed fiscal year, (2) demonstrates that it was current in its debt payments and has met all of its financial obligations for its two most recent fiscal years, and (3) complies with the provisions under the zone alternative.

Proposed Regulations: We propose to relocate to proposed new § 668.171(c) one of the oversight and financial events that an institution currently reports to the Department under the zone alternative in § 668.175(d)(2)(ii)—any withdrawal of owner's equity from the institution.

We propose to remove § 668.175(e) because the transition year alternative, which pertained only to fiscal years beginning after July 1, 1997 and before June 30, 1998, is no longer relevant.

Also, we propose to add a new paragraph (h) that would expand the types of financial protection the Secretary may accept. Specifically, in lieu of submitting a letter of credit, the Secretary may permit an institution to:

- Provide the amount required in the form of other surety or financial protection that the Secretary specifies in a notice published in the **Federal Register**;
- Provide cash for the amount required; or
- Enter into an arrangement under which the Secretary would offset the amount of title IV, HEA program funds that an institution has earned in a manner that ensures that, no later than the end of a six- to twelve-month period, the amount offset equals the amount of financial protection the institution is required to provide. Under this arrangement, the Secretary would use the funds offset to satisfy the debts and liabilities owed to the Secretary that are not otherwise paid directly by the institution, and would provide to the institution any funds not used for this purpose during the period covered by the agreement, or provide the institution any remaining funds if the institution subsequently submits other financial protection for the amount originally required.

In addition, we propose to amend the zone and provisional certification alternatives under § 668.175(d) and (f), to allow for these expanded types of financial protection.

Reasons: Because the costs of obtaining an irrevocable LOC have increased over time, to the point where financial institutions are not only charging fees but in many cases requiring the LOC to be fully collateralized, we are proposing to allow an institution to provide alternative forms of financial protection that would reduce the costs to an institution. Providing cash would eliminate the cost of fees associated with an LOC and the administrative offset alternative would relieve an institution from any collateralization requirements or from having to commit upfront the resources needed to obtain the required financial protection. However, we note that, to implement an administrative offset, the Department would need to control the title IV funds flowing to the institution and the current process for doing that is to place the institution on the heightened cash monitoring payment method (HCM2) under § 668.162(d)(2). The Secretary would provide funds to the institution under HCM2, but would withhold temporarily a portion of any reimbursement claim payable to the institution in an amount that ensures that by the end of the offset period, the total amount withheld equals the amount of cash or the letter of credit the institution would otherwise provide.

During negotiated rulemaking, we proposed that the offset agreement would have to provide that the entire amount of the financial protection required by the Department would have to be in place within a nine-month period. The non-Federal negotiators argued that the Department should have flexibility in setting the offset period depending on the amount of protection that is needed or the amount of the offset that the institution could reasonably provide on a monthly basis as specified in the agreement. We agreed and propose here the suggestion from the non-Federal negotiators that the total amount offset must be in place within a six- to 12-month period, as determined by the Department.

With regard to other types of surety, we are not aware of any instruments or surety products that would provide the Department with the level of financial protection, or ready access to funds, as an irrevocable letter of credit. However, should such surety products become available that the Department finds acceptable and that are less costly or more readily available to institutions, the Secretary would identify those products in a notice published in the **Federal Register**. After that, an institution could use those products to satisfy the financial protection requirements in these regulations.

Initial and Final Decisions (§ 668.90)

Statute: Section 498(d) of the HEA authorizes the Secretary to consider the past performance of an institution or of a person in control of an institution in determining whether an institution has the financial capability to participate in the title IV, HEA programs. Section 487(c)(1)(F) of the HEA, provides that the Secretary shall prescribe such regulations as may be necessary to provide for the limitation, suspension, or termination of the participation of an eligible institution in any program under title IV of the HEA.

Current Regulations: When the Department proposes to limit, suspend, or terminate a fully certified institution's participation in a title IV, HEA program, the institution is entitled to a hearing before a hearing official under § 668.91. In addition to describing the procedures for issuing initial and final decisions, § 668.91 also provides requirements for hearing officials in making initial and final decisions in specific circumstances.

The regulations generally provide that the hearing official is responsible for determining whether an adverse action—a fine, limitation, suspension, or termination—is ''warranted,'' but direct that, in specific instances, the sanction must be imposed if certain predicate conditions are proven. For instance, in an action involving a failure by the institution to provide a surety in the amount specified by the Secretary under § 668.15, the hearing official is required to consider the surety amount demanded to be ''appropriate,'' unless the institution can demonstrate that the amount was ''unreasonable.''

Further, § 668.91(a)(3)(v) states that, in a termination action brought on the grounds that the institution is not financially responsible under § 668.15(c)(1), the hearing official must find that termination is warranted unless the conditions in § 668.15(d)(4) are met. Section 668.15(c)(1) provides that an institution is not financially responsible if a person with substantial control over that institution exercises or exercised substantial control over another institution or third-party servicer that owes a liability to the Secretary for a violation of any title IV, HEA program requirements, and that liability is not being repaid. Section 668.15(d)(4) provides that the Secretary can nevertheless consider the first institution to be financially responsible if the person at issue has repaid a portion of the liability or the liability is being repaid by others, or the institution

demonstrates that the person at issue in fact currently lacks that ability to control or lacked that ability as to the debtor institution.

Proposed Regulations: The Secretary proposes to amend § 668.91(a)(3)(iii) by substituting the terms ''letter of credit or other financial protection'' for ''surety'' in describing what an institution must provide to demonstrate financial responsibility and adding § 668.171(b),(c), or (d) to the list of sections under which a condition or event may trigger a financial protection requirement. Additionally, we are proposing to modify § 668.91(a)(3)(iii) to require the hearing official to uphold the amount of a letter of credit or financial protection demanded by the Secretary, unless the institution demonstrates that the events or conditions on which the demand is based no longer exist or have been resolved, do not and will not have an material adverse effect on the institution's financial condition, or the institution has insurance that will cover the liabilities arising from those events or conditions. We propose to further modify § 668.91(a)(3)(v) to list the specific circumstances in which a hearing official may find that a termination or limitation action brought for a failure of financial responsibility for an institution's past performance failure under § 668.174(a), or a failure of a past performance condition for persons affiliated with an institution under § 668.174(b)(1), was not warranted. For the former, revised § 668.91(a)(3)(v) would state that these circumstances would be consistent with the provisional certification and financial protection alternative in § 668.175(f). For the latter, the circumstances would be those provided in § 668.174(b)(2).

Reasons: The proposed changes to § 668.91(a)(3)(iii) would update the regulations to reflect both the current language in § 668.175 and proposed changes to that section. We believe that the new language would provide more clarity than the current regulation, which provides only that the institution has to show that the amount was ''unreasonable.'' The proposed language would clearly state that the amount of the letter of credit or other financial protection would be considered unwarranted only if the reasons for which the Secretary required the financial protection no longer exist or have been resolved, do not and will not have an material adverse effect on the institution's financial condition, or the institution has insurance that will cover the liabilities arising from those events or conditions.

Our proposed revisions to § 668.91(a)(3)(iii) would reflect previous, as well as proposed, changes to the financial responsibility standards. First, the current financial responsibility standards in § 668.175 require an institution in some instances to provide a letter of credit to be considered financially responsible. We propose to modify § 668.91(a)(3)(iii) to reflect that language as well as changes proposed to § 668.175 by substituting the terms ''letter of credit or other financial protection'' for ''surety.'' Thus, the proposed changes to § 668.91 would clarify that a limitation, suspension, or termination action may involve a failure to provide any of the specified forms of financial protection.

We further propose to modify § 668.91(a)(3)(iii) to state the specific grounds on which a hearing official may find that a limitation or termination action for failure to provide financial protection demanded is not warranted. Under the proposed regulations, the hearing official must accept the amount of the letter of credit or financial protection demanded by the Secretary, unless the institution demonstrates that the events or conditions on which the demand for financial protection or letter of credit is based no longer exist or have been resolved, do not and will not have an material adverse effect on the institution's financial condition, or the institution has insurance that will cover the liabilities arising from those events or conditions. Consequently, under the proposed regulations, the institution could not claim that the event or condition does not support the demand for financial protection or that the amount demanded is unreasonable based on the institution's assessment of the risk posed by the event or condition.

The proposed changes to § 668.91(a)(3)(v) would also clarify the regulation and conform it with existing regulations describing the alternative methods by which an institution may meet the financial responsibility standards. Section 668.91(a)(3)(v) would be revised to state the grounds on which a hearing official could find that a termination or limitation action based on an institution's failure of financial responsibility, an institution's failure of a past performance condition under § 668.174(a) or a failure of a past performance condition for persons affiliated with an institution under § 668.174(b)(1) was not warranted. The changes would not add substantive new restrictions, but simply conform § 668.91 to the substantive requirements already in current regulations. Thus, as revised, § 668.91(a)(3)(v) would require the hearing official to find that the limitation or termination for adverse past performance by the institution itself was warranted, unless the institution met the provisional certification and financial protection alternatives in current § 668.175(f). For an action based on the adverse past performance of a person affiliated with an institution, the hearing official would be required to find that limitation or termination of the institution was warranted unless the institution demonstrated either proof of repayment or that the person asserted to have substantial control in fact lacks or lacked that control, as already provided in § 668.174(b)(2), or that the institution has accepted provisional certification and provided the financial protection required under § 668.175.

This proposal is very similar to changes made to this section (previously designated as § 668.90) in the 2016 final regulations. 81 FR 76072. It parallels the changes made in those regulations to conform this section to existing regulations, but departs from them to conform to changes we are proposing in this notification. Specifically, because we propose here different actions or events that might cause an institution not to be financially responsible than were included in the 2016 final regulations, the changes we now propose to this section to this section track our current proposal. Therefore, we propose to rescind this provision of the 2016 final regulations.

Limitation (§ 668.94)

Statute: Section 487(c)(1)(F) of the HEA, 20 U.S.C. 1094, provides that the Secretary shall prescribe such regulations as may be necessary to provide for the limitation, suspension, or termination of an eligible institution's participation in any program under title IV of the HEA.

Current Regulations: Section 668.86 provides that the Secretary may limit an institution's participation in a title IV, HEA program, under specific circumstances, and describes procedures for the institution to appeal the limitation. Current § 668.94 lists types of specific restrictions that may be imposed by a limitation action, and includes in paragraph (i) ''other conditions as may be determined by the Secretary to be reasonable and appropriate.'' 34 CFR 668.94(i).

The regulations at § 668.13(c) provide that the Secretary may provisionally certify an institution whose participation has been limited or suspended under subpart G of part 668, and § 668.171(e) provides that the Secretary may take action under subpart G to limit or terminate the participation

of an institution if the Secretary determines that the institution is not financially responsible under § 668.171 or § 668.175.

Proposed Regulations: The Secretary proposes to amend § 668.94 to clarify that a change in an institution's participation status from fully certified to provisionally certified to participate in a title IV, HEA program under § 668.13(c) is a type of limitation that may be the subject of a limitation proceeding under § 668.86.

Reasons: The proposed change to § 668.94 would clarify current policy and provide for a more complete set of limitations covered in § 668.94. The 2016 final regulations included this same change to this regulation (previously designated as § 668.93, see 81 FR 76072), and we propose it again here to seek comment on it in the context of our complete current proposal.

Guaranty Agency (GA) Collection Fees (34 CFR 682.202(b), 682.405(b), and 682.410(b)(2) and (4))

Statute: Section 428F(a) of the HEA provides that to complete a FFEL borrower's loan rehabilitation, the FFEL guaranty agency must sell the loan to a FFEL Program lender or assign the loan to the Secretary.

Section 428H(e)(2) of the HEA allows a FFEL Program lender to capitalize outstanding interest when the loan enters repayment, upon default, and upon the expiration of periods of deferment and forbearance, but does not specifically authorize the capitalization of interest when the borrower rehabilitates a defaulted loan.

Current Regulations: The current FFEL Program regulations in §§ 682.202, 682.405, and 682.410 permit FFEL Program lenders to capitalize interest when the borrower enters or resumes repayment and requires a guaranty agency to capitalize interest when it pays the FFEL Program lender's default claim. However, these regulations do not specifically address whether a guaranty agency may capitalize interest when the borrower has rehabilitated a defaulted FFEL Loan or whether a FFEL Program lender may capitalize interest when purchasing a rehabilitated FFEL Loan from a guaranty agency. In addition, the Department interprets these regulations to bar guaranty agencies from imposing collection costs when a borrower enters into a satisfactory repayment agreement within 60 days of the first notice of default sent to the borrower.

Proposed Regulations: The proposed revisions to §§ 682.202, 682.405, and 682.410 would provide that the only time a guaranty agency may capitalize interest owed by the borrower is when it pays the FFEL Program lender's default claim. Therefore, the guaranty agency would not be allowed to capitalize interest when it sells a rehabilitated FFEL Loan.

Similarly, the proposed regulations would bar a FFEL Program lender from capitalizing outstanding interest when purchasing a rehabilitated FFEL Loan.

The proposed regulations would also provide that when a guaranty agency holds a defaulted FFEL Loan and the guaranty agency has suspended collection activity to give the borrower time to submit a closed school or false certification discharge application, interest capitalization is not permitted if collection on the loan resumes because the borrower does not return the appropriate form within the allotted timeframe.

Finally, the Department proposes to prohibit guaranty agencies from charging collection costs to borrowers who, within 60 days of receiving notice of default, enter into an acceptable repayment arrangement, including a loan rehabilitation plan.

Reasons: Recently, the Department became aware that some guaranty agencies and FFEL Program lenders were capitalizing interest when a borrower rehabilitates a loan, while others were not. In addition, some guaranty agencies were capitalizing interest when resuming collection on a defaulted FFEL Loan when a borrower had not submitted a closed school or false certification discharge within a specific timeframe. The Department does not believe that interest capitalization in either circumstance is appropriate, and the Department does not capitalize interest on loans that it holds in comparable circumstances.

Additionally, to encourage borrowers to enter into satisfactory repayment plans, the Department proposes that guaranty agencies may not assess collection costs to a borrower who enters into an acceptable repayment agreement, including a rehabilitation agreement, and honors that agreement, within 60 days of receiving notice of default.

The negotiators did not object to any of these changes. In addition, the 2016 final regulations included the changes we propose in this NPRM regarding interest capitalization when a borrower rehabilitates a loan, as well as when a guaranty agency resumes collection on a defaulted FFEL Loan when a borrower had not submitted a closed school or false certification discharge within a specific timeframe. 81 FR 76079–80. We propose these changes again here to seek comment on them in the context of our complete current proposal.

The changes we propose regarding collection costs for borrowers who enter into an acceptable repayment arrangement, including a loan rehabilitation plan, within 60 days of receiving notice of default were not included in the 2016 final regulations. These changes are consistent with the interpretation and position that the Department previously took in Dear Colleague Letter (DCL) GE–15–14 (July 10, 2015). That DCL was withdrawn in order to allow for public comment on our interpretation, which we seek through this notification.

Subsidized Usage Period and Interest Accrual (34 CFR 685.200(f))

Statute: Section 455(q) of the HEA provides that a first-time borrower on or after July 1, 2013, is not eligible for additional Direct Subsidized Loans if the borrower has received Direct Subsidized Loans for a period that is equal to or greater than 150 percent of the length of the borrower's current program of study (''150 percent limit''). In addition, some borrowers who are not eligible for Direct Subsidized Loans because of the 150 percent limit become responsible for the interest that accrues on their loans when it would otherwise be paid by the government. The statute does not address what effect a discharge of a Direct Subsidized Loan has on the 150 percent limit. The statute also does not address whose responsibility it is to pay the outstanding interest on any remaining loans that have not been discharged, but which have previously lost eligibility for interest subsidy.

Current Regulations: Section 685.200(f)(4) provides two exceptions to the calculation of the period of time that counts against a borrower's 150 percent limit—the subsidized usage period—that can apply based on the borrower's enrollment status or loan amount. The regulations do not have an exception to the calculation of a subsidized usage period if the borrower receives a discharge of his or her Direct Subsidized Loan. They also do not address whose responsibility it is to pay the outstanding interest on any remaining loans that have not been discharged, but have previously lost eligibility for the interest subsidy based on the borrower's remaining eligibility period and enrollment.

Proposed Regulations: Proposed § 685.200(f)(4)(iii) would specify that a discharge based on a school closure, false certification, unpaid refund, or borrower defense will lead to the elimination, or recalculation, of the subsidized usage period that is

associated with the loan or loans discharged.

The proposed regulations would also specify that, when the full amount of a Direct Subsidized Loan or a portion of a Direct Subsidized Loan is discharged, the entire subsidized usage period associated with that loan is eliminated. In the event that a borrower receives a closed school, false certification, or, depending on the circumstances, borrower defense or unpaid refund discharge, the Department would completely discharge a Direct Subsidized Loan or a portion of a Direct Subsidized Consolidation Loan that is attributable to a Direct Subsidized Loan.

The proposed regulations would also specify that, when only a portion of a Direct Subsidized Loan or a portion of a Direct Consolidation Loan that is attributable to a Direct Subsidized Loan is discharged, the subsidized usage period would be recalculated instead of eliminated. Depending on the circumstances, discharges due to a borrower defense or unpaid refund could result in only part of a Direct Subsidized Loan or only a portion of the part of a Direct Consolidation Loan that is attributable to a Direct Subsidized Loan being discharged.

The proposed regulations would specify that when a subsidized usage period is recalculated, the period is only recalculated if the borrower's subsidized usage period was calculated as one year as a result of receiving the Direct Subsidized Loan in the amount of the annual loan limit for a period of less than an academic year. For example, if a borrower received a Direct Subsidized Loan in the amount of $3,500 as a first-year student on a full-time basis for a single semester of a two-semester academic year, the subsidized usage period would be one year. If the borrower later receives an unpaid refund discharge in the amount of $1,000, the subsidized usage period would be recalculated, and the subsidized usage period would become 0.5 years because the subsidized usage period was previously based on the amount of the loan and, after the discharge, is based on the relationship between the period for which the borrower received the loan (the loan period) and the academic year for which the borrower received the loan.

In contrast, if the borrower received a Direct Subsidized Loan in the amount of $3,500 as a first-year student on a full-time basis for a full two-semester academic year, the subsidized usage period would be one year. If the borrower later receives an unpaid refund discharge in the amount of $1,000, the subsidized usage period would still be one year because the subsidized usage period would still be calculated based on the relationship between the loan period and the academic year for which the borrower received the loan.

Proposed § 685.200(f)(3) would provide that, if a borrower receives a discharge based on a school closure, false certification, unpaid refund, or a borrower defense discharge that results in a remaining eligibility period greater than zero, the borrower is no longer responsible for the interest that accrues on a Direct Subsidized Loan or on the portion of a Direct Consolidation Loan that repaid a Direct Subsidized Loan, unless the borrower once again becomes responsible for the interest that accrues on a previously received Direct Subsidized Loan or on the portion of a Direct Consolidation Loan that repaid a Direct Subsidized Loan, for the life of the loan.

For example, suppose a borrower receives Direct Subsidized Loans for three years at school A and then transfers to school B and receives Direct Subsidized Loans for three additional years. Further suppose that at this point, the borrower has no remaining Subsidized Loan eligibility period and enrolls in an additional year of academic study at school B, which triggers the loss of interest subsidy on all Direct Subsidized Loans received at schools A and B. If the borrower later receives a false certification discharge with respect to school B, the borrower's remaining eligibility period is now greater than zero. The borrower is no longer responsible for paying the interest subsidy lost on the three loans from school A. If the borrower then enrolled in school C and received three additional years of Direct Subsidized Loans, resulting in a remaining eligibility period of zero, and then enrolled in an additional year of academic study, the borrower would lose the interest subsidy on the Direct Subsidized Loans received at schools A and C.

Reasons: The proposed regulations would clarify and codify the Department's current practice in this area. Under the circumstances in which a borrower receives a closed school, false certification, borrower defense, or unpaid refund discharge, the borrower has not received all or part of the benefit of the loan due to an act or omission of the school. In such an event, we believe that a student's eligibility for future loans and the interest subsidy on existing loans should not be negatively affected by having received the loan. Accordingly, under the proposed regulations, we would increase the borrower's eligibility for Direct Subsidized Loans or reinstate the interest subsidy on other Direct Subsidized Loans under the 150 percent limit where the borrower receives a discharge of a Direct Subsidized Loan and the discharge was based on an act or an omission of the school that caused the borrower to not receive all or part of the benefit of the loan. The negotiators did not raise any objections to this change. The 2016 final regulations included these same changes to this regulation (81 FR 76080), and we propose them again here to seek comment on them in the context of our complete current proposal.

Appendix A to Subpart L, Part 668: Ratio Methodology for Proprietary Institutions

Section 1: Ratio and Ratio Terms

Primary Reserve Ratio $\frac{\textit{Adjusted Equity}}{\text{Total Expenses and Losses}}$

Equity Ratio $\frac{\textit{Modified Equity}}{\text{Modified Assets}}$

Net Income Ratio $\frac{\textit{Income before Taxes}}{\text{Total Revenues and Gains}}$

Definitions

Adjusted Equity = (total owner's equity) − (intangible assets) − (unsecured related-party receivables) * − (net property, plant and equipment) ** + (post-employment and defined benefit pension liabilities) + (all debt obtained for long-term purposes, not to exceed total net property, plant and equipment) ***

Total Expenses and Losses excludes income tax, discontinued operations not classified as an operating expense or change in accounting principle and any losses on investments, post-employment and defined benefit pension plans and annuities. Any losses on investments would be the net loss for the investments. Total Expenses and Losses include the nonservice component of net periodic pension and other post-employment plan expenses.

Modified Equity = (total owner's equity) − (intangible assets) − (unsecured related-party receivables)

Modified Assets = (total assets) − (intangible assets) − (unsecured related-party receivables)

Income before Taxes includes all revenues, gains, expenses and losses incurred by the school during the accounting period. Income before taxes does not include income taxes, discontinued operations not classified as an operating expense or changes in accounting principle.

Total Revenues and Gains does not include positive income tax amounts, discontinued operations not classified

as an operating gain, or change in accounting principle (investment gains should be recorded net of investment losses.

* Unsecured related party receivables as required at 34 CFR 668.23(d).

** The value of property, plant and equipment includes construction in progress and lease right-of-use assets, and is net of accumulated depreciation/amortization.

*** All debt obtained for long-term purposes, not to exceed total net property, plant and equipment includes lease liabilities for lease right-of-use assets and the short-term portion of the debt, up to the amount of net property, plant and equipment. If an institution wishes to include the debt, including debt obtained through long-term lines of credit in total debt obtained for long-term purposes, the institution must include a disclosure in the financial statements that the debt, including lines of credit exceeds twelve months and was used to fund capitalized assets (*i.e.,* property, plant and equipment or capitalized expenditures per Generally Accepted Accounting Principles (GAAP)). The disclosures that must be presented for any debt to be used in adjusted equity include the issue date, term, nature of capitalized amounts and amounts capitalized. Institutions that do not include debt in total debt obtained for long-term purposes, including long-term lines of credit, do not need to provide any additional disclosures other than those required by GAAP. The debt obtained for long-term purposes will be limited to only those amounts disclosed in the financial statements that were used to fund capitalized assets. Any debt amount including long-term lines of credit used to fund operations must be excluded from debt obtained for long-term purposes.

Section 2: Financial Responsibility Supplemental Schedule Requirement and Example

A Supplemental Schedule must be submitted as part of the required audited financial statements submission. The Supplemental Schedule contains all of the financial elements required to compute the composite score. Each item in the Supplemental Schedule must have a reference to the Balance Sheet, Statement of (Loss) Income, or Notes to the Financial Statements. The amount entered in the Supplemental Schedules should tie directly to a line item, be part of a line item, tie directly to a note, or be part of a note in the financial statements. When an amount is zero, the institution would identify the source of the amount as NA (Not Applicable) and enter zero as the amount in the Supplemental Schedule. The audit opinion letter must contain a paragraph that references the auditor's additional analysis of the financial responsibility Supplemental Schedule.

Executive Orders 12866, 13563, and 13771

Under Executive Order 12866, the Secretary must determine whether this regulatory action is ''significant'' and, therefore, subject to the requirements of the Executive Order and subject to review by the Office of Management and Budget (OMB). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action likely to result in a rule that may—

(1) Have an annual effect on the economy of $100 million or more, or adversely affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities in a material way (also referred to as an ''economically significant'' rule).

(2) Create serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles stated in the Executive order.

Under Executive Order 12866,[9] section 3(f)(1), this regulatory action is economically significant and subject to review by OMB. Also under Executive Order 12866 and the Presidential Memorandum ''Plain Language in Government Writing'', the Secretary invites comment on how easy these regulations are to understand in the *Clarity of the Regulations* section.

Under Executive Order 13771,[10] for each new regulation that the Department proposes for notice and comment or otherwise promulgates that is a significant regulatory action under Executive Order 12866 and that imposes total costs greater than zero, it must identify two deregulatory actions. For FY 2018, no regulations exceeding the agency's total incremental cost allowance will be permitted, unless required by law or approved in writing by the Director of OMB. These proposed regulations are a deregulatory action under E.O. 13771 and therefore the two-for-one requirements of E.O. 13771 do not apply.

We have also reviewed these regulations under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency—

(1) Propose or adopt regulations only on a reasoned determination that their benefits justify their costs recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and taking into account—among other things, and to the extent practicable—the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives, rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives—such as user fees or marketable permits—to encourage the desired behavior, or provide information that enables the public to make choices.

Executive Order 13563 also requires an agency ''to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible.'' The Office of Information and Regulatory Affairs of OMB has emphasized that these techniques may include ''identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes.''

Under Executive Order 13563,[11] the Secretary certifies that the best available techniques were used to quantify the impacts of these regulations. Finally, the Secretary certifies that this regulatory action would not unduly interfere with State, local, and tribal governments in

[9] Exec. Order No. 12866, 58 FR 190 (October 4, 1993). *Regulatory Planning and Review.* Available at: *www.reginfo.gov/public/jsp/Utilities/EO_12866.pdf.*

[10] Exec. Order No. 13771, 82 FR 22 (January 30, 2017). *Reducing Regulation and Controlling Regulatory Costs.* Available at: *www.gpo.gov/fdsys/pkg/FR-2017-02-03/pdf/2017-02451.pdf.*

[11] Public Law 106–554 appendix C 114 STAT 2763A–153–155. section 515 Available at: *www.gpo.gov/fdsys/pkg/PLAW-106publ554/pdf/PLAW-106publ554.pdf.*

the exercise of their governmental functions.

The Department has analyzed the need for regulatory action, alternatives available to it, and measured the impact of the changes that would result from the proposed regulations relative to the existing regulatory baseline under a cost-benefit approach. The required Accounting Statement is included in the *Net Budget Impacts* section.

Regulatory Impact Analysis (RIA)

As further detailed in the *Net Budget Impacts* section, this proposed regulatory action would have an annual effect on the economy of approximately $697 million in transfers among borrowers, institutions, and the Federal Government related to defense to repayment and closed school discharges, as well as $1.15 million in costs to comply with paperwork requirements. This economic estimate was produced by comparing the proposed regulation to the PB2019 budget. As explained in Section (B)(1)(Baseline) of this RIA, we compare the proposed regulations to the delayed 2016 regulations. We discuss the need for regulatory action; regulatory alternatives considered; costs, benefits, and transfers; net budget impacts and accounting statement; regulatory flexibility act (small business impacts); and paperwork reduction.

A. Need for Regulatory Action

These proposed regulations address a significant increase in burden resulting from the vast increase in borrower defense claims since 2015. The 2016 borrower defense regulations fail to adequately address this increase in burden. These proposed regulations reduce burden by restoring the limitation of defense to repayment claims to those loans that are in certain collections proceedings, provide an opportunity for institutions to submit a response to borrower allegations, and provide for the Secretary to recover losses from institutions.

Although the borrower defense to repayment regulations have provided an option for borrower relief for borrowers in a collections proceeding since 1994, in 2015 the number of borrower defense to repayment claims increased dramatically when institutions owned by Corinthian Colleges, Inc., were placed on Heightened Cash Monitoring 1 (HCM1) status with an additional 20 day hold and the company declared bankruptcy. Students enrolled at Corinthian campuses and those who had left the institution within 120 days of its closure were eligible for a closed school loan discharge. The Department decided to also provide student loan discharge to additional borrowers who did not qualify for a closed school loan discharge, but could qualify under a new interpretation of the defense to repayment regulation (34 CFR 685.206(c)). The Department encouraged Corinthian borrowers to submit defense to repayment claims, which it agreed to consider for all Corinthian-related loans, including those not in a collections proceeding. We refer to these claims as affirmative claims, as opposed to defensive claims, which require the loan to be in a collections proceeding.

This resulted in a significant increase in claim volume compared to the prior years, when claim volume was no more than 10 in any given year. Since 2015, the Department has considered both affirmative and defensive claims, thus significantly expanding the number of claims received and the potential cost to the Federal budget. The 2016 regulations also provide that borrowers could submit both affirmative and defensive claims.

The proposed regulations revert back to the plain meaning of the regulation, as it had been implemented prior to 2015, such that only those borrowers in a collection proceeding would have a mechanism by which they could exercise defenses to repayment. With the anticipated substantial increase in the number of defense to repayment applications, the Department believes that revisions to the 2016 regulations are necessary.[12] However, the Department is also seeking comment on continuing to accept affirmative claims and, if such claims were accepted, on ways of reducing burden and taxpayer liability associated with affirmative claims, since borrowers have nothing to lose by attempting to seek student loan relief, even if misrepresentation or harm as a result of misrepresentation did not occur. In addition, provisions in the 2016 regulation that enable the Secretary to initiate defense to repayment claims on behalf of entire classes of borrowers in a collection proceeding to exercise defenses to repayment as a last resort after exhausting other available consumer protection processes. The Department also realized that claims received from borrowers who had attended institutions that the Department had not investigated or found instances of misrepresentation (*i.e.,* other than Corinthian)create the potential for unsubstantiated claims that place no burden on the part of the borrower, but significant burden on the part of the Department, it needed a mechanism to collect evidence from institutions and to provide an opportunity for those institutions to defend themselves against frivolous claims. Because an institution might withhold official transcripts from students who receive a defense to repayment loan discharge, (as institutions are permitted to do in the case of loan discharges), automatic discharges could have collateral consequences for students who unknowingly had their loans discharged. An ''opt out'' mechanism could result in borrowers who unknowingly lose the ability to verify the credentials they earned using the subsequently discharged loans. Therefore, the Department believes that it is imperative that individual borrowers apply for a closed school loan discharge rather than receiving it automatically.

The group discharge process, which would be removed by the proposed regulations, may otherwise create large and unnecessary liabilities for taxpayer funds. If group claims initiated by the Secretary include borrowers who were not subjected to the misrepresentation, did not rely on a misrepresentation to make an enrollment decision, or were not harmed by the misrepresentation then those borrowers' loans should not be forgiven with taxpayer funds. The Department believes that institutions should be held accountable for acts or omissions that constitute misrepresentation, but that arbitration, other student complaint resolution or legal proceedings brought in State court should serve as the primary means for borrowers to seek remedies against such acts.

The increased number of school closures in recent years has prompted the Department to review regulations related to closed schools and therefore to propose changes to them. Under the current regulations, students who are enrolled at institutions that close, as well as those who left the institution no more than 120 days prior to the closure, are entitled to a closed school student loan discharge provided that the student does not transfer credits from the closed school and complete the program at another institution. To ensure that borrowers who left an institution in the semester prior to its closure do not lose eligibility for closed school discharge because of a summer break, the Department proposes to expand the closed school discharge window from 120 days to 180 days prior to the school's closure. These regulations also

[12] U.S. Department of Education Office of Inspector General (December 8, 2017), ''Federal Student Aid's Borrower Defense to Repayment Loan Discharge Process'', retrieved from *www2.ed.gov/about/offices/list/oig/auditreports/fy2018/i04r0003.pdf.*

incentivize institutions to provide students with an opportunity to complete their program through an approved teach-out opportunity that takes place at the closing institution or at another institution. The teach-out opportunity must be approved by the accreditor and, if applicable, the State authorizing agency. In the proposed regulation, a borrower given the opportunity to complete his or her program through an orderly teach-out at a closing institution, or through a partnership with another institution, would not be eligible for closed school loan discharge. This mirrors the existing regulations that disallow students who transferred credits from the closed school to another school, or who finished the program elsewhere, to qualify for the closed school loan discharge. The teach-out opportunity must be approved by the accreditor and, if applicable, the State authorizing agency to ensure that the institution or its teach-out partner institution continues to provide educational and student support services that meet the accreditor's and agency's standards. Although the 2016 regulations included an automatic closed school loan discharge for eligible borrowers who did not re-enroll within 3 years of their school's closure, upon further consideration, the Department has determined that this could have unintended consequences for students because an institution, or the custodian of its student records, is permitted to and might withhold the official transcripts of borrowers who received a closed school discharge. Although the 2016 regulation included an opt-out provision, students who miss the notification (perhaps due to a change in email or mailing address) or who do not fully understand the opportunity or its potential consequences, could end up by default participating in an action that could prevent them from verifying their credits or credential in the future. The Department has heretofore favored opt-in requirements rather than opt-out requirements, such as in the case of Trial Enrollment Periods (*https://ifap.ed.gov/dpcletters/GEN1112.html*), to be sure that a student's omission does not result in actions with negative financial or academic consequences. The opt-out provision also could increase the cost to the taxpayer, including for borrowers who are not seeking relief, because default provisions typically capture a much larger population than opt-in provisions. Therefore, the proposed regulations require borrowers to submit an application in order to receive a closed school loan discharge.

The proposed regulations also update the Department's regulations regarding false certification loan discharges in response to the change made to the HEA by Public Law 112–74, Consolidated Appropriations Act, 2012, that eliminated the option for students who did not have a high school diploma or its equivalent to receive Title IV aid by demonstrating the ability to benefit and to codify current practices. Whereas the ability to benefit test once allowed students who were unable to obtain an official high school transcript or diploma to qualify for Title IV aid by other mechanisms, the elimination of this test prevents them from receiving Title IV aid. Now when a student is unable to obtain an official high school transcript, but attests in writing under penalty of perjury that he or she has completed a high school degree, the borrower may receive title IV financial aid, but will not then be eligible for a false certification discharge if the borrower had misstated the truth in signing the attestation.

These proposed regulations also address several provisions related to determining the financial responsibility of institutions and requiring surety in the event that the school's financial health is threatened. The Financial Accounting Standards Board (FASB) recently issued updated accounting standards that change the way that lease liabilities are considered in determining an institution's financial position. To align with these new standards, these proposed regulations update the definition of terms used in 34 CFR part 668, subpart L, appendices A and B, which are used to calculate an institution's composite score. The composite score methodology must be updated to align with the new FASB standards, but in the meantime, the misalignment between the new FASB standards and the old composite score methodology could have unintended consequences. Some of these consequences could include institutions signing shorter term equipment or facilities leases, thereby increasing the cost of education, or potentially even closing schools whose financial position hasn't changed from prior years, thereby increasing the number of closed school loan discharges. Therefore, the Department would continue to calculate the composite score under the prior FASB standard (''alternative composite score'') for institutions that would have passed the composite score under that standard but not the current standard. This alternative composite score methodology will be in place for the six years following the implementation of the new FASB standard or until an updated composite score is developed through negotiated rulemaking, whichever is sooner.

In addition, the proposed regulations expand the financial responsibility requirements and add surety requirements in response to certain triggering events that occur between audit cycles. Instead of relying solely on information contained in an institution's audited financial statements, which are submitted to the Department six to nine months after the end of the institution's fiscal year, we propose to determine at the time that certain events occur whether those events have a material adverse effect on the institution's financial condition. In cases where the Department determines that an event poses a materially adverse risk, this approach would enable us to address that risk quickly by taking the steps necessary to protect the Federal interest.

We adopted a similar approach in the 2016 final regulations, but here we propose to focus on known and quantifiable expenses. For example, the actual liabilities incurred from defense to repayment discharges could trigger surety requirements, but the existence of pending litigation may or may not have a financial impact on the school. We are proposing additional surety requirements for other metrics or events for which the potential consequences pose a severe and imminent risk (for example, SEC or stock exchange actions) to the Federal interest.

We propose other triggering events, such as high cohort defaults rates, loan agreement violations, and accrediting agency actions, that could have a material adverse effect on an institution's operations or its ability to continue operating, but the Department intends to fully consider the circumstances surrounding such event before making a determination that the institution is not financially responsible. In that regard, these proposed regulations do not contain certain mandatory triggering events that were included in the 2016 regulations because the cost and burden of seeking surety is significant, and in many cases speculative events, such as pending litigation or pending defense to repayment claims, may be resolved with no or minimal financial impact on the institution. Similarly, while the 2016 regulations included a mandatory surety for all State law violations, the Department recognizes that many violations do not threaten the financial stability or existence of the institution and therefore should not trigger

mandatory surety requirements. These regulations also do not include as a mandatory triggering event the results of a financial stress test, which was included in the 2016 regulations without an explanation of what that stress test would be and on what empirical basis it would be developed.

B. Alternatives Considered

The Department and the non-Federal negotiators exchanged proposals on every topic included in these proposed regulations. The table below provides a side-by-side comparison of the 2016 regulations, the proposed regulations, and two alternatives—Scenario 1 and Scenario 2. OMB circular A–4 requires that agencies carefully consider all appropriate alternatives for the key attributes or provisions of a rule. They generally should analyze at least three options: The preferred option; a more stringent option that achieves additional benefits (and presumably costs more) beyond those realized by the preferred option; and a less stringent option that costs less (and presumably generates fewer benefits) than the preferred option. The 2016 regulations are summarized in this section and are also available to the reader online.[13] The specifics of the alternatives selected are discussed more thoroughly in this section. Scenario 1 reflects a more stringent option. Scenario 2 reflects the regulations currently in effect (which in the case of defense to repayment dates back to 1994). Further, the HEA refers to proprietary institutions, but some of the Department's prior notifications and regulations use the term ''private, for-profit institutions.'' For the purposes of discussion, the Department defines private, for-profit institutions to be the same as proprietary institutions, and uses the term ''proprietary institution'' throughout in order to be consistent with the HEA.

TABLE 1—COMPARISON OF ALTERNATIVES

Topic	Baseline	Proposal	Scenario 1	Scenario 2
Closed school discharge eligibility window.	120 days	180 days	150 days	120 days.
Closed school discharge exclusions.	Borrower completed teach-out or transferred credits.	School offered a teach-out plan.	School offered a teach-out plan.	Borrower completed teach-out or transferred credits.
Borrower Defense claims accepted.	Affirmative and defensive	Defensive only	Affirmative and defensive	Defensive only.
Party that adjudicates borrower defense claims.	Department	Department	State court or arbiter	Department.
Standard for borrower defense claims.	Federal Standard	Federal standard	State laws	State laws.
Borrower defense application process.	Application	Select borrower defense in response to wage garnishment or similar actions.	Submit judgment from state court or similar using application.	Submit sworn attestation or application.
Loans associated with BD claims.	Forbearance during adjudication Interest accrues.	Forbearance not necessary	Forbearance not necessary	Forbearance during adjudication Interest accrues.
Composite score calculation and timeline.	No FASB updates	Higher of current or FASB-updated score forever.	Higher of current or FASB-updated score for 6 years, then FASB-updated score.	No FASB updates.
Financial responsibility triggers	Reporting that automatically results in surety request.	New reporting that may result in surety request.	New reporting that automatically results in surety request.	None.
Notification of mandatory arbitration and class action waivers.	Prohibits mandatory arbitration clauses and class action waivers.	On website and entrance counseling.	On website, during entrance and exit counseling, and annually by email to students.	None.

1. Baseline

Usually, the impact of a regulation is quantified relative to the regulations currently in effect, which in this case would be the borrower defense regulations from 1995, and associated data. However, this impact analysis does not follow that practice because the 2016 regulations, although not yet in effect, would go into effect were it not for these proposed regulations. Therefore, this analysis compares the proposed regulations to the 2016 borrower defense regulations rather than the 1995 regulations. Similarly, the delayed 2016 regulations on financial responsibility, closed school discharges, and false certification discharges are used as a baseline for these topics. Composite score calculations and FASB standards were not covered in the 2016 regulations, so they are compared to the regulations currently in effect.

2. Summary of Proposed Regulations

The proposed regulations would amend the baseline regulations to update composite score calculations to comply with new FASB standards, create an alternative composite score that does not include new FASB standards for lease liabilities, require institutions to disclose fewer adverse events to the Department and notify students of mandatory arbitration or class-action prohibitions, permit mandatory arbitration clauses and class-action waivers, expand the closed school discharge eligibility period, modify the conditions under which a Direct Loan borrower may qualify for false certification and closed school discharges, create a different process for adjudicating defense to repayment applications, and, as part of the adjudication process, provide that the Secretary will used the revised misrepresentation standard explained in this NPRM, request evidence from institutions prior to completing adjudication of any borrower defense claims. Finally, the Department is also proposing changes to the regulations regarding subsidy usage periods and collection costs charged by guaranty agencies.

3. Alternative Scenario 1

Under Scenario 1, the Department would require borrowers to submit a judgment from a Federal or State court or arbitration panel to qualify for a defense to repayment discharge. Scenario 1 would not include a process for the Department to adjudicate claims because claimants would already have obtained a decision from a court or arbitrator at the State level. This alternative would place an increased burden on borrowers if they decide to

[13] *https://www.gpo.gov/fdsys/pkg/FR-2016-11-01/pdf/2016-25448.pdf.*

hire a lawyer in order to present their claims to a State court or incur costs associated with an arbitration proceeding. Moreover, because consumer protection laws vary by State, a borrower filing a claim in one State may be subject to different criteria compared to a borrower filing a defense to repayment claim in another State. It may also be unclear as to which State serves as the relevant jurisdiction for a given borrower.

Under Scenario 1, a guaranty agency would be able to charge a borrower collection fees and capitalize interest after rehabilitating a loan. The closed school discharge eligibility window would be expanded to 150 days, but only students whose institutions did not offer them a teach-out plan would be eligible for such a discharge.

This scenario would require an institution to notify current and potential students of its pre-dispute arbitration and class-action waiver policies on its website, at entrance and exit counselling for all title IV borrowers, and annually to all enrolled students by email. Institutions would also be required to disclose certain financial responsibility risk events to the Department if they occur.

Lastly, this scenario would implement revisions to FASB standards in the calculation of an institution's composite score without a transition period and would prevent an institution from appealing the composite score calculation. This scenario would include a requirement that the institution automatically provide a surety in the event that a financial responsibility risk event occurs.

4. Alternative Scenario 2

Scenario 2 would be to rescind the 2016 regulations on borrower defenses and go back to the 1995 regulations. In Scenario 2 the Department would accept only defensive borrower defense claims to repayment applications or attestations and adjudicate them, applying a State law standard. Under this alternative, borrowers could elect to have loans placed in forbearance while their claims are adjudicated.

Scenario 2 would return the eligibility period for closed school discharge to 120 days. Borrowers who complete a teach-out or transfer credits would not qualify. The technical changes to the false certification discharge provisions reflected in the 2016 regulations would be rescinded.

C. In Scenario 2, no Changes to the Composite Score or Financial Responsibility Standards Would Be Made as a Result of Changes to the FASB Standards

Under this scenario, a guaranty agency could not capitalize interest or charge collection fees on a loan that is sold following the completion of loan rehabilitation, which is current Department practice in the Direct Loan Program.[14]

Costs, Benefits, and Transfers

These proposed regulations will affect all parties participating in the title IV, HEA programs. In the following sections, the Department discusses the effects these proposed regulations may have on borrowers, institutions, guaranty agencies, and the Federal government.

1. Borrowers

These proposed regulations would affect borrowers relative to defense to repayment applications, closed school discharges, false certification discharges, loan rehabilitation, and institutional disclosures. Borrowers may benefit from an ability to appeal to the Secretary if a guaranty agency denies their closed school discharge application, from the cost savings and campus stability associated with longer leases from a more generous ''look back'' period with regard to closed school loan discharges, and from the ability to increased opportunities for borrowers to complete their program through an approved teach-out plan. Borrowers are also more likely to have their defense to repayment applications processed and decided more quickly if the Department has a smaller volume of unjustified or ineligible claims.

Borrowers may be disadvantaged by receiving fewer opportunities to discharge loans if the Department returns to the pre-2015 practice of accepting defense to repayment claims only from borrowers in a collections proceeding. In addition, the Department is concerned that students could engage in strategic defaults in order to avail themselves to defense to repayment relief. Students who default and then are unsuccessful in receiving defense to repayment loan relief may suffer additional financial penalties and have the default listed on their credit report. Therefore, the Department is considering continuing to accept affirmative claims to enable borrowers who are harmed by misrepresentations to seek relief while they are in repayment. In the event that the Department continues to accept affirmative claims, it will place certain limits and conditions on the affirmative claims process to serve borrowers who were harmed while preventing frivolous claims. These limits will also ensure that the affirmative claim process aligns with the Department's record retention policies so that institutions will have the ability to respond to the borrower's claim. Some borrowers may incur burden to review institutional disclosures on mandatory arbitration and class action waivers, or to complete applications for defense to repayment discharges, and there could be additional burden to borrowers who would otherwise, through no affirmative action on their part, be included in a class-action proceeding.

a. Borrower Defenses

When defense to repayment discharge applications are successful, dollars are transferred from the Federal government to borrowers because borrowers are relieved of an obligation to pay the government for the loans being discharged. As further detailed in the *Net Budget Impacts* section, the Department estimates that annualized transfers from the Federal Government to affected borrowers, partially reimbursed by institutions, would be reduced by $693.9 million. This is based on the difference in cashflows associated with loan discharges when the proposed regulations are compared to the President's Budget 2019 baseline (PB2019) and discounted at 7 percent. The proposed regulations do not include a formula for computing partial discharges because partial discharges are based on the nature of each borrower's application and the magnitude of the harm experienced by the borrower. The Department is interested in options for determining partial relief and invites commenters to submit specific formulae for determining partial relief derived from an assessment of the financial harm the borrower experienced, as well as sources of data that could be used to support the recommended formulae. To the extent borrowers with successful defense to repayment claims have subsidized loans, the elimination or recalculation of the borrowers' subsidized usage periods could relieve them of their responsibility for accrued interest and make them eligible for additional subsidized loans. A borrower defense discharge is a remedy available to students when other consumer protection tools are ineffective. Students harmed by institutional misrepresentations continue to have the right to seek relief directly from the

[14] *https://ifap.ed.gov/dpcletters/GEN1514.html.*

institution through arbitration, lawsuits in State court, or other available means. Borrowers would possibly receive quicker and more generous financial remedies from institutions through arbitration since schools may be more motivated to make students whole in order to avoid defense to repayment claims. The 2016 regulations would have eliminated this complaint resolution option by prohibiting mandatory arbitration, and while institutions may have continued to provide voluntary arbitration, schools may not have made it obvious to students how to avail themselves of arbitration opportunities. The proposed regulation allows for mandatory arbitration clauses, but requires institutions to provide the borrower with information about the meaning of a mandatory arbitration clauses and how to use the arbitration process in the event of a complaint against the institution. The benefit of arbitration is that it is more accessible and less costly to students and institutions than litigation. For borrowers who seek relief from a court, there may be additional advantages since courts can award damages beyond the loan value, which the Department cannot do. The proposed regulations, therefore, would provide borrowers with the incentive to seek redress first from institutions that should incur the cost of the harm to the student. Only as a last resort should taxpayer funds be used to pay the costs of institutional misrepresentations.

b. Closed School Discharges

Some borrowers may be impacted by the proposed changes to the closed school discharge regulations. These proposed regulations would extend the window for a student's eligibility for a closed school discharge from 120 to 180 days from the date the school closed, to account for the days a student would be unable to attend an institution during a summer term at institutions that offer no or only limited classes during that time. The regulations would provide that borrowers offered a reasonable teach-out plan by their institutions would not be eligible for closed school discharges, if the plan was approved by the institution's accrediting agency and, if applicable, the institution's State authorizing agency. These proposed regulations also eliminate the regulations that provided for an automatic closed school discharge without application for students that had not received a closed school discharge or re-enrolled at a title IV participating institution within 3 years of a school's closure. While the automatic discharge may benefit some students who no longer would need to submit an application to receive relief, it may have disadvantaged students who wish to continue their education at a later time or provide proof of credit completion to future employers. There could also be tax implications associated with closed school loan discharges, and borrowers should be aware of those implications and given the opportunity to make a decision according to their needs and priorities.

The expansion of the eligibility period would increase the number of students eligible under this criterion and encourage institutions to provide opportunities for students to complete their programs in the event that a school plans to close. The reduced availability of closed school discharges because of the teach-out provision and the elimination of the 3-year automatic discharge may reduce debt relief for students who believe that their education provided no benefits, but have not tried to transfer credits or complete their program elsewhere. As further detailed in the *Net Budget Impacts* section, the Department estimates that annualized closed school discharge transfers from the Federal Government to affected borrowers would be reduced by $96.5 million, primarily due to the elimination of automatic closed school discharges. This is based on the difference in cashflows associated with loan discharges when the proposed regulations are compared to the President's Budget 2019 baseline (PB2019) and discounted at 7 percent. The Department's accreditation standards [15] require accreditors to approve teach-out plans at institutions under certain circumstances, which emphasizes the importance of these plans to ensuring that students have a chance to complete their program should the school decide, or be required, to close. Teach-out plans that would require extended commuting time for students or that do not cover the same academic programs as the closing institution likely would not be approved by accreditors, and therefore would not negate a student's access to closed school discharges. In addition, an institution whose financial position is so degraded that it could not provide adequate instructional or support services would similarly not have their teach-out plan approved, thus enabling borrowers at those institutions to obtain a closed school discharge. In the case of two large, precipitous closures in 2015 and 2016, it is possible that enabling those institutions to teach-out their current students—including by arranging teach-outs plans delivered by other institutions or under the oversight of a qualified third party—would have benefited students and saved hundreds of millions of dollars of taxpayer funds.

Large numbers of small, private non-profit colleges could close in the next 10 years, which could contribute significantly to the cost of closed school discharges if these institutions are not encouraged to provide high quality teach-out options to their students.[16] By way of example, Mt. Ida College announced [17] that it would close at the end of the Spring 2018 semester and while the institution had considered entering into a teach-out arrangement with another institution, this did not materialize. While there may be other institutions that will accept credits earned at Mt. Ida, due to the distance between Mt. Ida and other campuses, it may be impractical for the student to attend another institution.[18] A proper teach-out plan may have enabled more students to complete their program. The requirement of accreditors to approve such options ensures protection for borrowers to ensure that a teach-out plan provides an accessible and high quality opportunity to complete the program.

c. False Certification Discharges

Some borrowers may be impacted by the proposed changes to the false certification discharge regulations, although this provision of the proposed regulations simply updates the regulations to codify current practice required as a result of the removal of the ability to benefit option as a pathway to eligibility for title IV aid. In the past, a student unable to obtain a high school diploma could still receive title IV funds if he or she could demonstrate that he or she could benefit from a college education.

With that pathway eliminated by a statutory change, prospective students unable to obtain high school transcripts when applying for admission to a postsecondary institution would be allowed to certify to their institutions that they graduated from high school or completed a home school program and qualify for Federal financial aid. At the same time, it will disallow students who misrepresented the truth in signing such an attestation from subsequently seeking

[15] 34 CFR 602.24(c).

[16] *www.insidehighered.com/news/2017/11/13/spate-recent-college-closures-has-some-seeking-long-predicted-consolidation-taking.*

[17] *www.insidehighered.com/news/2018/04/09/mount-ida-after-trying-merger-will-shut-down.*

[18] *www.insidehighered.com/news/2018/04/23/when-college-goes-under-everyone-suffers-mount-idas-faculty-feels-particular-sense.*

false certification discharge. Although the Department has not seen an increase in false certification discharges as a result of the elimination of the ability to benefit option, given the increased awareness of various loan discharge programs, the Department believes it is prudent to set forth in regulation that in the event a student falsely attests to having received a high school diploma, the student would not be eligible for a false certification discharge. Codifying this practice will not have a significant impact, but will ensure that students unable to obtain an official diploma or transcript will retain the opportunity to participate in postsecondary education. The Department does not believe that there are significant numbers of students who are unable to obtain an official transcript or diploma, but recent experiences related to working with institutions following natural disasters demonstrates that this alternative for those unable to obtain an official transcript is important.

d. Institutional Disclosures of Mandatory Arbitration Requirements and Class Action Waivers

Borrowers, students, and their families would benefit from increased transparency from institutions' disclosures of mandatory arbitration clauses and class action lawsuit waivers in their enrollment agreements. Under the proposed regulations, institutions would be required to disclose that their enrollment agreements contain class action waivers and mandatory arbitration clauses. Institutions would be required to make these disclosures to students, prospective students, borrowers, and their families on institutions' websites and in their marketing materials. Further, borrowers would be notified of these during entrance counselling. As further discussed in the *Paperwork Reduction Act section,* we estimate there is 5 minutes of burden to 342,407 borrowers annually at $16.30 [19] per hour to review these notifications during entrance counseling, for an annual burden of $446,506.

As institutions began preparing to implement the 2016 regulations, some eliminated both mandatory and voluntary arbitration provisions to be sure they would be in compliance with the letter and spirit of the regulations. Under the proposed regulations, institutions would be able to include these provisions in their enrollment agreements. The effect will be to require borrowers to redress their grievances through a quicker and less costly process, which we believe will benefit both the institution and the borrower by introducing the judgment of an impartial third party, but at a lower cost and burden than litigation. Arbitration may be in the best interest of the student because it could negate the need to hire legal counsel and result in adjudication of a claim more quickly than in a lawsuit or the Department's 2016 borrower defense claim adjudication process. Mandatory arbitration also reduces the cost impact of unjustified lawsuits to institutions and to future students, because litigation costs are ultimately passed on to future students through tuition and fees. It also increases the likelihood that damages will be paid directly to students, rather than used to pay legal fees.

2. Institutions

Institutions will be impacted by the proposed regulations in the areas of borrower defenses, closed school discharges, false certification discharges, FASB accounting standards, financial responsibility standards, and information disclosure. The benefits to institutions include a decrease in the number of reimbursement requests resulting from Department-decided loan discharges based on borrower defenses, closed school, and false certification; an increased involvement in the borrower defense adjudication process; the ability to continue to receive the benefit from the cost savings associated with longer-term leases and reduced relocation costs until such time as the composite score methodology can be updated through future negotiated rulemaking; and the ability to incorporate arbitration and class action waivers in enrollment agreements. Institutions may incur costs from increased arbitration and internal dispute resolution and increased expenses to provide for teach-out plans in the event of a school closure.

1. Borrower Defenses

Most institutions would not be burdened by the proposed regulatory changes in borrower defense to repayment. We estimate that successful defense to repayment applications under the proposed Federal standard and process for defensive claims will affect only a small proportion of institutions. The Department expects that the changes in these regulations would result in fewer successful defense to repayment applications, and therefore fewer discharges of loans. Therefore, the Department expects to request fewer repayment transfers from institutions to cover discharges of borrowers' loans. Under the main budget estimate explained further in the *Net Budget Impacts* section, the Department estimates an annual reduction of reimbursements of borrower defense claims from institutions to the government of $223 million under the seven percent discount rate. However, the Department believes that by requiring institutions that utilize mandatory arbitration clauses to provide plain language information to students about the role of mandatory arbitration clauses and the process to access arbitration, more students may take advantage of arbitration to settle disputes. In addition, given the benefits to both students and institutions of resolving complaints through arbitration, more institutions could offer arbitration opportunities, which could result in added costs to institutions for arbitration and added financial benefits to students who may more easily seek and be awarded financial remedies.

2. Closed School Discharges

A small percentage of institutions close annually, with some institutions providing teach-out opportunities to enable students to complete their programs and others leaving students to navigate the closure on their own, resulting in their eligibility for closed school loan discharges. Although the proposed regulations expand the eligibility window for students who left the institution but are still eligible to receive closed school loan discharges from 120 to 180 days it codifies current practice under which borrowers who were provided an approved teach-out plan by their institution will have completed their credential, and therefore would not qualify for closed school loan discharges. The Department has worked with a number of schools that have successfully completed teach-out plans, to the benefit of borrowers and taxpayers. As additional schools close in the future, the Department wants to encourage them to engage in orderly teach-outs rather than precipitous closures. We believe the proposed regulations would encourage institutions to provide teach-out opportunities, despite their high cost, if they reduce the total liability that would result from having to reimburse the Secretary for losses due to closed school discharges. While teach-outs are costly to institutions, they better serve students and reduce the risk to taxpayers, and therefore should be incentivized.

Title IV-granting institutions are required by their accreditors [20] to have

[19] Students' hourly rate estimated using BLS for Sales and Related Workers, All Other, available at: *www.bls.gov/oes/2017/may/oes_nat.htm#41-9099.*

[20] 34 CFR 602.24(c).

an approved teach-out plan on file and to update that plan with more specific information in the event that the institution is financially distressed, is in danger of losing accreditation or State authorization, or is considering a voluntary teach-out for other reasons. Because accreditors, and in some cases, State authorizing agencies, must approve teach-out plans and carefully monitor teach-out activities, only those students who can be provided a high quality education will not be eligible for a closed school loan discharge under this provision.

The Department is not including in these regulations provisions for automatic closed school discharges for students who do not complete their program 3 years after the school closed, which it included in the 2016 regulations. It is inappropriate for the Secretary to grant such loan discharges without receiving an application from the borrower.

These proposed regulations will encourage more institutions to engage in teach-out plans rather than precipitous closures, which would generate significant savings to taxpayers. Although teach-outs have considerable cost for institutions, these costs will be offset by reducing the number of borrowers who seek and are granted closed school discharges. It is important to keep in mind that closed schools include branch campuses and additional locations of main campuses that continue to operate. The Department has recognized the benefits of helping students complete their programs prior to school closures, and therefore sees benefit in promoting orderly teach-outs.

3. False Certification Discharges

A small percentage of institutions are affected by false certification discharges annually. However, elimination of the ability to benefit option for Title IV eligibility could result in growth in the coming years of the number of students who enroll having attested to receiving a high school diploma since an official high school diploma or transcript is not available. To ensure that the unintended consequence of this policy change is not an increase in the frequency or cost of false certification discharges, the Department believes it is necessary to specify that a student who misrepresents his or her high school completion status under penalty of perjury cannot then pursue a false certification loan discharge due to non-completion of high school, a GED or a home school program.

The proposed regulations would continue to permit institutions to obtain written assurance from prospective students who are unable to obtain their high school transcripts when applying for admission and Federal financial aid, without exposing themselves to financial liabilities should those students misrepresent the truth in their attestations. Although we believe this proposed regulation will not have a significant impact in the short term, primarily because the Department receives very few false certification discharge requests, the elimination of the ability to benefit option could result in increased numbers of enrollments by attestation, which could in turn increase the frequency and cost of false certification discharges in the future. The proposed regulations also will protect institutions as they seek to serve students who are pursuing postsecondary education but cannot obtain an official diploma or transcript.

This provision may result in small cost savings to some affected institutions, but mostly it ensures that adult students who are most likely to have difficulty in obtaining official transcripts maintain the ability to pursue higher education without increasing the risk of financial losses to taxpayers.

4. Financial Responsibility Standards

Both the 2016 final regulations and the proposed regulations include conditions under which institutions would have to provide a letter of credit or other form of surety in order to continue to participate in the title IV, HEA programs. The following table compares the financial responsibility triggers established by the 2016 final regulations and in the proposed regulations. Mandatory events or actions automatically result in a determination that the institution is not financially responsible and trigger a request for surety from the institution, whereas discretionary events or actions give the Secretary the discretion to make that determination at the time the event or action may occur.

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Table 2: Financial Responsibility Triggers

Financial Responsibility Trigger		2016 Regulation	Proposed Regulation	Change Summary
Mandatory Actions or Events: Recalculated composite score < 1.0	Action or Event triggers Secretary decision and surety to Department	Actual or projected expenses incurred from a triggering event	Actual expense incurred from a triggering event	Eliminates projected expenses
	Defense to repayment that does or could lead to an institution repaying government for discharges	Department has received or adjudicated claims associated with the institution	Department has discharged loans resulting from adjudicated claims	• Changed from Discretionary to Mandatory • Reduced to actual discharges only
	Lawsuits and Other Actions that does or could lead to institution paying a debt or incurring a liability	• Final judgment in a judicial proceeding, administrative proceeding or determination, or final settlement • Legal action brought by a Federal or State Authority pending for 120 days • Other lawsuits that have survived a motion for summary judgment or the time for such a motion has passed	• Final judgment in a judicial proceeding, administrative proceeding, or determination	Reduced to final judgments with public records
	Withdrawal of Owner's Equity at proprietary institutions	Excludes transfers between institutions with a common composite score	Excludes transfers to affiliated entities included in composite score or to an owner	Revised
ry Actions or	Non-Title IV Revenue (90/10): fails in most recent fiscal year	At proprietary institutions	At proprietary institutions	No Change

Financial Responsibility Trigger		2016 Regulation	Proposed Regulation	Change Summary
	Cohort Default Rates	Two most recent rates are 30 percent or above after any challenges or appeals	Two most recent rates are 30 percent or above after any challenges or appeals	No Change
	SEC or Exchange Actions regarding the institution's stock (Publicly Traded Institutions)	• Warned SEC may suspend trading • Failed to file required report with SEC on-time • Notified of noncompliance with Stock exchange requirements • Stock delisted	• Notified that SEC will suspend trading • Failed to file required report with SEC on-time and outside of a negotiated extension • Notified of noncompliance with Stock exchange requirements • Stock delisted	Changed notification requirements from warning by the SEC, which a publicly traded company is not required to communicate to shareholders, to a notification by the SEC, about which a company must notify shareholders.
	Accreditor Actions – Teach-Outs	Accreditor requires institution to submit a teach-out plan for closing the institution, a branch, or additional location	Removed	Reduced liability
	Gainful Employment	Programs one year away from losing their eligibility for title IV, HEA program funds due to GE metrics	Removed	Regulatory update
Discretionary Actions or Events	Accreditor Actions – probation, show-cause, or other equivalent or greater action	Accreditor takes action on institution	Accreditor issues a show-cause order that, if not resolved, would result in the loss of institutional accreditation.	Limits trigger to accreditor actions that could lead to loss of institutional accreditation and/or closure of the school

Financial Responsibility Trigger	2016 Regulation	Proposed Regulation	Change Summary
Security or Loan Agreement violations	Creditor requires an increase in collateral, a change in contractual obligations, an increase in interest rates or payments, or other sanctions, penalties, or fees	Creditor requires an increase in collateral, a change in contractual obligations, an increase in interest rates or payments, or other sanctions, penalties, or fees	No Change
Cited for Failing State licensing or authorizing agency requirements	Notified of noncompliance with any provision	Notified of noncompliance relating to termination or withdrawal of licensure or authorization if institution does not take corrective action	Reduced liability
Significant Fluctuations in Pell Grant and Direct Loan funds	Changes in consecutive award years, or over a period of award years, not due to title IV program changes	Removed	None because consecutive year-over-year award levels were never evaluated
Financial Stress Test developed or adopted by the Secretary	• Institution fails the test • Specific stress test never proposed or developed	Removed	None because test never created
High Drop-Out Rates, as defined by the Secretary	• Institution has high annual drop-out rate Specific threshold never developed	Removed	None because threshold never set
Anticipated Borrower Defense Claims	Secretary predicts claims as a result of a lawsuit, settlement, judgment, or finding from a State or Federal administrative proceeding	Removed	Reduced Liability

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Some institutions may incur burden from the requirement to report any action or event described in § 668.171(e) within the specified number of days after the action or event occurs. As further explained in the *Paperwork Reduction Act of 1995* section, the Department estimates the burden for reporting these events to the Secretary would be 720 hours annually for private schools and 2,274 hours for proprietary institutions for a total burden of 2,994 hours. Using an hourly rate of $44.41,[21] we estimate that the costs incurred by this regulatory change would be $132,964 annually ($44.41*2,994).

[21] Hourly wage data uses the Bureau of Labor Statistics, available at *swww.bls.gov/ooh/management/postsecondary-education-administrators.thm.*

FASB is a standard-setting body that establishes generally accepted accounting principles and the Department requires that institutions participating in the title IV, HEA programs file audited financial statements annually, with the audits performed under FASB standards. Therefore, financial statements will begin to contain elements that are either

new or reported differently, including long-term lease liabilities. These changes were not included in the 2016 regulations and are new to these proposed regulations.

Changes in the definition of terms used under the financial responsibility standards are being proposed to align the regulations with current FASB standards.[22] However, the new FASB lease standard could have a profound impact on an institution's composite score and the Department has no mechanism to make a timely adjustment to the composite score calculation to accommodate this change. The Department also has no data to understand what the impact of this change will be on institutional composite scores. Models were created in SAS [23] to perform impact and sensitivity analyses on the proposed changes to the composite score calculations. However, the Department does not have structured data for these 12 values used in the calculation:

- Lease Right-of-use Assets (VAR1);
- Lease Right-of-use Liabilities (VAR2);
- Net Assets With Donor Restrictions (VAR3);
- Net Assets Without Donor Restrictions (VAR4);
- Net Assets With Donor Restrictions: Restricted in Perpetuity (VAR5);
- Post–employment and defined benefit pension plan liabilities (VAR6);
- Loss for defined pension and other post-employment, investments and annuities (VAR7);
- Investment Gains (VAR8);
- Non-operating investment amount needed for separation of expenses (VAR9);
- Annuities, term endowments and life funds not restricted in perpetuity (VAR10);
- Construction in process (VAR11); and
- Debt purpose and related amount (VAR12).

The Department invites commenters to submit data to the Department on these variables. Specific, numeric values submitted will be considered for inclusion in the Department's models prior to publication of the final regulations. We invite submission of data at the institutional level as well as means or medians. Please submit data in the format provided in Tables 3 and 4 (data without OPEID will also be accepted).

TABLE 3—FINANCIAL DATA FOR PROPRIETARY INSTITUTIONS

OPEID	VAR1	VAR2	VAR3	VAR4	VAR5	VAR6	VAR7	VAR8	VAR9	VAR10	VAR11	VAR12
Median												
Mean												

TABLE 4—FINANCIAL DATA FOR NONPROFIT INSTITUTIONS

OPEID	VAR1	VAR2	VAR3	VAR4	VAR5	VAR6	VAR7	VAR8	VAR9	VAR10	VAR11	VAR12
Median												
Mean												

Therefore, while the Department must obtain audited financial statements prepared in accordance with FASB standards, and it will automatically calculate a composite score for all institutions using the audited financial statements, those institutions that wish to have an alternative composite score calculated based on the current methodology (minus long term lease liabilities) can provide supplemental data to the Department and request the alternative score to be calculated. The Department will use the higher of the two scores to determine an institution's financial responsibility. Under this proposal, an institution can continue to rely on long-term leases that reduce costs, increase campus stability and prevent increased school closures that result from short-term leases that cannot be extended or satisfactorily renegotiated.

The Department may use the data it would collect under the proposed regulations to conduct analyses that might inform future negotiated rulemaking to update the composite score methodology. As explained further in the *Paperwork Reduction Act of 1995* section, 1,896 proprietary institutions and 1,799 private institutions will each need 1 hour annually to prepare a Supplemental Schedule to post along with their annual audit ((1,896+1,799) × 1 hour × $44.41). This will result in an additional annual burden of $164,095. Further, 450 private institutions and 474 proprietary institutions would each need 15 minutes to request that the Secretary make the second composite score calculation, for an additional annual burden of $10,303. The Department is not yet receiving these data on

[22] *www.fasb.org/jsp/FASB/Page/LandingPage&cid=1175805317350.*

[23] SAS Software. SAS Institute Inc. SAS and all other SAS Institute Inc. product or service names are registered trademarks or trademarks of SAS Institute Inc., Cary, NC, USA.

institutions' financial statements, so it is unable to quantify anticipated changes. We invite data submissions in this section for the Department to use in composite score sensitivity analyses. If the Department receives a sufficient number of complete data submissions, it may include this sensitivity analysis in the RIA in the final regulations.

5. Enrollment Agreements

The proposed regulations would permit institutions to include mandatory arbitration clauses and class action waivers in enrollment agreements they have with students receiving title IV financial aid. These provisions were prohibited by the 2016 regulations. The recent Supreme Court decision in *Epic Systems Corp.* v. *Lewis,* 584 U.S.____, 2018 WL 2292444 (May 21, 2018) held that arbitration clauses in employment contracts must be enforced by the courts as written, in essence confirming the right of private parties to sign contracts that compel arbitration and waive class action rights. Institutions may benefit from arbitration in that it is a faster and less expensive way to resolve disputes, while reducing reputational effects; however, they may incur costs resulting from an increased use of arbitration under the proposed regulations. Students may also benefit from arbitration, which is easier and less costly to navigate. On the other hand, students will have reduced access to a judicial forum, which would decrease the ability of a borrower to hold the institution publicly accountable.

6. Institutional Disclosures

Some institutions will incur costs under the proposed disclosure requirements. Institutions that include mandatory pre-dispute arbitration clauses or class action waivers in their enrollment agreements would be required to make certain disclosures. As further explained in the *Paperwork Reduction Act of 1995* section, the Department estimates the burden for making these disclosures would affect 944 proprietary institutions for a total of 4,720 hours annually. Using an hourly rate of $44.41,[24] we estimate the costs incurred by this regulatory change would be $209,615. Also as discussed in the *Paperwork Reduction Act of 1995* section, we estimate these same institutions would be required to include this information to borrowers during entrance counseling, for a further burden of 3 hours each annually, totaling $125,769 annually (944*3*44.41). Therefore, we estimate the total burden for disclosures would be $335,384 annually ($209,615 + $125,769).

3. Guaranty Agencies

Guaranty agencies would incur one-time costs as well as annual costs under the proposed regulations. The one-time costs would be to update their systems to identify borrowers now eligible for closed school discharges for reporting to lenders and to update their notifications and establish a process for forwarding requests for escalated reviews to the Secretary. As further explained in the *Paperwork Reduction Act of 1995* section, the Department estimates the burden for making these system changes would be 336 hours (240+96). Using an hourly rate of $44.41,[25] we estimate costs incurred by this regulatory change would be $14,921.76 (336 hours * $44.41 per hour). Finally, there would be an ongoing, annual burden on guaranty agencies to forward a borrower's request for escalated review of a denied closed school discharge to the Secretary. We estimate this burden would be 74 hours annually. Using the same hourly rate, we estimate costs incurred by this regulatory change would be $3,286.34 (74 hours * $44.41 per hour). Therefore, the Department estimates increased costs to guaranty agencies of $3,286 annually and $14,922 additional one-time costs in the first year.

The Department does not have data on interest capitalization and collection costs for rehabilitated loans to estimate the impact of the changes in the proposed regulations. The Department invites commenters to submit the following data points: proportion of rehabilitated loans where collection costs were charged, mean collection costs charged under this circumstance per loan, proportion of rehabilitated loans where interest is capitalized prior to sale, and mean interest capitalized under this circumstance per loan.

3. Federal Government

These proposed regulations would affect the Federal government's administration of the title IV, HEA programs. The Federal government would benefit in several ways, including significant reductions in student loan discharge transfers, reduced administrative burden, increased (or at least steady) public confidence in the student loan program, and increased access to data. The Federal government would incur costs to update its IT systems to implement the proposed changes.

a. Borrower Defenses

Borrower defense to repayment was described in the 1994 regulations promulgated by the Department as a right that a borrower could exercise once involved in a collections proceeding. The Department altered this approach in 2015 by allowing borrowers to file affirmative borrower defense claims, meaning claims while loans are in repayment or forbearance, and the 2016 regulations continued that approach. The proposed regulations would return to accepting defensive claims only, transferring the cost burden of misrepresentation back to institutions and the cost of administering consumer fraud allegations to the appropriate entities—courts or arbitration. It is more likely that the cost of misrepresentation would be incurred by institutions committing the act or omission than the taxpayer, because borrowers would be encouraged first to go to the institution to litigate claims of misrepresentation and because the Department would recoup defense to repayment discharge transfers from institutions.

In addition, although not quantifiable, a Federal student loan program that does not result in additional financial burden to the taxpayer is likely to be more stable and viable over the long term, and therefore more likely to continue receiving Congressional and taxpayer support. Therefore, restoring defense to repayment as a last resort option rather than a first resort consumer protection mechanism will likely ensure that the student loan program continues to serve borrowers into the future.

Finally, the Department expects a marked reduction in administrative burden as a result of the proposed changes to the circumstances under which it would consider a borrower's defense to repayment application. While the proposed regulations would rely heavily upon existing collection processes to initiate a defense against collection actions, the Department has also requested public comment on how affirmative claims might be adjudicated and how sufficient guardrails could be put in place to minimize the submission of unjustified claims or those that do not fall within the scope of a defense to repayment claim. Thus, until the final determination is made regarding the Department's acceptance of affirmative claims, defensive claims, or both, it is unable to provide an estimate of this reduction in adjudication burden.

[24] Hourly wage data uses the Bureau of Labor Statistics, available at *www.bls.gov/ooh/management/postsecondary-education-administrators.thm.*

[25] Hourly wage data uses the Bureau of Labor Statistics, available at *www.bls.gov/ooh/management/postsecondary-education-administrators.thm.*

b. Loan Discharges

Under the proposed regulations, the Department would expect to process and award fewer closed school and false certification loan discharges than it would have under the 2016 regulations. To the extent defense to repayment, closed school, and false certification loan discharges are not reimbursed by institutions, Federal government resources that could have been used for other purposes will be transferred to affected borrowers. As further detailed in the *Net Budget Impacts* section, the Department estimates that annualized transfers from the Federal government to affected borrowers, partially reimbursed by institutions, would be reduced by $693.9 million for borrower defenses and $96.5 million for closed school discharges with reductions in reimbursement from institutions of $223 million annually. This is based on the difference in cashflows associated with loan discharges when the proposed regulation is compared to the President's Budget 2019 baseline (PB2019) and discounted at 7 percent.

c. Financial Responsibility Standards

The Department will benefit from receiving updated financial statements consistent with FASB standards. By receiving information to calculate both composite scores, the Department would have data necessary for developing updated composite score regulations through future rulemaking. The financial responsibility disclosures will enable the Department to receive information to continue to calculate the composite score.

The Department would incur one-time costs for modifying eZ-Audit and other systems to collect the data needed to calculate composite scores under the new FASB reporting requirements and other systems to collect financial responsibility disclosures. The Department has not yet conducted the Independent Government Cost Estimate (IGCE) to determine the costs for making these system changes. Further, the Department expects ongoing, increased administrative burden because it would need to compute two composite scores for each institution under the proposed regulations. However, the Department has not yet developed its internal process for implementing the proposed regulations, which may necessitate a software modification or individually-generated calculations; consequently, it is unable to estimate the change in administrative burden. Therefore, the Department is unable to estimate its burden for implementing the proposed regulatory changes in the financial responsibility provisions.

Net Budget Impacts & Accounting Statement

These proposed regulations are estimated to have a net Federal budget impact over the 2019–2028 loan cohorts of $[−12.715] billion in the primary estimate scenario, including $[−10.487] billion for changes to the defense to repayment provisions and $−2.227 billion for changes related to closed school discharges. A cohort reflects all loans originated in a given fiscal year. Consistent with the requirements of the Credit Reform Act of 1990, budget cost estimates for the student loan programs reflect the estimated net present value of all future non-administrative Federal costs associated with a cohort of loans. The Net Budget Impact is compared to the 2019 President's Budget baseline (PB2019). This baseline assumed that the borrower defense regulations published by the Department on November 1, 2016, would go into effect in 2019 and utilized the primary estimate scenario,[26] as modified by the change in the effective date to 2019, described in the final rule published February 14, 2018.[27]

The proposed regulatory provisions with the greatest impact on the Federal budget are those related to the discharge of borrowers' loans. Borrowers may pursue closed school, false certification, or defense to repayment discharges. The precise allocation across the types of discharges will depend on the borrower's eligibility and ease of pursuing the different discharges, and we recognize that some applications may be fluid in classification between defense to repayment and the other discharges. In this analysis, we assign any estimated effects from defense to repayment applications to the defense to repayment estimate and the remaining effects associated with eligibility and process changes related to closed school discharges to the closed school discharge estimate.

1. Defense to Repayment Discharges

As noted previously, the Department had to incorporate the changes to the defense to repayment provisions related to the 2016 final regulations into its ongoing budget estimates, and changes described here are evaluated against that baseline. In our main estimate, based on the assumptions described in Table 5, we present our best estimate of the impact of the changes to the defense to repayment provisions in the proposed regulation.

a. Assumptions and Estimation Process

The net present value of the reduced stream of cash flows compared to what the Department would have expected from a particular cohort, risk group, and loan type generates the expected cost of the proposed regulations. We applied an assumed level of school misconduct, defensive claims, defense to repayment applications success, and recoveries from institutions (respectively labeled as Conduct Percent, Defensive Claims Percent, Borrower Percent, and Recovery Percent in Table 5) to loan volume estimates to generate the estimated net number of borrower defense applications for each cohort, loan type, and sector. Table 5 presents the assumptions for the main budget estimate with the budget estimate for each scenario presented in Table 6. We also estimated the impact if the Department received no recoveries from institutions, the results of which are discussed after Table 6.

The model can be described as follows: To generate gross applications (gc), loan volumes (lv) by sector were multiplied by the Conduct Percent (cp), the Defensive Applications Percent (dcp) and the Borrower Percent (bp); to generate net applications (nc) processed in the Student Loan Model, gross applications were then multiplied by the Recovery Percent (rp). That is, gc = (lv * cp * dcp * bp) and nc = gc − (gc * rp). The Conduct Percent represents the share of loan volume estimated to be affected by institutional behavior resulting in a defense to repayment application. The Borrower Percent captures the percent of loan volume associated with approved defense to repayment applications, and the Recovery Percent estimates the percent of net loans eventually discharged. The numbers in Table 5 are the percentages applied for the main estimate and PB2019 baseline scenarios for each assumption for cohorts 2019–2028.

[26] See 81 FR 76057 published November 1, 2016, available at *ifap.ed.gov/fregisters/attachments/FR110116.pdf.*

[27] See 83 FR 6468, available at *www.gpo.gov/fdsys/pkg/FR-2018-02-14/pdf/2018-03090.pdf.*

TABLE 5—ASSUMPTIONS FOR MAIN BUDGET ESTIMATE COMPARED TO PB2019 BASELINE

Cohort	PB2019 baseline			NPRM main		
	Pub	Priv	Prop	Pub	Priv	Prop
Conduct Percent						
2019	1.8	1.8	12.24	1.71	1.71	11.63
2020	1.7	1.7	11.6	1.62	1.62	11.02
2021	1.5	1.5	9.8	1.43	1.43	9.31
2022	1.4	1.4	8.8	1.33	1.33	8.36
2023	1.3	1.3	8.4	1.24	1.24	7.98
2024	1.2	1.2	8	1.14	1.14	7.6
2025	1.2	1.2	7.8	1.14	1.14	7.41
2026	1.1	1.1	7.7	1.05	1.05	7.32
2027	1.1	1.1	7.7	1.05	1.05	7.32
2028	1.1	1.1	7.7	1.05	1.05	7.32
	2Yr pub/priv	2Yr prop	4Yr pub/priv	4Yr prop		
Defensive Applications Percent (not in PB2019 Baseline)						
All Cohorts	40	34	16	21	.....	.....

Cohort	PB2019 baseline			NPRM main		
	Pub	Priv	Prop	Pub	Priv	Prop
Borrower Percent						
2019	36.8	36.8	47.3	4	4	6
2020	42.4	42.4	54.6	4.4	4.4	6.6
2021	46.7	46.7	60	5	5	7.3
2022	50	50	63	5.5	5.5	7.9
2023	50	50	65	6	6	8.4
2024	50	50	65	6.4	6.4	9
2025	50	50	65	7	7	9.3
2026	50	50	65	7	7	10
2027	50	50	65	7	7	10
2028	50	50	65	7	7	10
Recovery Percent						
2019	75	24.871	24.871	75	16	16
2020	75	28.8	28.8	75	16	16
2021	75	31.68	31.68	75	18.5	18.5
2022	75	33.26	33.26	75	18.5	18.5
2023	75	34.93	34.93	75	21	21
2024	75	36.67	36.67	75	21	21
2025	75	37.4	37.4	75	22.5	22.5
2026	75	37.4	37.4	75	22.5	22.5
2027	75	37.4	37.4	75	25	25
2028	75	37.4	37.4	75	25	25

As in previous estimates, the recovery percentage reflects the fact that public institutions are not subject to the changes in the financial responsibility triggers because of their presumed backing by their respective States. Therefore, the PB2019 baseline and main recovery scenarios are the same for public institutions and set at a high level to reflect the Department's confidence in recovering amounts from the expected low number of claims against public institutions. The decrease in the recovery percentage assumption for private and proprietary institutions compared to the PB2019 baseline reflects the removal or modification of some financial responsibility triggers as described in Table 2. We do not specify how many institutions are represented in the estimate as the assumptions are based on loan volumes and the scenario could represent a substantial number of institutions engaging in acts giving rise to defense to repayment applications or could represent a small number of institutions with significant loan volume subject to a large number of applications. According to Federal Student Aid data center loan volume reports, the five largest proprietary institutions in loan volume received 24.59 percent of Direct Loans disbursed in the proprietary sector in award year 2016–17 and the 50 largest proprietary institutions represent 66.6 percent of Direct Loans disbursed in that same time period.[28] The share of volume captured in the conduct percentage may be conservative and estimate a higher number of defense to repayment applications than may occur in the future as we did not want to underestimate costs associated with changes to the borrower defense regulations. Due to the similarities between the conduct covered by the standard in the proposed regulations and the standard in the 2016 final regulations, as described in the *Discussion* segment, the Conduct Percent did not change from the PB2019 Baseline as much as the Borrower Percent. As recent loan cohorts progress further in their repayment cycles if

[28] Federal Student Aid, Student Aid Data: Title IV Program Volume by School Direct Loan Program AY2015–16, Q4, available at *studentaid.ed.gov/sa/about/data-center/student/title-iv* accessed August 22, 2016.

future data indicate that the percent of volume affected by conduct that meets the standard that would give rise to defense to repayment applications differs from current estimates, that difference will be reflected in future baseline re-estimates.

b. Discussion

The Department has some additional experience with processing defense to repayment applications and data on the approximately 138,990 applications received since 2015, but while this information has helped inform these estimates, it does not eliminate the uncertainty about institutional and borrower response to the proposed regulations. As noted earlier, given the limited number of applications that the Department has adjudicated, both in number and sector of institutions that are represented in this number, our data may not reflect the final results of the Department's review and approval process.

By itself, the proposed Federal standard is not expected to significantly change the percent of loan volume subject to conduct that might give rise to a borrower defense claim. The conduct percent is assumed to be 95 percent of the PB2019 baseline level.

As has been estimated previously, we are incorporating a deterrent effect of the borrower defense to repayment provisions on institutional behavior as is reflected in the decrease in the conduct percent in Table 5. We believe that institutions will not want to suffer the scrutiny that a significant number of borrower defense to repayment applications would invite. As expected, when regulatory provisions target specific institutional action or performance, institutional behavior changes over several years, resulting in removal of the worst performers and adaptation of other institutions' behavior so that a lower steady state is established. We still expect a similar pattern to develop with respect to borrower defense to repayment, as reflected in the Conduct Percent in Table 5. Also, allowing institutions to present evidence may result in fewer findings of misrepresentation that lead to an adjudicated claim. We have not included the impact of this potential evidence in our calculations as we have no basis for determining the impact that an institutional defense will have on the adjudication of applications.

Overall, we expect that the changes in the proposed regulations that will reduce the anticipated number of borrower defense applications are related more to changes in the process and emphasis on defensive claims, not due to changes in the type of conduct on the part of an institution that would result in a successful defense, as demonstrated by the 95 percent overlap compared to the PB2019 baseline.

The proposed regulations reestablish a framework in which borrower defense to repayment applications are submitted in response to certain collection activities initiated by the Department, specifically administrative wage garnishment, Treasury offset, credit bureau default reporting, and Federal salary offset. As has always been the case, borrowers will be able to seek relief from their institutions in State or Federal courts or from State or Federal agencies, and the inclusion of mandatory arbitration clauses in enrollment agreements may increase financial settlements with students, but defense to repayment applications through the Department will be reserved as a defense to collection efforts. The Defensive Applications Percent attempts to quantify the effect of this proposal by examining estimated lifetime default rates for loans in standard repayment plans by SLM risk group. The 2-year not for profit risk group was used for the 2-year or less private and public sectors, and the 2-year proprietary risk group was used for the 2-year proprietary sector. For 4-year institutions, the 4-year freshman/sophomore risk group rate was used for 4-year proprietary schools, and the weighted average of the 4-year freshman/sophomore and 4-year junior/senior rates were used for 4-year public and private nonprofit institutions. The estimated default rates were used to estimate the percent of loan volume associated with borrowers who, over the life of the loan, might be in a position to raise a defense to repayment. We used the higher estimated default rates associated with the standard repayment plan so that we did not underestimate potential future costs of the proposed defense to repayment regulations. Using the higher rates also accounts for the possibility of increased defaults by borrowers who may decide that the consequences of default are worth the risk of a potentially successful defense to repayment applications. However, now that institutions have the ability to present evidence as borrowers' applications are considered, there may be a decrease in frivolous and unsubstantiated defense to repayment applications that, under current practice, could be approved.

Several process changes contribute to the reduction in the Borrower Percent compared to the PB2019 baseline assumption. A separate assumption for the defensive claims provision was explicitly included so it could be varied in sensitivity runs or in response to comments. Another significant factor is the emphasis on determinations of individual applications and the lack of an explicit process for aggregating like applications. The Department will be able to group like applications against an institution for more efficient processing, but, even if there is a finding that covers multiple borrowers, relief will be determined on an individual basis and be related to the level of financial harm proven by the borrower. Additionally, while there is no statute of limitations on borrowers' ability to submit a defense to repayment application in response to collection activities, borrowers will have to inform the Department of their intent to raise a defense to repayment within the timeframe specified for requesting a hearing in their notice of collection activity to guarantee their filing will be reviewed. The timeframes vary from 30 days for consumer reporting and wage garnishment to 65 days for Federal salary offset and tax refund offset. Together, these changes could require more effort on the part of individual borrowers to submit a borrower defense application, which is reflected in the change in the Borrower Percent assumption.

The net budget impact of the emphasis on other avenues for relief is complicated by the potential for amounts received in lawsuits, arbitration, or agency actions to reduce the amount borrowers would be eligible to receive through a defense to repayment filing. While it would be prudent for borrowers to use any funds received with respect to the Federal loans in such proceedings to pay off the loans, there is no mechanism in the proposed regulations to require this. This offset of funds received in other actions was also a feature in the 2016 final regulations, but the majority of applications processed did not have offsetting funds to consider due to the precipitous closure of two large institutions. Accordingly, we are not assuming a budgetary impact resulting from prepayments attributable to the possible availability of funds from judgments or settlement of claims related to Federal student loans. Another factor that could affect the number of defense applications presented is the role of State Attorneys General or State agencies in pursuing actions or settlements with institutions about which they receive complaints. The level of attention paid to this area of consumer protection could alert borrowers in a position to apply for a defense to repayment and result in a

different number of applications than the Department anticipates. Evidence developed in such proceedings could be used by borrowers to support their individual applications.

The Department has used data available on defense to repayment applications, associated loan volumes, Departmental expertise, the discussions at negotiated rulemaking, information about past investigations into the type of institutional acts or omissions that would give rise to defense to repayment applications, and decisions of the Department to create new sanctions and apply them to institutions thus instigating precipitous closures to develop the main estimate and sensitivity scenarios that we believe will capture the range of net budget impacts associated with the defense to repayment regulations.

c. Additional Scenarios

The Department recognizes the uncertainty associated with the factors contributing to the main budget assumption presented in Table 5. The uncertainty in the defense to repayment estimate, given the unknown level of future school conduct that could give rise to claims; institutions' reaction to the regulations to eliminate such activities; the impact of allowing institutions to present evidence in response to borrowers' applications; the extent of full versus partial relief granted; and the level of State activity, is reflected in additional analyses that demonstrate the effect of changes in the specific assumption being tested.

The Department designed the following scenarios to isolate the assumption being evaluated and adjust it in the direction that would increase costs, increasing the Defensive Applications or Borrower Percent and decreasing the recovery percent. The first scenario the Department considered is that the Defensive Applications Percent will increase by 15 percent (Def15). This could occur if economic conditions or strategic behavior by borrowers increase defaults. The second scenario the Department increased the Borrower Percent by 20 percent (Bor20) to reflect the possibility that outreach, model applications, or other efforts by students may increase the percent of loan volume associated with successful defense to repayment applications. As the gross borrower defense claims are generated by multiplying the estimated volumes by the Conduct Percent, Defensive Claims Percent, and the Borrower Percent, the scenarios capture the impact of a 15 percent or 20 percent change in any one of those assumptions. The Recovery Percentage is applied to the gross claims to generate the net claims, so the RECS scenario reduces recoveries by approximately 36 percent to demonstrate the impact of that assumption. The Department also estimated the effect of allowing affirmative claims by removing the Defensive Claims Percent (Affirmative Claims Allowed scenario) which reduced savings by approximately $960 million when estimated on top of the other changes in the proposed regulations. The net budget impacts of the various additional scenarios compared to the PB2019 baseline range from $ − 9,528 billion to $ − 10,452 billion and are presented in Table 6.

TABLE 6—BUDGET ESTIMATES FOR ADDITIONAL BORROWER DEFENSE SCENARIOS

Scenario	Estimated costs for cohorts 2019–2028 (outlays in $mns)
Main Estimate	$ − 10,487
Def15	− 10,452
Bor20	− 10,445
Recs	− 10,459
Affirmative Claims Allowed	− 9,528

The transfers among the Federal government, affected borrowers, and institutions associated with each scenario above are included in Table 7, with the difference in amounts transferred to borrowers and received from institutions generating the budget impact in Table 6. The amounts in Table 6 assume the Federal Government will recover from institutions some portion of amounts discharged. In the absence of any recovery from institutions, taxpayers would bear the full cost of approved defense to repayment applications. For the primary budget estimate, the annualized costs with no recovery are approximately $635.7 million at a 3 percent discount rate and $693.9 million at a 7 percent discount rate. This potential increase in costs demonstrates the effect that recoveries from institutions have on the net budget impact of the proposed defense to repayment regulations.

The Department may revise its model related to these provisions as more data become available over time. We welcome comments on the Defense to Repayment Discharge model, its assumptions, and its conclusions; the Department may incorporate well-documented comments into this model as we develop the final regulations.

2. Closed School Discharges

In addition to the provisions previously discussed, the proposed regulations also would make three changes to the closed school discharge process that are expected to have an estimated net budget impact of − $2.227 billion, of which − $359 million is a modification to cohorts 2014–2018 related to the elimination of the automatic 3-year discharge. The combined effect of the elimination of the 3-year automatic discharge, the limitation to students not offered a teach-out opportunity approved by the school's accrediting agency and the school's State authorizing agency, and the expansion of the eligibility window to 180 days is − $1.868 billion for cohorts 2019–2028. As with the estimates related to the borrower defense to repayment provisions, the net budget impact estimates for the closed school discharge provisions are developed from the PB2019 budget baseline that accounted for the delayed implementation of the 2016 final regulations and assumed the 2016 final regulations would take effect on July 1, 2019.

While the Secretary will retain the discretion to approve closed school discharges without applications, the standard path to such a discharge will require borrowers to submit an application. The Department does, however, plan to be more aggressive in informing students who are eligible for closed school discharges of their rights. In CY2015 to CY2017, closed school discharges excluding Corinthian and ITT ranged from 24.2 million to $69.9 million annually. Therefore, the savings from eliminating the 3-year automatic closed school discharge provisions offset the costs of expanding the eligibility window to 180 days for cohorts 2019–2028. The precise interaction between the two effects is uncertain as outreach and better information for borrowers about the closed school discharge process may increase the rate of borrowers who submit applications. In estimating the effect of the 2016 final regulations, the Department looked at all Direct Loan borrowers at schools that closed from 2008–2011 to see the percentage loan volume associated with borrowers that had not received a closed school discharge and had no NSLDS record of title-IV aided enrollment in the three years following their school's closure and found it was approximately double the amount of those who received a discharge. This could be because the students received a teach-out or transferred credits and completed

without additional title IV aid, or it could be that the students did not apply for the discharge because of a lack of awareness or other reasons. Whatever the reason, in estimating the potential cost of the 3-year automatic discharge provision in the PB2019 baseline, the Department applied this increase to the closed school discharge rate. For these proposed regulations, we have reversed the increase attributed to the 3-year automatic discharge.

The volume of additional discharges that might result from the expansion of the window is also difficult to predict. The Department analyzed borrowers who were enrolled within 180 days of the closure date for institutions that closed between July 1, 2011 and February 13, 2018 and found that borrowers who withdrew within the 121 to 180 day time frame would increase loan volumes eligible for discharge by approximately nine percent. However, it is possible that some borrowers who complete their programs in that window or the current 120 day window for eligibility would choose to withdraw and pursue a closed school discharge instead of completing if the school closure is known in advance. The likelihood of this is unclear as it might depend on the relative length of the program, the time the borrower has remaining in the program, and the borrower's perception of the value of the credential versus the burden of starting the program over again as compared to the prospect of debt relief. Further, if the student knows that the school plans to close, it is likely because the school has implemented a teach-out plan, which would negate the borrower's ability to claim a closed school discharge if the institution fulfilled the plan. For these reasons, and especially the potential effect of the teach-out provision, the Department did not adjust for this factor in estimating the impact of the expansion of the eligibility window, but welcomes comments on the likelihood of its impacts and will consider those comments in developing estimates of the impact of the final regulations.

While the expansion of the eligibility window and the elimination of the three-year automatic discharge provisions allow for borrower decisions to affect the number of closed school discharges, the proposal to add to the existing limitation on students who transferred credits and completed the program at another institution limits the availability of closed school discharges to borrowers not offered a reasonable approved, teach-out opportunity and places key eligibility factors in the hands of institutions. This makes closed school discharges a form of relief for borrowers who were enrolled at an institution that closed precipitously, decided implementation of a teach-out plan was not practical or worth the expense for some or all students, or failed to implement an approved plan. The Department's requirements that accreditors review and evaluate teach-out plans that must be submitted by institutions under certain circumstances emphasizes the importance of teach-out plans in serving the best interests of students. The Department expects that this proposed change could further reduce closed school discharges, but our data do not provide sufficient information to know if any of the past closed school discharges were awarded to students who were also provided with a reasonable teach-out opportunity. Students who took advantage of such activities would have completed their program, and therefore would not be eligible for a closed school discharge, including under the current regulation. It could be that the number of closed school discharges is relatively low (as compared with the potential pool of borrowers eligible) because most institutions provide a teach-out opportunity that allows the borrower to complete his or her program. To the extent many borrowers are currently completing teach-outs, the cost impact of the teach-out limitation may be minimal.

The proposed regulations provide incentives for institutions to offer teach-outs so as to provide students the opportunity to complete their programs. To capture this effect, the Department reduced baseline closed school discharges by 65 percent. As is demonstrated by the estimated net savings from the closed school discharge changes, the removal of the three-year automatic discharge provisions and the change in eligibility to those offered an approved teach-out plan are expected to reduce the anticipated closed school discharge claims significantly more than the expansion of the window to 180 days increases them. In other words, the proposed regulations provide an incentive for institutions rather than students or taxpayers to bear the cost and burden of a closed school. In some scenarios, such as the precipitous closure of large institutions, the expansion of the window to 180 days could increase closed school discharges more than the other provisions reduce them, but the Department does not consider such a scenario to be likely. The Department welcomes comments on the assumptions used in estimating the net budget impact of the closed school discharge provisions, especially information on the frequency of teach-outs offered.

3. Other Provisions

The proposed regulations will also make a number of changes that are not estimated to have a significant net budget impact including changes to the financial responsibility standards and treatment of leases, false certification discharges, guaranty agency collection fees and capitalization, and the calculation of the borrower's subsidized usage period process. The false certification discharge changes update the regulations to reflect current practices. The proposed regulations would also provide that borrowers who provide a written attestation of high school completion in place of an unavailable high school diploma would be ineligible for a false certification discharge. In FY2017, false certification discharges totaled approximately $7 million. As before, we do not expect a significant change in false certification discharge claims that would result in a significant budget impact from this change in terms or use of an application that has been available at least ten years in place of a sworn statement. False certification discharges may decrease due to the ineligibility of borrowers who submit a written attestation in place of a high school diploma, but given the low level of false certification discharges in the baseline, even if a large share were eliminated, it would not have a significant net budget impact. Therefore, we do not expect an increase in false certification discharge claims or their associated discharge value.

Some borrowers may be eligible for additional subsidized loans and no longer be responsible for accrued interest on their subsidized loans as a result of their subsidized usage period being eliminated or recalculated because of a closed school, false certification, unpaid refund, or defense to repayment discharge. As in the 2016 final regulations, we believe the institutions primarily affected by the 150 percent subsidized usage regulation are not those expected to generate many of the applicable discharges, so this reflection of current practice is not expected to have a significant budget impact.

4. Accounting Statement

As required by OMB Circular A–4 we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of these regulations (see Table 7). This table provides our best

estimate of the changes in annual monetized transfers as a result of these proposed regulations. The amounts presented in the Accounting Statement are generated by discounting the change in cashflows related to borrower discharges for cohorts 2019 to 2028 from the PB2019 baseline at 7 percent and 3 percent and annualizing them. This is a different calculation than the one used to generate the subsidy cost reflected in the net budget impact, which is focused on summarizing costs at the cohort level. As the life of a cohort is estimated to last 40 years, the discounting does have a significant effect on the impact of the difference in cashflows in the outyears. Expenditures are classified as transfers from the Federal Government to affected student loan borrowers.

TABLE 7—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES
(In millions)

Category	Benefits	
Disclosure to borrowers about use of mandatory pre-dispute arbitration clauses and potential increase in settlements between borrowers and institutions.	Not quantified.	
Reduced administrative burden related to processing defense to repayment applications	Not quantified.	
Category	**Costs**	
	7%	3%.
Cost of compliance with paperwork requirements	1.15	1.16.
Changes in Department's systems to collect relevant information and calculate revised composite score	Not Quantified.	
Category	**Transfers**	
	7%	3%.
Reduced defense to repayment discharges from the Federal Government to affected borrowers (partially borne by affected institutions, via reimbursements.	$693.9	$635.7.
Reduced reimbursements of borrower defense claims from affected institutions to affected student borrowers, via the Federal government.	$223	$205.
Reduced closed school discharges from the Federal Government to affected borrowers	$96.5	$61.9.

Previous Accounting Statements by the Department, including for the 2016 final regulations, presented a number that was the average cost for a single cohort. If calculated in that manner, the reduced transfers for defense to repayment from the Federal government to affected borrowers would be $-1,448 million, reimbursements would be reduced $-414 million, and closed school discharge transfers would be reduced $-233 million at a 7 percent discount rate.

D. Regulatory Flexibility Act

The U.S. Small Business Administration (SBA) Size Standards define proprietary institutions as small businesses if they are independently owned and operated, are not dominant in their field of operation, and have total annual revenue below $7,000,000. Nonprofit institutions are defined as small entities if they are independently owned and operated and not dominant in their field of operation. Public institutions are defined as small organizations if they are operated by a government overseeing a population below 50,000.

The Department's eZ-Audit data shows that there were 1,522 Title IV proprietary schools with revenue less than $7,000,000 for the 2015–2016 Award Year.[29] However, the Department lacks data to identify which public and private, nonprofit institutions qualify as small. Given the data limitations, the Department proposes a data-driven definition for ''small institution'' in each sector and uses its proposed definition to certify the RFA impacts of the proposed rule.

1. Proposed Definition

The Department has historically assumed that all private nonprofit institutions were small because none were considered dominant in their field. However, this approach masks significant differences in resources among different segments of these institutions. The Department proposes to use enrollment data for its definition of small institutions of postsecondary education. Prior analyses show that enrollment and revenue are correlated for proprietary institutions. Further, enrollment data are readily available to the Department for every postsecondary institution while revenue is not. The Department analyzed a number of data elements available in IPEDS, including Carnegie Size Definitions, IPEDS institutional size categories, total FTE, and its own previous research on proprietary institutions referenced in ED–2017–OPE–0076i. As a result of this analysis, the Department proposes to use this definition to define small institutions:

- Two-year IHEs, enrollment less than 500 FTE; and
- Four-year IHEs, enrollment less than 1,000 FTE.

Table 8 shows the distribution of small institutions under this proposed definition using the 2016 IPEDS institution file.[30]

TABLE 8—SMALL INSTITUTIONS UNDER PROPOSED DEFINITION

Level	Type	Small	Total	Percent
2-year	Public	342	1,240	28
2-year	Private	219	259	8
2-year	Proprietary	2,147	2,463	87
4-year	Public	64	759	8
4-year	Private	799	1,672	48

[29] *studentaid.ed.gov/sa/about/data-center/school/proprietary* (extracted from eZ-Audit on June 30, 2017)

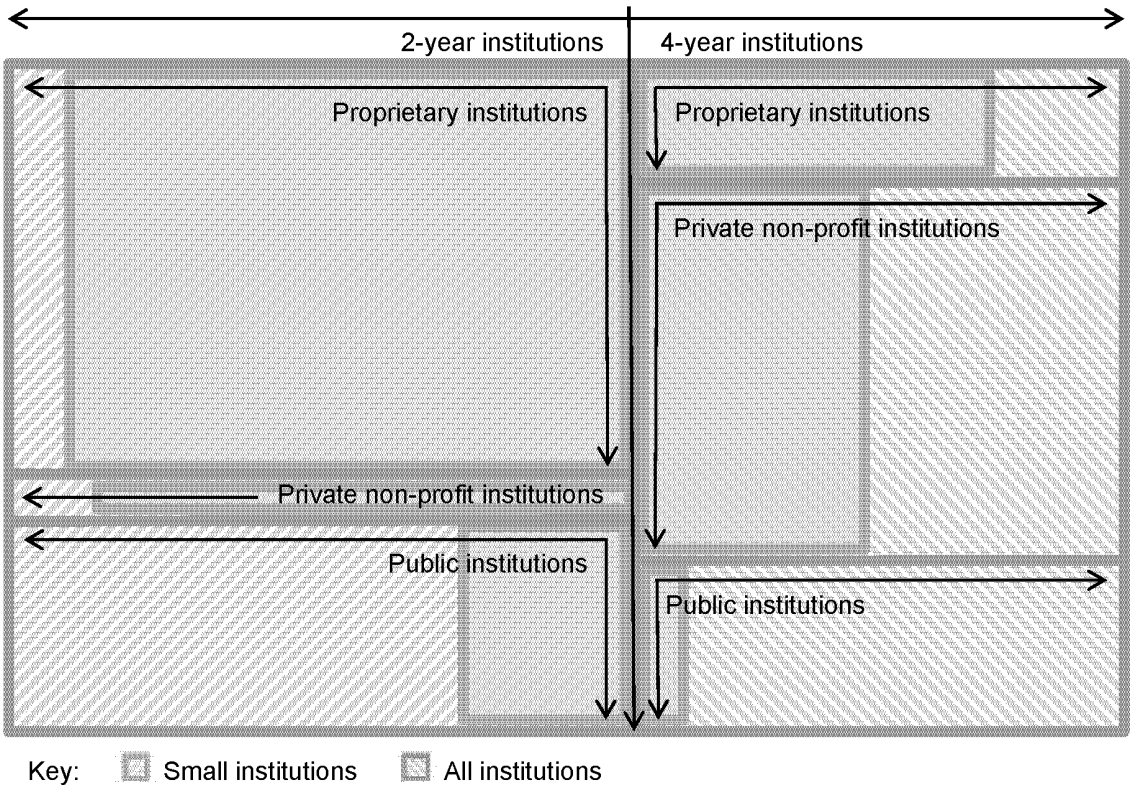
[30] U.S. Department of Education, National Center for Education Statistics. Integrated Postsecondary Education Data System 2016 Institutional Characteristics: Directory Information survey file downloaded March 3, 2018. Available at *nces.ed.gov/ipeds/datacenter/DataFiles.aspx.*

TABLE 8—SMALL INSTITUTIONS UNDER PROPOSED DEFINITION—Continued

Level	Type	Small	Total	Percent
4-year	Proprietary	425	558	76
Total		3,996	6,951	57

Under the proposed definition, the two-year small institutions are 68% of all two-year institutions (2,708/3,962), 68% of all small institutions (2,708/3,996), and 39% of the overall population of institutions (2,708/6,951); whereas, four-year small institutions are 43% of all four-year institutions (1,288/2,989), 32% of all small institutions (1,288/3,996), and 19% of the overall population of institutions (1,288/6,951). Figure 1 shows a visual representation of the universe and the percentage that would be defined as small using the above proposed definition.

Figure 1: Small Institutions as a subset of all institutions



Similarly, small public institutions are 20 percent of all public institutions (406/1,999), 10 percent of all small public institutions (406/3,996), and 6 percent of the overall population of institutions (406/6,951). Small private nonprofit institutions are 53 percent of all private nonprofit institutions (1,018/1,999), 25 percent of all small institutions (1,018/3,996), and 15 percent of the overall population of institutions (1,018/6,951). Finally, small proprietary institutions are 85 percent of all proprietary institutions (2,572/1,999), 64 percent of all small institutions (2,572/3,996), and 37 percent of the overall population of institutions (2,572/6,951).

The Department requests comments on the proposed definition. It will consider these suggestions in development of the final rule.

2. Certification

When an agency issues a rulemaking proposal, the Regulatory Flexibility Act (RFA) requires the agency to ''prepare and make available for public comment an initial regulatory flexibility analysis'' which will ''describe the impact of the proposed rule on small entities.'' (5 U.S.C. 603(a)). Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the proposed rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

This proposed rule directly affects all public nonprofit and proprietary institutions and a small proportion of all institutions participating in title IV programs. There are currently 5868 of these institutions, of which 1799 are public nonprofit and 1896 are proprietary. Using its proposed definition for small institution, below, the Department estimates that approximately 51 percent of these institutions are small entities. Further, 69 percent of the private nonprofit and proprietary institutions are small entities. Therefore, the Department has determined that this proposed rule would have an impact on a substantial number of small entities.

However, the Department has determined that the impact on entities affected by the proposed regulations would not be significant. The effect of the proposed regulations would be to update financial statements submitted to the Department to comply with the new FASB standards and to reduce liabilities at some institutions associated with borrower defense claims. The Department expects the impact of the proposed financial responsibility regulations would be a *de minimis* increase in paperwork burden for private nonprofit and proprietary institutions. The Department asserts that the economic impact of the paperwork burden would be minimal to small institutions. The Department expects the impact of the proposed borrower defense to repayment regulations would be a benefit of reduced liability for a small number of small entities, which represent less than 8 percent of title IV-participating institutions. The Department asserts that the economic impact of the reduced liability, if any, would be minimal and entirely beneficial to small institutions. Accordingly, the Secretary hereby certifies that these proposed regulations, if promulgated, would not have a significant economic impact on a substantial number of small entities. The Department invites comment from members of the public who believe there will be a significant impact on institutions.

Paperwork Reduction Act of 1995

As part of its continuing effort to reduce paperwork and respondent burden, the Department provides the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)). This helps ensure that: The public understands the Department's collection instructions, respondents can provide the requested data in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the Department can properly assess the impact of collection requirements on respondents.

Sections 668.41, 668.171, and 668.172, appendix A & B to part 668, subpart L, and §§ 674.33, 682.402, 685.206, 685.214 685.215, and 685.304 of this proposed rule contain information collection requirements. Under the PRA, the Department has or will at the required time submit a copy of these sections and an Information Collections Request to OMB for its review.

A Federal agency may not conduct or sponsor a collection of information unless OMB approves the collection under the PRA and the corresponding information collection instrument displays a currently valid OMB control number. Notwithstanding any other provision of law, no person is required to comply with, or is subject to penalty for failure to comply with, a collection of information if the collection instrument does not display a currently valid OMB control number.

In the final regulations, we will display the control numbers assigned by OMB to any information collection requirements proposed in this NPRM and adopted in the final regulations.

Section 668.41 Reporting and disclosure of information.

Requirements: Under the proposed changes in § 668.41(h), an institution that uses pre-dispute arbitration agreements and/or class action waivers would be required to disclose that information in a plain language disclosure available to enrolled and prospective students, and the public on its website where admissions and tuition and fees information is made available.

Burden Calculation: There will be burden on schools to make additional disclosures of the institution's use of a pre-dispute arbitration agreement and/or class action waiver to students, prospective students, and the public under this proposed regulation. Such agreements are currently used primarily by proprietary institutions. Of the 1,888 proprietary institutions participating in the title IV, HEA programs, we estimate that 50 percent or 944 would use a pre-dispute arbitration agreement and/or class action waiver and would provide the required information electronically. We anticipate that it will take an average of 5 hours to develop, program, and post the required information to the websites where admission and tuition and fees information is made available. The estimated burden would be 4,720 hours (944 x 5 hours) under OMB Control Number 1845–0004.

Section 668.171 General.

Requirements: Under the proposed § 668.171(f), in accordance with procedures to be established by the Secretary, an institution would notify the Secretary of any action or event described in the specified number of days after the action or event occurred. In the notice to the Secretary or in the institution's preliminary response, the institution may show that certain of the actions or events are not material or that the actions or events are resolved.

Burden Calculation: There will be burden on institutions to provide the notice to the Secretary when one of the actions or events occurs. We estimate that an institution will take two hours per action to prepare the appropriate notice and to provide it to the Secretary. We estimate that 180 private institutions may have two events annually to report for a total burden of 720 hours (180 institutions × 2 events × 2 hours). We estimate that 379 proprietary institutions may have three events annually to report for a total burden of 2,274 hours (379 institutions × 3 events × 2 hours). This total burden of 2,994 hours will be assessed under OMB Control Number 1845–0022.

Section 668.172 Financial Ratios.

Requirements: Under § 668.172(d), institutions can ask the Secretary to compute a second composite score excluding operating leases and have the higher of the two composite scores used to determine, in part, if the institution meets the financial responsibility requirements to participate in title IV financial aid programs.

Burden Calculation: There will be burden on institutions to request that the Secretary perform the second composite scoring calculation. We estimate that it will take a school .25 hours (15 minutes) to request the recalculation. We further estimate that 25% of the private institutions 450 (1,799 × .25) will request the recalculation for 113 hours (450 institutions × .25 hours). We estimate that 25% of the proprietary institutions 474 (1,896 × .25) will request the recalculation for 119 hours (474 institutions × .25 hours). This total burden of 232 hours (113 + 119) will be assessed under the OMB Control Number 1845–0022.

Appendix A and B for Section 668—Subpart L—Financial Responsibility

Requirements: Under proposed Section 2 for appendix A and B, proprietary and private schools would be required to submit a Supplemental Schedule as part of their audited financial statements. With the update from the FASB, some elements needed to calculate the composite score would no longer be readily available in the audited financial statements, particularly for private institutions. With the proposed updates to the Supplemental Schedule to reference the financial statements, this issue would be addressed in a convenient and transparent manner for both the schools and the Department by showing how the composite score is calculated.

Burden Calculation: There will be burden on schools to provide the Supplemental Schedule to the Department. In development of this

proposal, the members of the negotiated rulemaking subcommittee indicated that they believed that as the information would be readily available upon completion of the required audit the burden would be minimal. We estimate that it will take each proprietary and private institution one hour to prepare the Supplemental Schedule and have it made available for posting along with the annual audit. We estimate that 1,799 private schools will require 1 hour of burden to prepare the Supplemental Schedule and have it made available for posting along with the annual audit for a total burden of 1,799 hours (1,799 institutions × 1 hour). We estimate that 1,896 proprietary schools will require 1 hour of burden to prepare the Supplemental Schedule and have it made available for posting along with the annual audit for a total burden of 1,896 hours (1,896 institutions × 1 hour). This total burden of 3,695 hours will be assessed under OMB Control Number 1845–0022.

The total additional burden under OMB Control Number 1845–0022 would be 6,921 hours.

Section 674.33 Repayment.

Section 682.402 Death, disability, closed school, false certification, unpaid refunds, and bankruptcy payments.

Section 685.214 Closed school discharge.

Requirements: Under the proposed language in §§ 674.33(g), 682.402(d), and 685.214(c), the number of days that a borrower must have withdrawn from a closed school to qualify for a closed school discharge would be extended from 120 days to 180 days. Additionally if a closed school provided a borrower an opportunity to complete his or her academic program through a teach-out plan approved by the school's accrediting agency and, if applicable, the school's State authorizing agency, the borrower would not qualify for a closed school discharge. The proposed regulations further provide that the Secretary may extend that proposed 180 days further if there is a determination that exceptional circumstances justify an extension.

Burden Calculation: The proposed extension from 120 days to 180 days for withdrawal prior to the closing of the school would require an update to the current closed school discharge application form with OMB Control Number 1845–0058. We do not believe that the language update will change the amount of time currently assessed for the borrower to complete the form from those which has already been approved. The form update would be completed and made available for comment through a full public clearance package before being made available for use by the effective date of the regulations is finalized.

Section 682.402 Death, disability, closed school, false certification, unpaid refunds, and bankruptcy payments.

Requirements: Under proposed regulations in § 682.402 a second level of Departmental review for denied closed school discharge claim in the FFEL Program would be provided. The proposed regulations would require a guaranty agency that denies a closed school discharge application to inform the borrower of the opportunity for a review of the guaranty agency's decision by the Secretary, and an explanation of how the borrower may request such a review.

Burden Calculation: We believe there would be burden on the guaranty agencies to update their systems to identify borrowers who were enrolled or withdrew no more than 120 days to 180 days before an institution's closure for reporting to lenders. We estimate that it will take the 13 public guaranty agencies 10 hours for programming and testing to update their systems with this change for 130 hour burden increase (13 guaranty agencies × 10 hours = 130). We estimate that it will take the 11 non-profit guaranty agencies 10 hours for programming and testing to update their systems with this change for 110 hour burden increase (11 guaranty agencies × 10 hours = 110). There would be a total increase in burden of 240 hours under OMB Control Number 1845–0020.

There would also be burden on guaranty agencies to provide information to borrowers denied closed school discharges regarding the opportunity for further review of the discharge request by the Secretary. We estimate that it will take the 13 public guaranty agencies 4 hours totaling 52 hours (13 guaranty agencies × 4 hours = 52) to update their notifications and establish a process for forwarding any requests for escalated reviews to the Secretary. We further estimate that it will take the 11 non-profit guaranty agencies 4 hours totaling 44 hours (11 guaranty agencies × 4 hours = 44) to update their notifications and establish a process for forwarding any requests for escalated reviews to the Secretary. There would be a total increase in burden of 96 hours under OMB Control Number 1845–0020.

There would be burden on guaranty agencies, upon receipt of the request for escalated review from the borrower, to forward to the Secretary the discharge form and any relevant documents. For calendar year 2017 29,171 closed school discharge applications were received. It is estimated that 5 percent, or 1,459, of those borrowers would have their applications denied. We further estimate that 10 percent, or 146, of those borrowers whose applications were denied will request a review by the Secretary. We estimate that the process to forward the discharge to the Secretary will take 30 minutes per request. There would be an estimated burden of 40 hours for the 13 public guaranty agencies based on an estimated 79 requests (79 × .5 hours = 40 hours). There would be an estimated burden of 34 hours for the 11 non-profit guaranty agencies based on an estimated 67 requests (67 × .5 = 34 hours). There will be an increase in burden of 74 hours under OMB Control Number 1845–0020.

There will be a total increase in burden of 410 hours based on the proposed changes to section 682.402 under OMB Control Number 1845–0020.

Section 685.206 Borrower responsibilities and defenses.

Requirements: Under proposed § 685.206(d), a defense to repayment discharge claim on a Direct Loan disbursed after July 1, 2019 would be evaluated under the proposed Federal standard. Under proposed § 685.206(d), a defense to repayment must be submitted within three years from the date the student is no longer enrolled at the institution.

Burden Calculation: We believe that the burden will be associated with the new form that the borrower receives that accompanies the notice of action from the Department. The new form would be completed and made available for comment through a full public clearance package before being made available for use.

Section 685.215 Discharge for false certification of student eligibility or unauthorized payment.

Requirements: Under proposed § 685.215, the application requirements for false certification discharges would be amended to reflect the current practice of requiring a borrower to apply for the discharge using a Federal application form instead of a sworn statement. The proposed regulations also would remove the term ''ability to benefit'' to reflect changes to the HEA. Under the proposed regulatory changes, a Direct Loan borrower would not qualify for a false certification discharge based on not having a high school diploma in cases when the borrower did not obtain an official transcript or diploma from the high school, and the borrower provided an attestation to the institution that the borrower was a high school graduate.

Burden Calculation: The proposed clarification to require the submission of a Federal application to receive a

discharge and updating of the form to remove ''ability to benefit'' language will require an update to the current false certification application form with OMB Control Number 1845–0058. We do not believe that the language update will change the amount of time currently assessed for the borrower to complete the form, nor an increase in the number of borrowers who may qualify, to complete the form from those that have already been approved. The form update would be completed and made available for comment through a full public clearance package before being made available for use by the effective date of the regulations.

Section 685.304 Counseling Borrowers.

Requirements: Under proposed § 685.304 there are changes to the requirements to counsel Federal student loan borrowers prior to making the first disbursement of a Federal student loan (entrance counseling). Schools that use pre-dispute arbitration agreements and/or class action waivers will have to include in the required entrance counseling information on the school's internal dispute resolution process and who the borrower may contact regarding a dispute related to educational services for which the loan was made. Schools that require borrowers to accept a pre-dispute arbitration agreement and/or class action waiver would be required to provide information in writing to the student borrower about the plain language meaning of the agreement, when it would apply, how to enter into the process, and who to contact with questions.

Burden Calculation: We believe there will be burden on the schools to create any school specific pre-dispute arbitration agreement and/or class action waivers and provide that information in addition to complying with the current entrance counseling requirements. Of the 1,888 participating proprietary institutions, we estimate that 50 percent or 944 institutions would need to create additional entrance counseling information regarding the use of the pre-dispute arbitration agreement and/or class action waivers to provide to their student borrowers. We anticipate that it would take an average of 3 hours to adapt the information provided in proposed § 668.41 as a part of the required entrance counseling, to identify staff who would be able to answer additional questions, and to obtain evidence indicating the provision of the material for a total of 2,832 hours (944×3 hours).

Additionally, we believe that there will be minimum additional burden for borrowers to review the information when completing the required entrance counseling and provide the required evidence that the borrowers received the information. In calendar year 2017, 684,813 Direct Loan borrower completed entrance counseling using the Department's on-line entrance counseling. Assuming the same 50 percent of borrowers attend a school that uses pre-dispute arbitration agreements and/or class action waivers would require five minutes to review the material and provide evidence of receipt of the information, we estimate a total of 27,393 hours of additional burden (342,407 borrowers time .08 (5 minutes) = 27,393 hours). There would be a total increase in burden of 30,225 hours under OMB Control Number 1845–0021.

Consistent with the discussions above, the following chart describes the sections of the proposed regulations involving information collections, the information being collected and the collections that the Department will submit to OMB for approval and public comment under the PRA, and the estimated costs associated with the information collections. The monetized net cost of the increased burden for institutions, lenders, guaranty agencies and students, using wage data developed using Bureau of Labor Statistics data, available at *https://www.bls.gov/ooh/management/postsecondary-education-administrators.htm* is $1,107,460 as shown in the chart below. This cost is based on an estimated hourly rate of $44.41 for institutions, lenders, and guaranty agencies and $16.30 for students.

COLLECTION OF INFORMATION

Regulatory section	Information collection	OMB control No. and estimated burden (change in burden)	Estimated costs
§ 668.41	Under the proposed regulatory language in 668.41(h) institutions that use pre-dispute arbitration agreements and/or class action waivers would be required to disclose that information in a plain language disclosure available to enrolled and prospective students, and the public on its website where admissions and tuition and fees information is made available.	1845–0004; + 4,720 hours.	$209,615.
§ 668.171	Under the proposed regulatory language in 668.171(f) in accordance with procedures to be established by the Secretary, a school would notify the Secretary of any action or event described in the specified number of days after the action or event occurs. In the notice to the Secretary or in the school's response, the school may show that certain of the actions or events are not material or that the actions or events are resolved.	1845–0022; + 2,994 hours.	132,964.
§ 668.172	Under the proposed regulatory language in 668.172(d) institutions must request a second calculation of the composite score from the Secretary to exclude operating leases.	1845–0022; + 232 hours	10,303.
Appendix A & B of 668 subpart L.	Under proposed Section 2 for appendix A and B, proprietary and private schools would be required to submit a Supplemental Schedule as part of their audited financial statements. With the update from the Financial Standards Accounting Board (FASB) some elements needed to calculate the composite score would no longer be readily available in the audited financial statements, particularly for private institutions. With the proposed updates to the Supplemental Schedule to reference the financial statements, this issue would be addressed in a convenient and transparent manner for both the schools and the Department by showing how the composite score is calculated.	1845–0022; + 3,695 hours.	164,095.

COLLECTION OF INFORMATION—Continued

Regulatory section	Information collection	OMB control No. and estimated burden (change in burden)	Estimated costs
§ 674.33, § 682.402, § 685.2142.	Under the proposed regulations, the number of days that a borrower may have withdrawn from a closed school to qualify for a closed school discharge would extend from 120 days to 180 days, and if a closed school provided a borrower an opportunity to complete their academic program through a teach-out plan approved by the school's accrediting agency and, if applicable, the school's State authorizing agency, the borrower would not qualify for a closed school discharge. The proposed language further allows that the Secretary may extend that proposed 180 days further if there is a determination that exceptional circumstances justify an extension.	1845–0058; + 0 hours	0.
§ 682.402	Under proposed regulations in § 682.402 a second level of Departmental review for denied closed school discharge claim in the FFEL Program would be provided. The proposed regulations would require a guaranty agency that denies a closed school discharge request to inform the borrower of the opportunity for a review of the guaranty agency's decision by the Secretary, and an explanation of how the borrower may request such a review.	1845–0020; + 410	18,208.
§ 685.206	Under proposed § 685.206(d), a borrower defense claim related to a direct loan disbursed after July 1, 2019 would be evaluated under the proposed Federal standard. Under proposed § 685.206(d), a borrower defense must be submitted within three years from the date the borrower is no longer enrolled at the institution.	A new collection will be filed closer to the implementation of this requirement; + 0 hours.	0.
§ 685.215	Under the proposed regulatory language in § 685.215, the application requirements for false certification discharges are amended to reflect the current practice of requiring a borrower to apply for the discharge using a completed application form instead of a sworn statement. The proposed regulatory language proposed removing the use of term ''ability to benefit'' to bring the definition in line with the current HEA language. Under proposed regulatory language, a Direct Loan borrower will not qualify for a false certification discharge based on not having a high school diploma provide that in cases when they did not obtain an official transcript or diploma from the high school, and the borrower provided an attestation to the institution that the borrower was a high school graduate. The attestation would have to be provided under penalty of perjury.	1845–0058; + 0 hours	0.
§ 685.304	Under proposed § 685.304 there are changes to the requirements to counsel Federal student loan borrowers prior to making the first disbursement of a Federal student loan. Schools that use pre-dispute arbitration agreements and/or class action waivers include in the required entrance counseling information on the school's internal dispute resolution process and who the borrower may contact regarding a dispute related to educational services for which the loan was made. Schools that require a pre-dispute arbitration agreement and/or class action waiver would be required to review with the student borrower the agreement and when it would apply, how to enter into the process and who to contact with questions.	1845–0021; + 30,225 hours (2,832 institutions + 27,393 individual hours).	Inst. 125,769; Indiv. 446,506, TOTAL $572,275.

The chart below does not include the burden generated by 2016 final regulations because that regulatory package is not effective.

The total burden hours and change in burden hours associated with each OMB Control number affected by the proposed regulations follows:

Control No.	Total proposed burden hours	Proposed change in burden hours
1845–0004	23,390	+ 4,720
1845–0020	8,248,092	+ 410
1845–0021	739,746	+ 30,225
1845–0022	2,222,891	+ 6,921
Total	11,234,119	+ 42,276

We have prepared Information Collection Requests for these information collection requirements. If you wish to review and comment on the Information Collection Requests, please follow the instructions in the **ADDRESSES** section of this notification.

Note: The Office of Information and Regulatory Affairs in OMB and the Department review all comments posted at *www.regulations.gov.*

In preparing your comments, you may want to review the Information Collection Requests, including the supporting materials, in *www.regulations.gov* by using the Docket ID number specified in this notification. These proposed collections are identified as proposed collections 1845–0004, 1845–0020, 1845–0021, 1845–0022.

We consider your comments on these proposed collections of information in—

- Deciding whether the proposed collections are necessary for the proper performance of our functions, including whether the information will have practical use;
- Evaluating the accuracy of our estimate of the burden of the proposed collections, including the validity of our methodology and assumptions;
- Enhancing the quality, usefulness, and clarity of the information we collect; and
- Minimizing the burden on those who must respond. This includes exploring the use of appropriate automated, electronic, mechanical, or other technological collection techniques.

Between 30 and 60 days after publication of this document in the **Federal Register**, OMB is required to make a decision concerning the collections of information contained in these proposed regulations. Therefore, to ensure that OMB gives your comments full consideration, it is important that OMB receives your comments on these Information Collection Requests by August 30, 2018. This does not affect the deadline for your comments to us on the proposed regulations.

If your comments relate to the Information Collection Requests for these proposed regulations, please specify the Docket ID number and indicate ''Information Collection Comments'' on the top of your comments.

Intergovernmental Review

These programs are not subject to Executive Order 12372 and the regulations in 34 CFR part 79.

Assessment of Educational Impact

In accordance with section 411 of the General Education Provisions Act, 20 U.S.C. 1221e–4, the Secretary particularly requests comments on whether these proposed regulations would require transmission of information that any other agency or authority of the United States gathers or makes available.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (*e.g.,* Braille, large print, audiotape, or compact disc) on request to one of the persons listed under **FOR FURTHER INFORMATION CONTACT**.

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(Catalog of Federal Domestic Assistance Number does not apply.)

List of Subjects

34 CFR Part 668

Administrative practice and procedure, Colleges and universities, Consumer protection, Grant programs—education, Loan programs-education, Reporting and recordkeeping requirements, Selective Service System, Student aid, Vocational education.

34 CFR Part 674

Loan programs—education, Reporting and recordkeeping, Student aid.

34 CFR Parts 682 and 685

Administrative practice and procedure, Colleges and universities, Loan programs—education, Reporting and recordkeeping requirements, Student aid, Vocational education.

Dated: July 19, 2018.

Betsy DeVos,

Secretary of Education.

For the reasons discussed in the preamble, the Secretary of Education proposes to amend parts 668, 674, 682, and 685, of title 34 of the Code of Federal Regulations, as if the delayed amendments from the 2016 final regulations were never published, as follows:

PART 668—STUDENT ASSISTANCE GENERAL PROVISIONS

■ 1. The authority citation for part 668 is revised to read as follows:

Authority: 20 U.S.C. 1001–1003, 1070g, 1085, 1088, 1091, 1092, 1094, 1099c, 1099c–1, 1221–3, and 1231a, unless otherwise noted.

■ 2. Section 668.41 is amended by:

■ a. In paragraph (a), in the definition of ''Undergraduate students'', adding the words ''at or'' before ''below'' and adding the word ''level'' after ''baccalaureate''.

■ b. In paragraph (c)(2) introductory text, removing the phrase ''or (g)'' and adding the phrase ''(g), or (h)'' in its place.

■ c. Adding paragraph (h).

The addition reads as follows:

§ 668.41 Reporting and disclosure of information.

* * * * *

(h) *Enrolled students, prospective students, and the public—disclosure of an institution's use of pre-dispute arbitration agreements and/or class action waivers as a condition of enrollment for students receiving Title IV Federal student aid.*

(1) An institution of higher education that requires students receiving Title IV Federal student aid to accept or agree to a pre-dispute arbitration agreement and/or a class action waiver as a condition of enrollment must make available to enrolled students, prospective students, and the public, a written (electronic) plain language disclosure of those conditions of enrollment on its website where information regarding admissions and tuition and fees is presented. The institution may not rely solely on an intranet website for the purpose of providing this notice to prospective students or the public.

(2) For the purposes of this paragraph (h), the following definitions apply:

(i) *Class action* means a lawsuit or an arbitration proceeding in which one or more parties seeks class treatment pursuant to Federal Rule of Civil Procedure 23 or any State process analogous to Federal Rule of Civil Procedure 23.

(ii) *Class action waiver* means any agreement or part of an agreement, regardless of its form or structure, between a school, or a party acting on behalf of a school, and a student that relates to the making of a Direct Loan or the provision of educational services for which the student received title IV funding and prevents an individual from filing or participating in a class action that pertains to those services.

(iii) *Pre-dispute arbitration agreement* means any agreement or part of an agreement, regardless of its form or structure, between a school, or a party acting on behalf of a school, and a student requiring arbitration of any future dispute between the parties relating to the making of a Direct Loan or provision of educational services for which the student received title IV funding.

* * * * *

■ 3. Section 668.91 is amended by revising paragraphs (a)(3)(i) through (v) to read as follows:

§ 668.91 Initial and final decisions.

(a) * * *

(3) * * *

(i) If, in a termination action against an institution, the hearing official finds that the institution has violated the provisions of § 668.14(b)(18), the hearing official also finds that termination of the institution's participation is warranted;

(ii) If, in a termination action against a third-party servicer, the hearing official finds that the servicer has violated the provisions of § 668.82(d)(1), the hearing official also finds that termination of the institution's participation or servicer's eligibility, as applicable, is warranted;

(iii) In an action brought against an institution or third-party servicer that involves its failure to provide a letter of credit, or other financial protection under § 668.175(h), for a condition or event under § 668.15 or § 668.171(b), (c) or (d), the hearing official finds that the amount of the letter of credit or other financial protection established by the Secretary under § 668.175(c), (d), or (f) is appropriate, unless the institution demonstrates that the amount was not warranted because—

(A) The condition or event no longer exists or has been resolved;

(B) The condition or event does not and will not have a material adverse effect on the financial condition, business, or results of operations of the institution; or

(C) The institution has insurance that will cover the liabilities that arise from that condition or event;

(iv) In a termination action taken against an institution or third-party servicer based on the grounds that the institution or servicer failed to comply with the requirements of § 668.23(c)(3), if the hearing official finds that the institution or servicer failed to meet those requirements, the hearing official finds that the termination is warranted;

(v)(A) In a termination action against an institution based on the grounds that the institution is not financially responsible under § 668.15(c)(1), the hearing official finds that the termination is warranted unless the institution demonstrates that all applicable conditions described in § 668.15(d)(4) have been met; and

(B) In a termination or limitation action against an institution based on the grounds that the institution is not financially responsible—

(*1*) Upon proof of the conditions in § 668.174(a), the hearing official finds that the limitation or termination is warranted unless the institution demonstrates that all the conditions in § 668.175(f) have been met; and

(*2*) Upon proof of the conditions in § 668.174(b)(1), the hearing official finds that the limitation or termination is warranted unless the institution demonstrates that all applicable conditions described in § 668.174(b)(2) have been met; and

* * * * *

■ 4. Section 668.94 is amended by:

■ a. Redesignating paragraphs (h) and (i) as paragraphs (i) and (j), respectively.

■ b. Adding a new paragraph (h).

The addition reads as follows:

§ 668.94 Limitation.

* * * * *

(h) A change in the participation status of the institution from fully certified to participate to provisionally certified to participate under § 668.13(c);

* * * * *

■ 5. Section 668.171 is revised to read as follows:

§ 668.171 General.

(a) *Purpose.* To begin and to continue to participate in any title IV, HEA program, an institution must demonstrate to the Secretary that it is financially responsible under the standards established in this subpart. As provided under section 498(c)(1) of the HEA, the Secretary determines whether an institution is financially responsible based on the institution's ability to—

(1) Provide the services described in its official publications and statements;

(2) Meet all of its financial obligations; and

(3) Provide the administrative resources necessary to comply with title IV, HEA program requirements.

(b) *General standards of financial responsibility.* Except as provided under paragraphs (c), (d), and (h) of this section, the Secretary considers an institution to be financially responsible if the Secretary determines that—

(1) The institution's Equity, Primary Reserve, and Net Income ratios yield a composite score of at least 1.5, as provided under § 668.172 and appendices A and B to this subpart;

(2) The institution has sufficient cash reserves to make required returns of unearned title IV, HEA program funds, as provided under § 668.173;

(3) The institution is able to meet all of its financial obligations and provide the administrative resources necessary to comply with title IV, HEA program requirements. An institution is not be able to meet its financial or administrative obligations if—

(i) It fails to make refunds under its refund policy or return title IV, HEA program funds for which it is responsible under § 668.22;

(ii) It fails to make repayments to the Secretary for debts and liabilities arising from the institution's participation in the title IV, HEA programs; or

(iii) It is subject to an action or event described in paragraph (c) of this section (mandatory triggering events), or an action or event under paragraph (d) of this section (discretionary triggering events) that the Secretary determines is likely to have a material adverse effect on the financial condition of the institution. The Secretary considers a triggering event under these paragraphs only if it occurs on or after July 1, 2019; and

(4) The institution or persons affiliated with the institution are not subject to a condition of past performance under § 668.174(a) or (b).

(c) *Mandatory triggering events.* An institution is not able to meet its financial or administrative obligations under paragraph (b)(3)(iii) of this section if—

(1) After the end of the fiscal year for which the Secretary has most recently calculated an institution's composite score—

(i)(A) The institution incurs a liability arising from defense to repayment discharges adjudicated by the Secretary;

(B) The institution incurs a liability from a final judgment or determination arising from an administrative or judicial action or proceeding; or

(C) For a proprietary institution whose composite score is less than 1.5, there is a withdrawal of owner's equity from the institution by any means, including by declaring a dividend, unless the withdrawal is a transfer to an entity included in the affiliated entity group on whose basis the institution's composite score was calculated; and

(ii) As a result of that liability or withdrawal, the institution's recalculated composite score is less than 1.0, as determined by the Secretary under paragraph (e) of this section.

(2) For a publicly traded institution—

(i) The U.S. Securities and Exchange Commission (SEC) issues an order suspending or revoking the registration of the institution's securities pursuant to Section 12(j) of the Securities and Exchange Act of 1934 (the ''Exchange Act'') or suspends trading of the institution's securities on any national securities exchange pursuant to Section 12(k) of the Exchange Act;

(ii) The national securities exchange on which the institution's securities are traded notifies the institution that it is not in compliance with the exchange's listing requirements and, as a result, the institution's securities are delisted, either voluntarily or involuntarily, pursuant to the rules of the relevant national securities exchange; or

(iii) The U.S. SEC is not in timely receipt of a required report and did not issue an extension to file the report.

(d) *Discretionary triggering events.* The Secretary may determine that an institution is not able to meet its financial or administrative obligations under paragraph (b)(3)(iii) of this section if—

(1) The institution is issued a show-cause order that, if not satisfied, would result in the withdrawal, revocation or suspension of its institutional accreditation, by its institutional accrediting agency for failing to meet one or more of the agency's standards;

(2)(i) The institution violated a provision or requirement in a security or loan agreement with a creditor; and

(ii) As provided under the terms of that security or loan agreement, a monetary or nonmonetary default or delinquency event occurs, or other events occur, that trigger, or enable the creditor to require or impose on the institution, an increase in collateral, a change in contractual obligations, an increase in interest rates or payments, or other sanctions, penalties, or fees;

(3) The institution violated a State licensing or authorizing agency and was notified that its licensure or authorization will be withdrawn or terminated if the institution does not take the steps necessary to come into compliance with those requirements;

(4) For its most recently completed fiscal year, a proprietary institution did not receive at least 10 percent of its

revenue from sources other than title IV, HEA program funds, as provided under § 668.28(c); or

(5) The institution's two most recent official cohort default rates are 30 percent or greater, as determined under subpart N of this part, unless—

(i) The institution files a challenge, request for adjustment, or appeal under that subpart with respect to its rates for one or both of those fiscal years; and

(ii) That challenge, request, or appeal remains pending, results in reducing below 30 percent the official cohort default rate for either or both of those years, or precludes the rates from either or both years from resulting in a loss of eligibility or provisional certification.

(e) *Recalculating the composite score.* The Secretary recalculates an institution's most recent composite score by recognizing the actual amount of the liability incurred by an institution under paragraph (c)(1) of this section as an expense or accounting for the actual withdrawal of owner's equity under paragraph (c)(1)(i)(C) of this section as a reduction in equity. For purposes of this paragraph (e), the Secretary uses the audited financial statements from which the institution's composite score was calculated and the additional information from which the alternative composite score was calculated under § 668.172(d) and accounts for that expense by—

(1) For liabilities incurred by a proprietary institution—

(i) For the primary reserve ratio, increasing expenses and decreasing adjusted equity by that amount;

(ii) For the equity ratio, decreasing modified equity by that amount; and

(iii) For the net income ratio, decreasing income before taxes by that amount;

(2) For liabilities incurred by a non-profit institution—

(i) For the primary reserve ratio, increasing expenses and decreasing expendable net assets by that amount;

(ii) For the equity ratio, decreasing modified net assets by that amount; and

(iii) For the net income ratio, decreasing change in net assets without donor restrictions by that amount; and

(3) For the amount of owner's equity withdrawn from a proprietary institution—

(i) For the primary reserve ratio, decreasing adjusted equity by that amount; and

(ii) For the equity ratio, decreasing modified equity by that amount.

(f) *Reporting requirements.* (1) In accordance with procedures established by the Secretary, an institution must notify the Secretary of the following actions or events—

(i) For a liability incurred from a final judgment or determination under paragraph (c)(1)(ii) of this section, no later than 10 days after the date that the institution is notified of that judgment or determination;

(ii) For a withdrawal of owner's equity described in paragraph (c)(1)(iii) of this section, no later than 10 days after the date that the withdrawal is made;

(iii) For the provisions relating to a publicly traded institution under paragraph (c)(4) of this section, no later than 10 days after the date that:

(A) The SEC issues an order suspending or revoking the registration of the institution's securities pursuant to Section 12(j) of the Exchange Act or suspends trading of the institution's securities on any national securities exchange pursuant to Section 12(k) of the Exchange Act; or

(B) The national securities exchange on which the institution's securities are traded delists, either voluntarily or involuntarily, the institution's securities pursuant to the rules of the relevant national securities exchange;

(iv) For a probation or show cause action under paragraph (d)(1) of this section, 10 days after the institution is notified by its accrediting agency of that action;

(v) For the loan agreement provisions in paragraph (d)(2) of this section, 10 days after a loan violation occurs, the creditor waives the violation, or the creditor imposes sanctions or penalties in exchange or as a result of granting the waiver;

(vi) For a State or agency notice relating to terminating an institution's licensure or authorization under paragraph (d)(3) of this section, 10 days after the institution receives that notice; and

(vii) For the non-title IV revenue provision in paragraph (d)(4) of this section, no later than 45 days after the end of the institution's fiscal year, as provided in § 668.28(c)(3).

(2) The Secretary may take an administrative action under paragraph (h) of this section against an institution if it fails to provide timely notice to the Secretary under this paragraph (f).

(3)(i) In its notice to the Secretary under this paragraph (f), or in its response to a preliminary determination by the Secretary that the institution is not financially responsible because of a triggering event under paragraph (c) or (d) of this section, in accordance with procedures established by the Secretary, the institution may—

(A) Demonstrate that the reported withdrawal of owner's equity under paragraph (c)(1)(iii) of this section was used exclusively to meet tax liabilities of the institution or its owners for income derived from the institution;

(B) Show that the creditor waived a violation of a loan agreement under paragraph (d)(2) of this section. However, if the creditor imposes additional constraints or requirements as a condition of waiving the violation, or imposes penalties or requirements under paragraph (d)(2)(ii) of this section, the institution must identify and describe those penalties, constraints, or requirements and demonstrate that complying with those actions will not adversely affect the institution's ability to meet its financial obligations;

(C) Show that the triggering event has been resolved, or demonstrate that the institution has insurance that will cover all or part of the liabilities that arise from defense to repayment discharges or final judgments or determinations under paragraph (c)(1) of this section; or

(D) Explain or provide information about the conditions or circumstances that precipitated that triggering event that demonstrate that it has not or will not have a material adverse effect on the institution.

(ii) The Secretary will consider the information provided by the institution in determining whether to issue a final determination that the institution is not financially responsible.

(g) *Public institutions.* (1) The Secretary considers a domestic public institution to be financially responsible if the institution—

(i)(A) Notifies the Secretary that it is designated as a public institution by the State, local, or municipal government entity, tribal authority, or other government entity that has the legal authority to make that designation; and

(B) Provides a letter from an official of that State or other government entity confirming that the institution is a public institution; and

(ii) Is not subject to a condition of past performance under § 668.174.

(2) The Secretary considers a foreign public institution to be financially responsible if the institution—

(i)(A) Notifies the Secretary that it is designated as a public institution by the country or other government entity that has the legal authority to make that designation; and

(B) Provides documentation from an official of that country or other government entity confirming that the institution is a public institution and is backed by the full faith and credit of the country or other government entity; and

(ii) Is not subject to a condition of past performance under § 668.174.

(h) *Audit opinions.* Even if an institution satisfies all of the general standards of financial responsibility under paragraph (b) of this section, the Secretary does not consider the institution to be financially responsible if, in the institution's audited financial statements, the opinion expressed by the auditor was an adverse, qualified, or disclaimed opinion, or the auditor expressed doubt about the continued existence of the institution as a going concern, unless the Secretary determines that a qualified or disclaimed opinion does not have a significant bearing on the institution's financial condition.

(i) *Administrative actions.* If the Secretary determines that an institution is not financially responsible under the standards and provisions of this section or under an alternative standard in § 668.175, or the institution does not submit its financial and compliance audits by the date and in the manner required under § 668.23, the Secretary may—

(1) Initiate an action under subpart G of this part to fine the institution, or limit, suspend, or terminate the institution's participation in the title IV, HEA programs; or

(2) For an institution that is provisionally certified, take an action against the institution under the procedures established in § 668.13(d).

■ 6. Section 668.172 is amended by adding paragraph (d) to read as follows:

§ 668.172 Financial ratios.

* * * * *

(d) *Accounting for operating leases.* The Secretary calculates a composite score in accordance with ASU 2016–02, ASC 842 (Leases), but upon request by an institution the Secretary will also compute a second composite score using supplemental information provided by the institution that enables the composite score to be calculated excluding operating leases, and uses the higher of those two composite scores to determine, in part, whether the institution is financially responsible.

* * * * *

■ 7. Section 668.175 is amended by revising paragraphs (a) through (d) and (f) and adding paragraph (h) to read as follows:

§ 668.175 Alternative standards and requirements.

(a) *General.* An institution that is not financially responsible under the general standards and provisions in § 668.171, may begin or continue to participate in the title IV, HEA programs by qualifying under an alternate standard set forth in this section.

(b) *Letter of credit or surety alternative for new institutions.* A new institution that is not financially responsible solely because the Secretary determines that its composite score is less than 1.5, qualifies as a financially responsible institution by submitting an irrevocable letter of credit that is acceptable and payable to the Secretary, or providing other surety described under paragraph (h)(1)(i) of this section, for an amount equal to at least one-half of the amount of title IV, HEA program funds that the Secretary determines the institution will receive during its initial year of participation. A new institution is an institution that seeks to participate for the first time in the title IV, HEA programs.

(c) *Financial protection alternative for participating institutions.* A participating institution that is not financially responsible either because it does not satisfy one or more of the standards of financial responsibility under § 668.171(b), (c) or (d), or because of an audit opinion described under § 668.171(h), qualifies as a financially responsible institution by submitting an irrevocable letter of credit that is acceptable and payable to the Secretary, or providing other financial protection described under paragraph (h) of this section, for an amount determined by the Secretary that is not less than one-half of the title IV, HEA program funds received by the institution during its most recently completed fiscal year, except that this requirement does not apply to a public institution.

(d) *Zone alternative.* (1) A participating institution that is not financially responsible solely because the Secretary determines that its composite score under § 668.172 is less than 1.5 may participate in the title IV, HEA programs as a financially responsible institution for no more than three consecutive years, beginning with the year in which the Secretary determines that the institution qualifies under this alternative.

(i)(A) An institution qualifies initially under this alternative if, based on the institution's audited financial statement for its most recently completed fiscal year, the Secretary determines that its composite score is in the range from 1.0 to 1.4; and

(B) An institution continues to qualify under this alternative if, based on the institution's audited financial statement for each of its subsequent two fiscal years, the Secretary determines that the institution's composite score is in the range from 1.0 to 1.4.

(ii) An institution that qualified under this alternative for three consecutive years, or for one of those years, may not seek to qualify again under this alternative until the year after the institution achieves a composite score of at least 1.5, as determined by the Secretary.

(2) Under the zone alternative, the Secretary—

(i) Requires the institution to make disbursements to eligible students and parents under either the heightened cash monitoring or reimbursement payment method described in § 668.162;

(ii) Requires the institution to provide timely information regarding any of the following oversight and financial events—

(A) Any adverse action, including a probation or similar action, taken against the institution by its accrediting agency;

(B) Any event that causes the institution, or related entity as defined in Accounting Standards Codification (ASC) 850, to realize any liability that was noted as a contingent liability in the institution's or related entity's most recent audited financial statement;

(C) Any violation by the institution of any loan agreement;

(D) Any failure of the institution to make a payment in accordance with its debt obligations that results in a creditor filing suit to recover funds under those obligations; or

(E) Any losses that are unusual in nature or infrequently occur, or both, as defined in accordance with Accounting Standards Update (ASU) No. 2015–01 and ASC 225;

(iii) May require the institution to submit its financial statement and compliance audits earlier than the time specified under § 668.23(a)(4); and

(iv) May require the institution to provide information about its current operations and future plans.

(3) Under the zone alternative, the institution must—

(i) For any oversight or financial event described under paragraph (d)(2)(ii) of this section, in accordance with established procedures, notify the Secretary no later than 10 days after that event occurs; and

(ii) As part of its compliance audit, require its auditor to express an opinion on the institution's compliance with the requirements under the zone alternative, including the institution's administration of the payment method under which the institution received and disbursed title IV, HEA program funds.

(4) If an institution fails to comply with the requirements under paragraph (d)(2) or (3) of this section, the Secretary may determine that the institution no longer qualifies under this alternative.

* * * * *

(f) *Provisional certification alternative.* (1) The Secretary may permit an institution that is not financially responsible to participate in the title IV, HEA programs under a provisional certification for no more than three consecutive years if—

(i) The institution is not financially responsible because it does not satisfy the general standards under § 668.171(b), its recalculated composite score under § 668.171(e) is less than 1.0, it is subject to an action or event under § 668.171(c) or (d) that has an adverse material effect on the institution as determined by the Secretary, or because of an audit opinion described in § 668.171(h); or

(ii) The institution is not financially responsible because of a condition of past performance, as provided under § 668.174(a), and the institution demonstrates to the Secretary that it has satisfied or resolved that condition; and

(2) Under this alternative, the institution must—

(i) Submit to the Secretary an irrevocable letter of credit that is acceptable and payable to the Secretary, or provide other financial protection described under paragraph (h) of this section, for an amount determined by the Secretary that is not less than 10 percent of the title IV, HEA program funds received by the institution during its most recently completed fiscal year, except that this requirement does not apply to a public institution;

(ii) Demonstrate that it was current on its debt payments and has met all of its financial obligations, as required under § 668.171(b)(3), for its two most recent fiscal years; and

(iii) Comply with the provisions under the zone alternative, as provided under paragraphs (d)(2) and (3) of this section.

(3) If at the end of the period for which the Secretary provisionally certified the institution, the institution is still not financially responsible, the Secretary may again permit the institution to participate under a provisional certification but the Secretary—

(i) May require the institution, or one or more persons or entities that exercise substantial control over the institution, as determined under § 668.174(b)(1) and (c), or both, to provide to the Secretary financial guarantees for an amount determined by the Secretary to be sufficient to satisfy any potential liabilities that may arise from the institution's participation in the title IV, HEA programs; and

(ii) May require one or more of the persons or entities that exercise substantial control over the institution, as determined under § 668.174(b)(1) and (c), to be jointly or severally liable for any liabilities that may arise from the institution's participation in the title IV, HEA programs.

* * * * *

(h) *Financial protection.* In lieu of submitting a letter of credit for the amount required by the Secretary under this section, the Secretary may permit an institution to—

(1) Provide the amount required in the form of other surety or financial protection that the Secretary specifies in a notice published in the **Federal Register**;

(2) Provide cash for the amount required; or

(3) Enter into an arrangement under which the Secretary offsets the amount of title IV, HEA program funds that an institution has earned in a manner that ensures that, no later than the end of a six to twelve-month period selected by the Secretary, the amount offset equals the amount of financial protection the institution is required to provide. The Secretary uses the funds to satisfy the debts and liabilities owed to the Secretary that are not otherwise paid directly by the institution, and provides to the institution any funds not used for this purpose during the period covered by the agreement, or provides the institution any remaining funds if the institution subsequently submits other financial protection for the amount originally required.

* * * * *

■ 8. Appendix A to subpart L is revised to read as follows:

Appendix A to Subpart L of Part 668—Ratio Methodology for Propriety Institutions

Section 1: Ratio and Ratio Terms

Primary Reserve Ratio $\frac{\textit{Adjusted Equity}}{\text{Total Expenses and Losses}}$

Equity Ratio $\frac{\textit{Modified Equity}}{\text{Modified Assets}}$

Net Income Ratio $\frac{\textit{Income Before Taxes}}{\text{Total Revenue and Gains}}$

Total Expenses and Losses excludes income tax, discontinued operations not classified as an operating expense or change in accounting principle and any losses on investments, post-employment and defined benefit pension plans and annuities. Any losses on investments would be the net loss for the investments. Total Expenses and Losses includes the nonservice component of net periodic pension and other post-employment plan expenses.

Modified Equity = (total owner's equity) − (intangible assets) − (unsecured related-party receivables)

Modified Assets = (total assets) − (intangible assets) − (unsecured related-party receivables)

Income Before Taxes includes all revenues, gains, expenses and losses incurred by the school during the accounting period. Income before taxes does not include income taxes, discontinued operations not classified as an operating expense or changes in accounting principle.

Total Revenues and Gains does not include positive income tax amounts, discontinued operations not classified as an operating gain, or change in accounting principle (investment gains should be recorded net of investment losses.

* Unsecured related party receivables as required at 34 CFR 668.23(d)

** The value of property, plant and equipment includes construction in progress and lease right-of-use assets, and is net of accumulated depreciation/amortization.

*** All debt obtained for long-term purposes, not to exceed total net property, plant and equipment includes lease liabilities for lease right-of-use assets and the short-term portion of the debt, up to the amount of net property, plant and equipment. If an institution wishes to include the debt, including debt obtained through long-term lines of credit in total debt obtained for long-term purposes, the institution must include a disclosure in the financial statements that the debt, including lines of credit exceeds twelve months and was used to fund capitalized assets (*i.e.* property, plant and equipment or capitalized expenditures per Generally Accepted Accounting Principles (GAAP)). The disclosures that must be presented for any debt to be used in adjusted equity include the issue date, term, nature of capitalized amounts and amounts capitalized. Institutions that do not include debt in total debt obtained for long-term purposes, including long-term lines of credit, do not need to provide any additional disclosures other than those required by GAAP. The debt obtained for long-term purposes will be limited to only those amounts disclosed in the financial statements that were used to fund capitalized assets. Any debt amount including long-term lines of credit used to fund operations must be excluded from debt obtained for long-term purposes.

BILLING CODE 4000–01–P

SECTION 2: Financial Responsibility Supplemental Schedule Requirement and Example

A Supplemental Schedule must be submitted as part of the required audited financial statements submission. The Supplemental Schedule contains all of the financial elements required to compute the composite score. Each item in the Supplemental Schedule must have a reference to the Balance Sheet, Statement of (Loss) Income, or Notes to the Financial Statements. The amount entered in the Supplemental Schedules should tie directly to a line item, be part of a line item, tie directly to a note, or be part of a note in the financial statements. When an amount is zero, the institution would identify the source of the amount as NA (Not Applicable) and enter zero as the amount in the Supplemental Schedule. The audit opinion letter must contain a paragraph that references the auditor's additional analysis of the financial responsibility Supplemental Schedule.

"Financial Responsibility Supplemental Schedule"

Example location of number in the financial statements and/or notes - the number reference to sample numbers; however, could be more lines based on financial statements and/or notes.

Line			
		Primary Reserve Ratio: Adjusted Equity	
31	Balance Sheet - Total Equity	Total equity	3,035,000
4, 10	Balance Sheet - Related party receivable, net and Receivable from affiliate, net and Related party note*	Unsecured related party receivables and/or other related party assets	1,130,000
8	Balance Sheet - Property, Plant and Equipment, net*	Property, plant and equipment, net - including construction in progress	7,000,000
9	Balance Sheet - Lease right-of-use asset*	Lease right-of use asset	2,500,000
11	Balance Sheet - Goodwill*	Intangible assets	80,000
27	Balance Sheet - Post-employment and pension liability*	Post-employment and defined pension plan liabilities	300,000
20, 24	Balance Sheet - Notes payable (both current and long-term)*	Long-term debt - for long-term purposes	5,400,000
17, 25	Balance Sheet - Lease right-of-use assets liability (both current and long-term)*	Lease right-of-use asset liability	2,100,000
19, 23	Balance Sheet - Line of Credit-for Long-Term Purposes (both current and long-term) and Line of credit note*	Line of credit - for long-term purposes	575,000
40, 42, 44, 45	Statement of (Loss) Income - Total Operating Expenses, Interest Expense, Loss on Impairment of Assets and Loss on Disposal of Assets*	**Total Expenses and Losses:**	5,900,000
		Equity Ratio: Modified Equity	
31	Balance Sheet - Total Equity	Total equity	3,035,000
11	Balance Sheet - Goodwill*	Intangible assets	80,000
4, 10	Balance Sheet - Related party receivable, net and Receivable from affiliate, net and Related party note*	Unsecured related party receivables and/or other related party assets	1,130,000
		Modified Assets:	

13	Balance Sheet - Total Assets	Total assets	14,210,000
11	Balance Sheet - Goodwill*	Intangible assets	80,000
4,10	Balance Sheet - Related party receivable, net and Receivable from affiliate, net and Related party note*	Unsecured related party receivables and/or other related party assets	1,130,000
		Net Income Ratio:	
48	Statement of (Loss) Income - Net Income Before Income Taxes	**Income Before Taxes**	1,070,000
35, 43, 46	Statement of (Loss) Income - Total Revenue, Interest income and Other miscellaneous income*	**Total Revenues and Gains**	6,970,000
Lease right-of-use assets, net in place as of 7/1/2019 included in Financial Statements as a result of ASU 2016-2			1,500,000
Related Lease right-of-use assets liability for the above lease right-of use-assets as a result of ASU 2016-2			1,250,000
* In the example the number came from the actual financial statements; however, the number could come from the notes.			

SECTION 3: Example Financial Statement and Composite Score Calculation

BALANCE SHEET

Line		
	Current Assets	
1	Cash and cash equivalents	790,000
2	Accounts receivable, net	1,010,000
3	Prepaid expenses	150,000
4	Related party receivable	130,000
5	Related party receivable, secured	200,000
6	Student loans receivable, net	1,330,000
7	**Total Current Assets**	3,610,000
8	Property, plant and equipment, net	7,000,000
9	Lease right-of-use assets, net	2,500,000
10	Receivable from affiliate, net	1,000,000
11	Goodwill	80,000
12	Deposits	20,000
13	**Total Assets**	14,210,000
	Current Liabilities	
14	Accounts payable	350,000
15	Accrued expenses	500,000
16	Deferred revenue	650,000
17	Leases right-of-use assets liability	100,000
18	Line of credit – operating	100,000
19	Line of credit - for long term purposes	75,000
20	Note payable	400,000
21	**Total Current Liabilities**	2,175,000
22	Line of credit – operating	200,000
23	Line of credit - for long term purposes	500,000
24	Notes payable	5,000,000
25	Lease right-of-use asset liabilities	2,000,000
26	Other liabilities	1,000,000
27	Post-employment and pension liability	300,000
28	**Total Liabilities**	11,175,000
	Equity	
29	Common stock	500,000
30	Retained earnings	2,535,000
31	**Total Equity**	3,035,000
32	**Total Liabilities and Equity**	14,210,000

STATEMENT OF (LOSS) INCOME

Line		
	Revenue	
33	Tuition and fees, net	6,400,000
34	Clinic revenue	300,000
35	**Total Revenue**	6,700,000
	Operating Expenses	
36	Education expense	2,000,000
37	General expense	1,400,000
38	Occupancy expense	500,000
39	Depreciation and Amortization	350,000
40	**Total Operating Expenses**	4,250,000
41	**Operating Income (Loss)**	2,450,000
	Other Income (expense)	
42	Interest expense	(750,000)
43	Interest income	20,000
44	Loss on impairment of assets	(400,000)
45	Loss on disposal of assets	(500,000)
46	Other miscellaneous income	250,000
47	**Total Other Income (Expense)**	(1,380,000)
48	**Net Income Before Income Taxes**	1,070,000
49	Income taxes	267,000
50	**Net Income (Loss)**	803,000

Calculating the Composite Score	Lines		
Primary Reserve Ratio = Adjusted Equity	31-11-(4+10)-(8+9)+27+(17+19+20+23+24+25)	700,000	**0.1186**
/ Total Expenses and Losses	40 +42 +44 +45	5,900,000	
Equity Ratio = Modified Equity	31 -(4 +10) -11	1,825,000	**0.1404**
/ Modified assets	13 -(4 +10) -11	13,000,000	
Net Income Ratio = Income Before Taxes	48	1,070,000	**0.1535**
/Total Revenues and Gains	35 +43 +46	6,970,000	

Step 1: Calculate the strength factor score for each ratio by using the following algorithms:

Primary Reserve strength factor score = 20 x the primary reserve ratio result

Equity strength factor score = 6 x the equity ratio result

Net Income strength factor score = 1 + (33.3 x net income ratio result)

If the strength factor score for any ratio is greater than or equal to 3, the strength factor score for that ratio is 3.

If the strength factor score for any ratio is less than or equal to -1, the strength factor score for that ratio is -1

Step 2: Calculate the weighted score for each ratio and calculate the composite score by adding the three weighted scores

Primary Reserve weighted score = 30% x the primary reserve strength factor score

Equity weighted score = 40% x the equity strength factor score

Net Income weighted score = 30% x the net income strength factor score

Composite Score = the sum of all weighted scores

Round the composite score to one digit after the decimal point to determine the final score

RATIO	Ratio	Strength Factor	Weight	Composite Scores
Primary Reserve Ratio	0.1186	2.3729	30%	0.7119
Equity Ratio	0.1404	0.8423	40%	0.3369
Net Income Ratio	0.1535	3.0000	30%	0.9000
				1.9488
TOTAL Composite Score - Rounded				**1.9**

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■ 9. Appendix B to subpart L is revised to read as follows:

Appendix B Subpart L of Part 668—Ratio Methodology for Private Non-Profit Institutions

Section 1: Ratio and Ratio Terms

Primary Reserve Ratio *Expendable Net Assets*
Total Expenses without Donor Restrictions and Losses without Donor Restrictions

Equity Ratio *Modified Net Assets*
Modified Assets

Net Income Ratio *Change in Net Assets without Donor Restrictions*
Total Revenue without Donor Restrictions and Gains without Donor Restrictions

Definitions

Expendable Net Assets = (net assets without donor restrictions) + (net assets with donor restrictions) − (net assets with donor restrictions: restricted in perpetuity) * − (annuities, term endowments and life income funds with donor restrictions) ** − (intangible assets) − (net property, plant and equipment) *** + (post-employment and defined benefit pension plan liabilities) + (all long-term debt obtained for long-term purposes, not to exceed total net property, plant and equipment) **** − (unsecured related party transactions) *****

Total Expenses without Donor Restrictions and Losses without Donor Restrictions = All expenses and losses without donor restrictions from the Statement of Activities less any losses without donor restrictions on investments, post-employment and defined benefit pension plans and annuities. (For institutions that have defined benefit pension and other post-employment plans, total expenses include the nonservice component of net periodic pension and other post-employment plan expenses, and these expenses will be classified as non-operating. Consequently such expenses will be labeled non-operating or included with ''other changes—nonoperating changes—in net assets without donor restrictions'' when the Statement of Activities includes an operating measure).

Modified Net Assets = (net assets without donor restrictions) + (net assets with donor restrictions) − (intangible assets) − (unsecured related party receivables)

Modified Assets = (total assets) − (intangible assets) − (unsecured related party receivables)

Change in net assets without donor restrictions is taken directly from the audited financial statements.

Total Revenue without Donor Restriction and Gains without Donor Restrictions = total revenue (including amounts released from restriction) plus total gains. With regard to gains, investment returns are reported as a net amount (interest, dividends, unrealized and realized gains and losses net of external and direct internal investment expense). Institutions that separately report investment spending as operating revenue (*e.g.,* spending from funds functioning as endowment) and remaining net investment return as a non-operating item, will need to aggregate these two amounts to determine if there is a net investment gain or a net investment loss (net investment gains are included with total gains).

* Net assets with donor restrictions: Restricted in perpetuity is subtracted from total net assets. The amount of net assets with donor restrictions: Restricted in perpetuity is disclosed as a line item, part of line item, in a note, or part of a note in the financial statements.

** Annuities, term endowments and life income funds with donor restrictions is subtracted from total net assets. The amount of annuities, term endowments and life income funds with donor restrictions is disclosed in as a line item, part of line item, in a note, or part of a note in the financial statements.

*** The value of property, plant and equipment includes construction in progress and lease right-of-use assets, and is net of accumulated depreciation/amortization.

**** All Debt obtained for long-term purposes, not to exceed total net property, plant and equipment includes lease liabilities for lease right-of-use assets and the short-term portion of the debt, up to the amount of net property, plant and equipment. All Debt obtained for long-term purposes, not to exceed total net property, plant and equipment includes lease liabilities for lease right-of-use assets and the short-term portion of the debt, up to the amount of net property, plant and equipment. If an institution wishes to include the debt, including debt obtained through long-term lines of credit in total debt obtained for long-term purposes, the institution must include a disclosure in the financial statements that the debt, including lines of credit exceeds twelve months and was used to fund capitalized assets (*i.e.,* property, plant and equipment or capitalized expenditures per Generally Accepted Accounting Principles (GAAP)). The disclosures that must be presented for any debt to be included in expendable net assets include the issue date, term, nature of capitalized amounts and amounts capitalized. Institutions that do not include debt in total debt obtained for long-term purposes, including long-term lines of credit, do not need to provide any additional disclosures other than those required by GAAP. The debt obtained for long-term purposes will be limited to only those amounts disclosed in the financial statements that were used to fund capitalized assets. Any debt amount including long-term lines of credit used to fund operations must be excluded from debt obtained for long-term purposes.

***** Unsecured related party receivables as required at 34 CFR 668.23(d).

BILLING CODE 4000–01–P

SECTION 2: Financial Responsibility Supplemental Schedule Requirement and Example

A Supplemental Schedule must be submitted as part of the required audited financial statements submission. The Supplemental Schedule contains all of the financial elements required to compute the composite score. Each item in the Supplemental Schedule must have a reference to the Statement of Financial Position, Statement of Activities, Schedule of Natural to Functional Expenses, or Notes to the Financial Statements. The amount entered in the Supplemental Schedule should tie directly to a line item, be part of a line item, tie directly to a note, or be part of a note in the financial statements. When an amount is zero, the institution would identify the source of the amount as NA (Not Applicable) and enter zero as the amount in the Supplemental Schedule. The audit opinion letter must contain a paragraph that references the auditor's additional analysis of the financial responsibility Supplemental Schedule.

"Financial Responsibility Supplemental Schedule"

Example location of number in the financial statements and/or notes - the number reference to sample numbers; however, could be more lines based on financial statements and/or notes

		Primary Reserve Ratio:	
		Expendable Net Assets:	
31	Statement of Financial Position - Total Net Assets	Total net assets	26,990,000
4	Statement of Financial Position - Related party receivable and Related party note disclosure	Unsecured related party receivable	100,000
NA	Statement of Financial Position -Contribution receivable, net and Related party note disclosure**	Related party contribution receivable, net - only with significant relationship	0
8	Statement of Financial Position - Property, plant and equipment, net	Property, plant and equipment, net	40,000,000
9	Statement of Financial Position - Lease right-of-use assets, net	Lease right-of-use asset, net	10,000,000
10	Statement of Financial Position - Goodwill	Intangible assets	500,000
17	Statement of Financial Position - Post-employment and pension liabilities	Post-employment and pension liabilities	6,600,000
20	Statement of Financial Position - Note Payable*	Long-term debt	24,000,000
21	Statement of Financial Position - Lease right-of-use of asset liability	Lease right-of-use asset liability	10,000,000
22	Statement of Financial Position - Line of credit - for long-term purposes*	Line of credit - for long-term purposes	2,000,000
25	Statement of Financial Position - Annuities**	Annuities with donor restrictions	300,000
26	Statement of Financial Position - Term Endowments**	Term endowments with donor restrictions	50,000
27	Statement of Financial Positions—Life Income Funds**	Life income funds with donor restrictions	150,000
29	Statement of Financial Position –Perpetual Funds**	Net assets with donor restrictions: restricted in perpetuity	8,800,000
		Total Expenses and Losses:	

(35), 43, 45, 46, 47, 48, 49	Statement of Activities - (Investment return appropriated for spending), Total Operating Expenses, Investments, net of annual spending gain (loss), Other components of net periodic pension costs, Pension-related changes other than net periodic pension, Change in value of split-interest agreements and Other gains (loss)*	Total expenses without donor restrictions	52,980,000
(35), 45	Statement of Activities - (Investment return appropriated for spending) and Investments, net of annual spending, gain (loss)*	Net investment losses	400,000
48	Statement of Activities - Change in value of split-interest agreements	Change in value of split-interest agreements	80,000
47	Statement of Activities - Pension-related changes other than periodic pension*	Pension -related changes other than net periodic costs	350,000
	-	**Equity Ratio:** **Modified Net Assets:**	
24	Statement of Financial Position - Net Assets without Donor Restrictions	Net assets without donor restrictions	15,190,000
30	Statement of Financial Position - Total Net Assets with Donor Restriction	Net assets with donor restrictions	11,800,000
10	Statement of Financial Position - Goodwill	Intangible assets	500,000
4	Statement of Financial Position - Related party receivable and Related party note disclosure	Unsecured related party receivables	100,000
NA	Statement of Financial Position -Contribution receivable, net and Related party note disclosure**	Related party contribution receivable, net - only with significant relationship	0
		Modified Assets:	
12	Statement of Financial Position - Total assets	Total assets	76,240,000
10	Statement of Financial Position – Goodwill	Intangible assets	500,000
4	Statement of Financial Position - Related party receivables and Related party note disclosure	Unsecured related party receivables	100,000
NA	Statement of Financial Position -Contribution receivable, net and Related party note disclosure**	Related party contribution receivable, net - only with significant relationship	0
		Net Income Ratio:	
51	Statement of Activities - Change in Net Assets Without Donor Restrictions	**Change in Net Assets Without Donor Restrictions**	(80,000)
38, (35), 50	Statement of Activities - (Net assets released from restriction), Total Operating Revenue and Other Additions and Sale of Fixed Assets, gains (losses)	**Total Revenues and Gains**	52,900,000

Lease right-of-use assets, net in place as of 7/1/2019 included in Financial Statements as a result of ASU 2016-02	8,000,000
Related Lease right-of-use liability for the above Lease right-of use assets as a result of ASU 2016-02	8,000,000

* In the example the number came from the actual financial statements; however, the number could come from the notes of the financial statements.

SECTION 3: Example Financial Statements and Composite Score Calculation

Line	STATEMENT OF FINANCIAL POSITION	
1	Cash and cash equivalents	1,720,000
2	Accounts receivable, net	6,000,000
3	Prepaid expenses	1,900,000
4	Related party receivable	100,000
5	Contributions receivable, net	2,000,000
6	Student loans receivable, net	8,000,000
7	Investments	6,000,000
8	Property, plant and equipment, net	40,000,000
9	Lease right-of-use asset, net	10,000,000
10	Goodwill	500,000
11	Deposits	20,000
12	**Total Assets**	**76,240,000**
13	Line of credit - short term	300,000
14	Accounts payable	1,000,000
15	Accrued expenses	3,500,000
16	Deferred revenue	650,000
17	Post-employment and pension liability	6,600,000
18	Line of credit - operating	200,000
19	Other liabilities	1,000,000
20	Notes payable	24,000,000
21	Lease right-of-use asset liability	10,000,000
22	Line of credit for long term purposes	2,000,000
23	**Total Liabilities**	**49,250,000**
24	**Net Assets without Donor Restrictions**	**15,190,000**
	Net Assets with Donor Restrictions	
25	Annuities	300,000
26	Term endowments	50,000
27	Life income funds	150,000
28	Other restricted by purpose and time	2,500,000

Line	STATEMENT OF ACTIVITIES	
	Changes in Net Assets Without Donor Restrictions	
	Operating Revenue and Other Additions:	
33	Tuition and fees, net	43,200,000
34	Contributions	1,200,000
35	Investment return appropriated for spending	200,000
36	Auxiliary enterprises	7,000,000
37	Net assets released from restriction	500,000
38	**Total Operating Revenue and Other Additions**	**52,100,000**
	Operating Expenses and Other Deductions:	
39	Education and research expenses	38,000,000
40	Depreciation and Amortization	5,000,000
41	Interest expense	2,880,000
42	Auxiliary enterprises	5,200,000
43	**Total Operating Expenses**	**51,080,000**
44	**Change in Net Assets from Operations**	**1,020,000**
	Non-Operating Changes	
45	Investments, net of annual spending, gain (loss)	(600,000)
46	Other components of net periodic pension costs	(1,000,000)
47	Pension-related changes other than net periodic pension costs	(350,000)
48	Change in value of split-interest agreements	(80,000)
49	Other gains (losses)	(70,000)

29	Restricted in perpetuity	8,800,000
		11,800,00
30	**Total Net Assets with Donor Restrictions**	**0**
		26,990,00
31	**Total Net Assets**	**0**
		76,240,00
32	**Total Liabilities and Net Assets**	**0**

50	Sale of fixed assets, gains (losses)	1,000,000
	Total Non-Operating Changes	**(1,100,000)**
51	**Change in Net Assets Without Donor Restrictions**	**(80,000)**
	Change in Net Assets With Donor Restrictions	
52	Contributions	400,000
53	Net assets released from restriction	(500,000)
54	**Change in Net Assets With Donor Restrictions**	**(100,000)**
55	**Change in Net Assets**	**(180,000)**
56	**Net Assets, Beginning of Year**	**27,170,000**
31	**Net Assets, End of Year**	**26,990,000**

Calculating the Composite Score	Lines		
Primary Reserve Ratio = Adjusted Equity	31-11-(4+10)-(8+9)+27+(17+19+20+23+24+25)	700,000	**0.1186**
/ Total Expenses and Losses	40 +42 +44 +45	5,900,000	
Equity Ratio = Modified Equity	31 -(4 +10) -11	1,825,000	**0.1404**
/ Modified assets	13 -(4 +10) -11	13,000,000	
Net Income Ratio = Income Before Taxes	48	1,070,000	**0.1535**
Total Revenues and Gains	35 +43 +46	6,970,000	

Step 1: Calculate the strength factor score for each ratio by using the following algorithms:

Primary Reserve strength factor score = 10 x the primary reserve ratio result

Equity strength factor score = 6 x the equity ratio result

Negative net income ratio result: Net Income strength factor = 1 + (25 x net income ratio result)

Positive net income ratio result: Net income strength factor = 1 + (50 x net income ratio result)

Zero result for net income ratio: Net income strength factor = 1

If the strength factor score for any ratio is greater than or equal to 3, the strength factor score for the ratio is 3.

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If the strength factor score for any ratio is less than or equal to -1, the strength factor score for the ratio is -1.

Step 2: Calculate the weighted score for each ratio and calculate the composite score by adding the three weighted scores

Primary Reserve weighted score = 40% x the primary reserve strength factor score

Equity weighted score = 40% x the equity strength factor score

Net Income weighted score = 20% x the net income strength factor score

Composite Score = the sum of all weighted scores

Round the composite score to one digit after the decimal point to determine the final score

RATIO	Ratio	Strength Factor	Weight	Composite Scores
Primary Reserve Ratio	0.1855	1.8553	40%	0.7421
Equity Ratio	0.3489	2.0933	40%	0.8373
Net Income Ratio	(0.0015)	0.9622	20%	0.1924
				1.7719
TOTAL Composite Score - Rounded				**1.8**

PART 674—FEDERAL PERKINS LOAN PROGRAM

■ 10. The authority citation for part 674 continues to read as follows:

Authority: 20 U.S.C. 1070g, 1087aa–1087hh; Pub. L. 111–256, 124 Stat. 2643; unless otherwise noted.

■ 11. Section 674.33 is amended by:
■ a. Revising paragraph (g)(4).
■ b. In paragraph (g)(8)(i), removing the number ''120'' and adding, in its place, the number ''180''.

The revision reads as follows:

§ 674.33 Repayment.

* * * * *

(g) * * *

(4) *Borrower qualification for discharge.* Except as provided in paragraph (g)(3) of this section, in order to qualify for discharge of an NDSL or Federal Perkins Loan, a borrower must submit to the holder of the loan a completed discharge application on a form approved by the Secretary, and the factual assertions in the application must be true and made by the borrower under penalty of perjury. The application explains the procedures and eligibility criteria for obtaining a discharge and requires the borrower to—

(i) Certify that—

(A) The borrower received the proceeds of a loan to attend a school;

(B) The borrower did not complete the program of study at that school because the school closed while the student was enrolled, or the student withdrew from the school not more than 180 days before the school closed. The Secretary may extend the 180-day period if the Secretary determines that exceptional circumstances related to the school's closing justify an extension. Exceptional circumstances for this purpose may include, but are not limited to: Revocation or withdrawal by an accrediting agency of the school's institutional accreditation; or the State's revocation or withdrawal of the school's license to operate or to award academic credentials in the State;

(C) The borrower did not complete and is not in the process of completing the program of study by transferring academic credit earned at the closed school to another school, or by any other comparable means; and

(D) The school did not provide the borrower an opportunity to complete the program of study in which the borrower was enrolled through a teach-out plan approved by the school's accrediting agency and, if applicable, the school's State authorizing agency.

(ii) [Reserved]

* * * * *

PART 682—FEDERAL FAMILY EDUCATION LOAN (FFEL) PROGRAM

■ 12. The authority citation for part 682 continues to read as follows:

Authority: 20 U.S.C. 1071–1087–4, unless otherwise noted.

§ 682.202 [Amended]

■ 13. Section 682.202 is amended in paragraph (b)(1) by removing the word ''A'' before ''lender'' and adding in in place ''Except as provided in § 682.405(b)(4), a''.
■ 14. Section 682.402 is amended by:
■ a. Revising paragraph (d)(1)(i).
■ b. Revising paragraphs (d)(3) introductory text through (d)(3)(ii)(C).
■ c. Redesignating paragraphs (d)(3)(iii) and (iv) as paragraphs (d)(3)(iv) and (v).
■ d. Adding a new paragraph (d)(3)(iii).
■ e. Revising paragraph (d)(6)(ii)(B).
■ f. Revising the introductory text of paragraph (d)(6)(ii)(F).
■ g. In paragraph (d)(6)(ii)(F)(*3*), removing the number ''120'' and adding, in its place, the number ''180''.
■ h. In paragraph (d)(6)(ii)(F)(*5*), removing the words ''and sworn statement''.
■ i. Revising paragraphs (d)(6)(ii)(G) and (H).
■ j. Adding paragraph (d)(6)(ii)(J).

The revisions and additions read as follows:

§ 682.402 Death, disability, closed school, false certification, unpaid refunds, and bankruptcy payments.

* * * * *

(d) *Closed school*—(1) *General.* (i) The Secretary reimburses the holder of a loan received by a borrower on or after January 1, 1986, and discharges the borrower's obligation with respect to the loan in accordance with the provisions of paragraph (d) of this section, if the borrower (or the student for whom a parent received a PLUS loan) could not complete the program of study for which the loan was intended because the school at which the borrower (or student) was enrolled closed, or the borrower (or student) withdrew from the school not more than 180 days prior to the date the school closed. The Secretary may extend the 180-day period if the Secretary determines that exceptional circumstances related to a school's closing justify an extension. Exceptional circumstances for this purpose may include, but are not limited to: Revocation or withdrawal by an accrediting agency of the school's institutional accreditation, or revocation or withdrawal of the school's license to operate or to award academic credentials in the State.

* * * * *

(3) *Borrower qualification for discharge.* Except as provided in paragraph (d)(8) of this section, in order to qualify for discharge of a loan under paragraph (d) of this section a borrower must submit to the holder of the loan a completed application on a form approved by the Secretary, and the factual assertions in the application must be true and made by the borrower under penalty of perjury. The application explains the procedures and eligibility criteria for obtaining a discharge and requires the borrower to state—

(i) Whether the borrower has made a claim with respect to the school's closing with any third party, such as the holder of a performance bond or a tuition recovery program, and if so, the amount of any payment received by the borrower (or student) or credited to the borrower's loan obligation;

(ii) That the borrower (or the student for whom a parent received a PLUS loan)—

(A) Received, on or after January 1, 1986, the proceeds of any disbursement of a loan disbursed, in whole or in part, on or after January 1, 1986 to attend a school;

(B) Did not complete the educational program at that school because the school closed while the student was enrolled or on an approved leave of absence in accordance with § 668.22(d), or the student withdrew from the school not more than 180 days before the school closed; and

(C) Did not complete the program of study by transferring academic credits or hours earned at the closed school to another school or by any other comparable means;

(iii) The school did not provide the borrower an opportunity to complete the program of study through a teach-out plan approved by the school's accrediting agency and, if applicable, the school's State authorizing agency;

* * * * *

(6) * * *

(ii) * * *

(B) If the guaranty agency determines that a school appears to have closed, it must, within 30 days of making that determination, notify all lenders participating in its program to suspend collection efforts against individuals with respect to loans made for attendance at the closed school, if the student to whom (or on whose behalf) a loan was made, appears to have been enrolled at the school on the closing date, or withdrew not more than 180 days prior to the date the school appears to have closed. Within 30 days after receiving confirmation of the date of a

school's closure from the Secretary, the agency must—

(*1*) Notify all lenders participating in its program to mail a discharge application approved by the Secretary to all borrowers who may be eligible for a closed school discharge; and

(*2*) Review the records of loans that it holds, identify the loans made to any borrower (or student) who appears to have been enrolled at the school on the school closure date or who withdrew not more than 180 days prior to the closure date, and mail a discharge application to the borrower. The application informs the borrower of the procedures and eligibility criteria for obtaining a discharge.

* * * * *

(F) If the guaranty agency determines that a borrower identified in paragraph (d)(6)(ii)(C) or (D) of this section does not qualify for a discharge, the agency must notify the borrower in writing of that determination, the reasons for the decision, and how the borrower may ask the Secretary to review the decision within 30 days after the date the agency—

* * * * *

(G) Upon receipt of a closed school discharge claim filed by a lender, the agency must review the borrower's completed application in light of the information available from the records of the agency and from other sources, including other guaranty agencies, state authorities, and cognizant accrediting associations, and must take the following actions—

(*1*) If the agency determines that the borrower satisfies the requirements for discharge under paragraph (d) of this section, it must pay the claim in accordance with § 682.402(h) not later than 90 days after the agency received the claim; or

(*2*) If the agency determines that the borrower does not qualify for a discharge, the agency must, not later than 90 days after the agency received the claim, return the claim to the lender with an explanation of the reasons for its determination.

(H) If a borrower fails to submit the completed application described in paragraph (d)(3) of this section within 60 days of being notified of that option, the lender or guaranty agency must resume collection and must be deemed to have exercised forbearance of payment of principal and interest from the date it suspended collection activity. The lender or guaranty agency may capitalize, in accordance with § 682.202(b), any interest accrued and not paid during that period.

* * * * *

(J)(*1*) Within 30 days after receiving the borrower's request for review of its decision that the borrower did not qualify for a discharge under paragraph (d)(6)(ii)(F) of this section, the agency must forward the borrower's discharge request and all relevant documentation to the Secretary.

(*2*) After reviewing the documents provided by the agency, the Secretary notifies the agency and the borrower of the decision on the borrower's application for a discharge. If the Secretary determines that the borrower is not eligible for a discharge under paragraph (d) of this section, within 30 days after being informed of the Secretary's decision, the agency must take the actions described in paragraph (d)(6)(ii)(H) of this section, as applicable.

(*3*) If the Secretary determines that the borrower meets the requirements for a discharge under paragraph (d) of this section, the agency must, within 30 days after being informed of the Secretary's decision, take the actions required under paragraphs (d)(6)(ii)(E) and (d)(6)(ii)(G)(*1*) of this section and the lender must take the actions described in paragraph (d)(7)(iv) of this section, as applicable.

* * * * *

■ 15. Section 682.405 is amended by adding paragraph (b)(4)(ii) to read as follows:

§ 682.405 Loan rehabilitation agreement.

* * * * *

(b) * * *

(4) * * *

(ii) The purchase of a rehabilitated loan is not considered a borrower's entry into repayment or resumption of repayment for the purposes of interest capitalization under § 682.202(b).

* * * * *

■ 16. Section 682.410 is amended by revising paragraphs (b)(2) and (4) to read as follows:

§ 682.410 Fiscal, administrative, and enforcement requirements.

* * * * *

(b) * * *

(2) *Collection charges.* (i) Whether or not provided for in the borrower's promissory note and subject to any limitation on the amount of those costs in that note, the guaranty agency may charge a borrower an amount equal to the reasonable costs incurred by the agency in collecting a loan on which the agency has paid a default or bankruptcy claim unless, within the 60-day period following the initial notice described in paragraph (b)(6)(ii) of this section, the borrower enters into an acceptable repayment agreement, including a rehabilitation agreement, and honors that agreement, in which case the guaranty agency must not charge a borrower any collection costs.

(ii) An acceptable repayment agreement may include an agreement described in § 682.200(b) (Satisfactory repayment arrangement), § 682.405, or paragraph (b)(5)(ii)(D) of this section. An acceptable repayment agreement constitutes a repayment arrangement or agreement on repayment terms satisfactory to the guaranty agency, under this section.

(iii) The costs under this paragraph (b)(2) include, but are not limited to, all attorneys' fees, collection agency charges, and court costs. Except as provided in §§ 682.401(b)(18)(i) and 682.405(b)(1)(vi)(B), the amount charged a borrower must equal the lesser of—

(A) The amount the same borrower would be charged for the cost of collection under the formula in 34 CFR 30.60; or

(B) The amount the same borrower would be charged for the cost of collection if the loan was held by the U.S. Department of Education.

* * * * *

(4) *Capitalization of unpaid interest.* The guaranty agency must capitalize any unpaid interest due on the loan at the time the agency pays a default claim to the lender, but must not capitalize any unpaid interest thereafter.

* * * * *

PART 685—WILLIAM D. FORD FEDERAL DIRECT LOAN PROGRAM

■ 17. The authority citation for part 685 continues to read as follows:

Authority: 20 U.S.C. 1070g, 1087a, *et seq.,* unless otherwise noted.

■ 18. Section 685.200 is amended by adding paragraphs (f)(3)(v) and (f)(4)(iii) to read as follows:

§ 685.200 Borrower eligibility.

* * * * *

(f) * * *

(3) * * *

(v) A borrower who receives a closed school, false certification, unpaid refund, or defense to repayment discharge that results in a remaining eligibility period greater than zero is not responsible for the interest that accrues on a Direct Subsidized Loan or on the portion of a Direct Consolidation Loan that repaid a Direct Subsidized Loan unless the borrower once again becomes responsible for the interest that accrues on a previously received Direct Subsidized Loan or on the portion of a Direct Consolidation Loan that repaid a Direct Subsidized Loan, for the life of

the loan, as described in paragraph (f)(3)(i) of this section.

(4) * * *

(iii) For a first-time borrower who receives a closed school, false certification, unpaid refund, or borrower defense discharge on a Direct Subsidized Loan or a portion of a Direct Consolidation Loan that is attributable to a Direct Subsidized Loan, the Subsidized Usage Period is reduced. If the Direct Subsidized Loan or a portion of a Direct Consolidation Loan that is attributable to a Direct Subsidized Loan is discharged in full, the Subsidized Usage Period of those loans is zero years. If the Direct Subsidized Loan or a portion of a Direct Consolidation Loan that is attributable to a Direct Subsidized Loan is discharged in part, the Subsidized Usage Period may be reduced if the discharge results in the inapplicability of paragraph (f)(4)(i) of this section.

* * * * *

■ 19. Section 685.206 is amended by revising paragraph (c) and adding paragraph (d) to read as follows:

§ 685.206 Borrower responsibilities and defenses.

* * * * *

(c)(1) In any proceeding to collect on a Direct Loan first disbursed prior to July 1, 2019, the borrower may assert as a borrower defense to repayment, any act or omission of the school attended by the student that would give rise to a cause of action against the school under applicable State law. These proceedings include, but are not limited to, the following:

(i) Tax refund offset proceedings under 26 U.S.C. 6402(d), 31 U.S.C. 3716 and 3720A.

(ii) Wage garnishment proceedings under section 488A of the Act or under 31 U.S.C. 3720D and 34 CFR part 34.

(iii) Salary offset proceedings for Federal employees under 34 CFR part 31, 5 U.S.C. 5514, and 31 U.S.C. 3716.

(iv) Consumer reporting proceedings under 31 U.S.C. 3711(e).

(2) If a defense to repayment discharge is approved, the Secretary determines the amount of financial relief to be provided and notifies the borrower that the borrower is relieved of the obligation to repay all or part of the loan and associated costs and fees that the borrower would otherwise be obligated to pay. The Secretary affords the borrower such further relief as the Secretary determines is appropriate under the circumstances. Further relief may include, but is not limited to, the following:

(i) Reimbursing the borrower for amounts paid toward the loan voluntarily or through enforced collection.

(ii) Determining that the borrower is not in default on the loan and is eligible to receive assistance under title IV of the Act.

(iii) Updating reports to consumer reporting agencies to which the Secretary previously made adverse credit reports with regard to the borrower's Direct Loan.

(3) The Secretary may initiate an appropriate proceeding to require the school whose act or omission resulted in an approved defense to repayment discharge on a Direct Loan to pay to the Secretary the amount of the loan to which the defense applies. The Secretary will not initiate such a proceeding more than three years after the last award year in which the student attended the school, unless the school received actual notice of the defense to repayment during that period.

(d)(1) For purposes of this paragraph (d):

(i) The term ''borrower'' includes the student who attended the institution or the student on whose behalf a parent borrowed.

(ii) A borrower defense to repayment includes—

(A) A defense to repayment of amounts owed to the Secretary on a Direct Loan; and

(B) Any accompanying request for reimbursement of payments previously made to the Secretary on a Direct Loan.

(iii) The term ''provision of educational services'' refers to the educational resources provided by the institution that are required by an accreditation agency or a State licensing or authorizing agency for the completion of the student's educational program.

(iv) The terms ''school'' and ''institution'' may be used interchangeably and include an eligible institution or school, its officers, directors, employees, representatives, and agents, or any institution or school, organization, or person with whom the eligible school or institution has an agreement to provide educational programs, marketing, advertising, recruiting, or admissions services.

Alternative A for Paragraph (d)(2)(Defensive)

(2) In any proceeding to collect on a Direct Loan first disbursed on or after July 1, 2019, the borrower may assert a claim under this section. These proceedings include the following:

(i) Tax refund offset proceedings under 26 U.S.C. 6402(d), 31 U.S.C. 3716 and 3720A.

(ii) Wage garnishment proceedings under section 488A of the Act or under 31 U.S.C. 3720D and 34 CFR part 34.

(iii) Salary offset proceedings for Federal employees under 34 CFR part 31, 5 U.S.C. 5514, and 31 U.S.C. 3716.

(iv) Consumer reporting agency reporting proceedings under 31 U.S.C. 3711(e).

Alternative B for Paragraph (d)(2) (Defensive and Affirmative)

(2)(i) For loans first disbursed on or after July 1, 2019, a borrower may assert a claim under this section if the borrower establishes by a preponderance of the evidence that—

(A) The institution at which the borrower enrolled acted with an intent to deceive, knowledge of the falsity of a misrepresentation, or a reckless disregard for the truth in making a misrepresentation of material fact, opinion, intention, or law upon which the borrower reasonably relied in deciding to obtain a Direct Loan to enroll or continue enrollment in a program at the institution; and

(B) The borrower was financially harmed by the misrepresentation.

(ii) In any proceeding to collect on a Direct Loan first disbursed on or after July 1, 2019, the borrower may assert a claim under this section. These proceedings include the following:

(A) Tax refund offset proceedings under 26 U.S.C. 6402(d), 31 U.S.C. 3716 and 3720A.

(B) Wage garnishment proceedings under section 488A of the Act or under 31 U.S.C. 3720D and 34 CFR part 34.

(C) Salary offset proceedings for Federal employees under 34 CFR part 31, 5 U.S.C. 5514, and 31 U.S.C. 3716.

(D) Consumer reporting agency reporting proceedings under 31 U.S.C. 3711(e).

(3) To assert a borrower defense to repayment under this paragraph (d), a borrower must submit an application under penalty of perjury on a form approved by the Secretary and sign a waiver permitting the institution to provide the Department with items from the borrower's education record relevant to the defense to repayment claim. The application must—

(i) Certify that the borrower received the proceeds of a loan, in whole or in part, to attend the named school;

(ii) Provide evidence that supports the borrower defense to repayment application;

(iii) State whether the borrower has made a claim with any other third party, such as the holder of a performance bond, a public fund, or a tuition recovery program, based on the same act

or omission of the school on which the borrower defense to repayment is based;

(iv) State the amount of any payment received by the borrower or credited to the borrower's loan obligation through the third party, in connection with a claim described in paragraph (d)(3)(iii) of this section;

(v) State the amount of harm that the borrower alleges to have been caused by the school's action and supply any information relevant to assessing this allegation of harm, including information about whether the borrower failed to actively pursue employment in the field if the borrower is a recent graduate; whether the borrower was terminated or removed for performance reasons from a position in the field for which the borrower's education prepared the borrower, or a related field; and whether the borrower failed to meet other requirements of or qualifications for a job in such field for reasons unrelated to the school's action underlying the borrower defense, such as the borrower's ability to pass a drug test, satisfy criminal history or driving record requirements, and meet any health qualifications; and

(vi) State that the borrower understands that in the event that the borrower receives a 100 percent discharge of the loan for which the defense to repayment application has been submitted, the institution may refuse to verify, or to provide an official transcript that verifies the borrower's completion of credits or a credential associated with the discharged loan.

(4) In the case of a Direct Consolidation Loan first disbursed on or after July 1, 2019, a borrower may assert a borrower defense under the standards in this paragraph (d) with respect to a loan that was repaid by the Direct Consolidation Loan.

Alternative A for Paragraphs (d)(5) Introductory Text and (d)(5)(i) and (ii) (Defensive)

(5) The Secretary will approve the borrower's defense to repayment claim submitted under this paragraph (d) if the borrower in a collections proceeding, in the applicable timeframes for the proceeding, establishes by a preponderance of the evidence that—

(i) The institution at which the student enrolled made a misrepresentation, upon which the borrower reasonably relied under the circumstances in deciding to obtain a Direct Loan, or a loan repaid by a Direct Consolidation Loan, for the student to enroll or continue enrollment in a program at the institution; and

(ii) The borrower suffered financial harm as a result of the misrepresentation by the school.

Alternative B for Paragraphs (d)(5) Introductory Text and (d)(5)(i) and (ii) (Affirmative and Defensive)

(5) The Secretary will approve the borrower's defense to repayment claim submitted under this paragraph (d) if—

(i) In the case of an affirmative claim made by a borrower in repayment under paragraph (d)(2)(ii) of this section—

(A) The borrower submits the claim to the Department within three years from the date the student is no longer enrolled at the institution; and

(B) The Secretary finds that a preponderance of the evidence supports the approval of a borrower defense to repayment; or

(ii) In the case of a defensive claim submitted by a borrower under paragraph (d)(2)(ii) of this section, the borrower in a collections proceeding, in the applicable timeframes for the proceeding, establishes by a preponderance of the evidence that—

(A) The institution at which the student enrolled made a misrepresentation, upon which the borrower reasonably relied under the circumstances in deciding to obtain a Direct Loan, or a loan repaid by a Direct Consolidation Loan, for the student to enroll or continue enrollment in a program at the institution; and

(B) The borrower suffered financial harm as a result of the misrepresentation by the school.

(iii) The Secretary may also consider evidence otherwise in the possession of the Secretary, including from the Department's internal records or other relevant evidence obtained by the Secretary, provided that the Secretary permits the institution to review and respond to this evidence and to submit additional evidence.

(iv) A ''misrepresentation'' is a statement, act, or omission by an eligible school to a borrower that is false, misleading, or deceptive; that was made with knowledge of its false, misleading, or deceptive nature or with a reckless disregard for the truth; and that directly and clearly relates to the making of a Direct Loan, or a loan repaid by a Direct Consolidation Loan, for enrollment at the school or to the provision of educational services for which the loan was made. Evidence that a misrepresentation described in paragraph (d)(5) of this section may have occurred includes:

(A) Actual licensure passage rates materially different from those included in the institution's marketing materials, website, or other communications made to the student;

(B) Actual employment rates materially different from those included in the institution's marketing materials, website, or other communications made to the student;

(C) Actual institutional selectivity rates or rankings, student admission profiles, or institutional rankings that are materially different from those included in the institution's marketing materials, website, or other communications made to the student;

(D) The inclusion in the institution's marketing materials, website, or other communication made to the student of specialized, programmatic, or institutional certifications, accreditation, or approvals not actually obtained, or the failure to remove within a reasonable period of time such certifications or approvals from marketing materials, website, or other communication when revoked or withdrawn;

(E) The inclusion in the institution's marketing materials, website, or other communication made to the student of representations regarding the widespread or general transferability of credits that are only transferrable to limited types of programs or institutions or the transferability of credits to a specific program or institution when no reciprocal agreement exists with another institution or such agreement is materially different than what was represented;

(F) A representation regarding the employability or specific earnings of graduates without an agreement between the institution and another entity for such employment or sufficient evidence of past employment or earnings to justify such a representation or without citing appropriate national data for earnings in the same field as provided by an appropriate Federal agency that provides such data;

(G) A representation regarding the availability, amount, or nature of any financial assistance available to students from the institution or any other entity to pay the costs of attendance at the institution that the school does not fulfill following the enrollment of the borrower;

(H) A representation regarding the amount of tuition and fees that the student would be charged for the program that is materially different in amount, method, or timing of payment from the actual tuition and fees charged to the student;

(I) A representation that the institution, its courses, or programs are endorsed by vocational counselors, high schools, colleges, educational

organizations, employment agencies, members of a particular industry, students, former students, governmental officials, the United States armed forces, or other individuals or entities when the institution has no permission or is not otherwise authorized to use such an endorsement;

(J) A representation regarding the educational resources provided by the institution that are required for the completion of the student's educational program that are materially different from the institution's actual circumstances at the time the representation is made, such as representations regarding the institution's size, location, facilities, training equipment, or the number, availability, or qualifications of its personnel; and

(K) A representation regarding the nature or extent of prerequisites for enrollment in a course or program offered by the institution that are that are materially different from the institution's actual circumstances at the time the representation is made, or that the institution knows will be materially different during the student's anticipated enrollment at the institution.

(v) Financial harm to the borrower has occurred when the borrower suffers monetary loss as a consequence of a misrepresentation described in paragraph (d)(5) of this section and defined in paragraph (d)(5)(iv) of this section. Financial harm does not include damages for nonmonetary loss, such as personal injury, inconvenience, aggravation, emotional distress, pain and suffering, punitive damages, or opportunity costs. The Department does not consider the act of taking out a Direct Loan as evidence of financial harm to the borrower. Financial harm is such monetary loss that is not predominantly due to intervening local, regional, or national economic or labor market conditions as demonstrated by evidence before the Secretary or provided to the Secretary by the borrower or the school. Financial harm cannot arise from the borrower's voluntary decision to pursue less than full-time work or not to work, or result from a voluntary change in occupation. Evidence of financial harm includes the following circumstances:

(A) Extended periods of unemployment upon graduating from the school's programs that are unrelated to national or local economic downturns or recessions;

(B) A significant difference between the amount or nature of the tuition and fees that the institution represented to the borrower that the institution would charge or was charging and the actual amount or nature of the tuition and fees charged by the institution for which the Direct Loan was disbursed;

(C) The borrower's inability to secure employment in the field of study for which the institution expressly guaranteed employment; and

(D) The borrower's inability to complete the program because the institution no longer offers a requirement necessary for completion of the program in which the borrower enrolled and the institution did not provide for an acceptable alternative requirement to enable completion of the program.

(6) The Secretary will not accept the following as a basis for a borrower defense to repayment—

(i) A violation by the institution of a requirement of the Act or the Department's regulations for a borrower defense to repayment under paragraph (c) or (d) of this section, unless the violation would otherwise constitute the basis for a successful borrower defense; or

(ii) A claim that is not directly and clearly related to the making of the loan or the provision of educational services by the school including, but not limited to—

(A) Personal injury;

(B) Sexual harassment;

(C) A violation of civil rights;

(D) Slander or defamation;

(E) Property damage;

(F) The general quality of the student's education or the reasonableness of an educator's conduct in providing educational services;

(G) Informal communication from other students;

(H) Academic disputes and disciplinary matters; and

(I) Breach of contract unless the school's act or omission would otherwise constitute the basis for a successful defense to repayment under this section.

(7) Upon receipt of a borrower's request for relief based on defense to repayment, the Department will notify the school of the pending request, provide a copy of the borrower's request and any supporting documents to the school, provide a waiver signed by the student permitting the institution to provide the Department with items from the student's education record relevant to the defense to repayment claim, and invite the school to respond and to submit evidence within the specified timeframe included in the notice. The borrower will receive a copy of the school's response and related evidence.

(8)(i) The Secretary will provide the school the information that will be considered when determining whether to grant the borrower defense to repayment discharge and allow a reasonable opportunity to respond and submit additional evidence. This information may include—

(A) The Department's internal records;

(B) The borrower defense to repayment application and any supporting evidence submitted by the borrower;

(C) The response and any supporting evidence submitted by the school; and

(D) Any other relevant evidence obtained by the Secretary.

(ii) After considering the borrower's application and evidence and any information or evidence provided by the school, the Secretary issues a written decision—

(A) Notifying the borrower and the school of the decision on the borrower defense to repayment;

(B) Providing the reasons for the decision; and

(C) Informing the borrower and the school of the relief, if any, that the borrower will receive, consistent with paragraph (d)(9) of this section.

(9)(i) If the Secretary grants the borrower's request for relief based on defense to repayment, the Secretary notifies the borrower and the school that the borrower is relieved of the obligation to repay all or part of the loan and associated costs and fees that the borrower would otherwise be obligated to pay. In awarding relief, the Secretary shall consider any payments reported by the borrower pursuant to paragraph (d)(3)(iv) of this section.

(ii) The Secretary affords the borrower such further relief as the Secretary determines is appropriate under the circumstances. Further relief includes, if applicable:

(A) Reimbursing the borrower for amounts paid toward the loan voluntarily or through enforced collection;

(B) Determining that the borrower is not in default on the loan and is eligible to receive assistance under title IV of the Act;

(C) Eliminating or recalculating the subsidized usage period that is associated with the loan or loans discharged; and

(D) Updating reports to consumer reporting agencies to which the Secretary previously made adverse credit reports with regard to the borrower's Direct Loan.

(10) The determination of a borrower's defense to repayment by the Department included in the written decision referenced in paragraph (d)(9)

of this section is the final decision of the Department and is not subject to appeal.

(11) The Secretary may revoke any relief granted to a borrower under this section who refuses to cooperate with the Secretary in any proceeding under paragraph (c) or (d) of this section or under subpart G of this part. Such cooperation includes, but is not limited to—

(i) Providing testimony regarding any representation made by the borrower to support a successful borrower defense to repayment; and

(ii) Producing, within timeframes established by the Secretary, any documentation reasonably available to the borrower with respect to those representations and any sworn statement required by the Secretary with respect to those representations and documents.

(12)(i) Upon the grant of any relief under paragraph (c) or (d) of this section, the borrower is deemed to have assigned to, and relinquished in favor of, the Secretary any right to a loan refund (up to the amount discharged) that the borrower may have by contract or applicable law with respect to the loan or the provision of educational services for which the loan was received, against the school, its principals, its affiliates and their successors, or its sureties, and any private fund, including the portion of a public fund that represents funds received from a private party. If the borrower asserts a claim to, and recovers from, a public fund, the Secretary may reinstate the borrower's obligation to repay on the loan an amount based on the amount recovered from the public fund, if the Secretary determines that the borrower's recovery from the public fund was based on the same borrower defense and for the same loan for which the discharge was granted under this section.

(ii) The provisions of this paragraph (d)(12) apply notwithstanding any provision of State law that would otherwise restrict transfer of those rights by the borrower, limit or prevent a transferee from exercising those rights, or establish procedures or a scheme of distribution that would prejudice the Secretary's ability to recover on those rights.

(iii) Nothing in this paragraph (d)(12) limits or forecloses the borrower's right to pursue legal and equitable relief arising under applicable law against a party described in this paragraph (d)(12) for recovery of any portion of a claim exceeding that assigned to the Secretary or any other claims arising from matters unrelated to the claim on which the loan is discharged.

(13)(i) The Secretary may initiate an appropriate proceeding to require the school whose misrepresentation resulted in the borrower's successful borrower defense to pay to the Secretary the amount of the loan to which the defense applies in accordance with 34 CFR part 668, subpart G. This paragraph (d)(13) would also be applicable for provisionally certified institutions.

(ii) The Secretary will not initiate such a proceeding more than five years after the date of the final determination included in the written decision referenced in paragraph (d)(9) of this section. The Department will notify the school of the defense to repayment application.

(iii) The school must repay the Secretary the amount of the loan which has been discharged and amounts refunded to a borrower for payments made by the borrower to the Secretary, unless the school demonstrates that the Secretary's decision to approve the defense to repayment application was clearly erroneous.

* * * * *

■ 20. Section 685.212 is amended by adding paragraph (k) to read as follows:

§ 685.212 Discharge of loan obligation.

* * * * *

(k) *Borrower defenses.* (1) If a borrower's application for a discharge of a loan based on a borrower defense is approved under § 685.206(c) or (d), the Secretary discharges the obligation of the borrower, in whole or in part, in accordance with the procedures described in § 685.206(c) or (d), respectively.

(2) [Reserved]

* * * * *

■ 21. Section 685.214 is amended by:
■ a. Revising paragraphs (c)(1) introductory text through (c)(1)(i)(C).
■ b. Redesignating paragraphs (c)(1)(ii) and (iii) as paragraphs (c)(1)(iii) and (iv).
■ c. Adding a new paragraph (c)(1)(ii).
■ d. In paragraph (f)(1), removing the number ''120'' and adding, in its place, the number ''180''.
■ e. In paragraph (f)(4), removing the words ''the written request and sworn statement'' and adding, in their place, the words ''a completed application''.

The revisions and addition read as follows:

§ 685.214 Closed school discharge.

* * * * *

(c) *Borrower qualifications for discharge.* (1) In order to qualify for discharge of a loan under this section, a borrower must submit to the Secretary a completed application, and the factual assertions in the application must be true and made by the borrower under penalty of perjury. The application explains the procedures and eligibility criteria for obtaining a discharge and requires the borrower to—

(i) Certify that the borrower (or the student on whose behalf a parent borrowed)—

(A) Received the proceeds of a loan, in whole or in part, on or after January 1, 1986 to attend a school;

(B) Did not complete the program of study at that school because the school closed while the student was enrolled, or the student withdrew from the school not more than 180 days before the school closed. The Secretary may extend the 180-day period if the Secretary determines that exceptional circumstances related to a school's closing justify an extension. Exceptional circumstances for this purpose may include, but are not limited to: The revocation or withdrawal by an accrediting agency of the school's institutional accreditation, or revocation or withdrawal of the school's license to operate or to award academic credentials in the State; and

(C) Did not complete the program of study by transferring academic credits or hours earned at the closed school to another school;

(ii) Certify that the school did not provide the borrower an opportunity to complete the program of study in which the borrower was enrolled through a teach-out plan approved by the school's accrediting agency and, if applicable the school's State authorizing agency;

* * * * *

■ 22. Section 685.215 is amended by:
■ a. Revising paragraph (a)(1)(i).
■ b. Revising paragraphs (c) introductory text through (c)(1)(ii).
■ c. Revising paragraphs (d)(1) through (3).

The revisions read as follows:

§ 685.215 Discharge for false certification of student eligibility or unauthorized payment.

(a) * * *

(1) * * *

(i) Certified eligibility for a Direct Loan for a student who did not have a high school diploma or its recognized equivalent and did not meet the alternative eligibility requirements described in 34 CFR part 668 and section 484(d) of the Act applicable at the time of disbursement.

* * * * *

(c) *Borrower qualification for discharge.* In order to qualify for discharge under this section, the borrower must submit to the Secretary an application for discharge on a form approved by the Secretary, and the factual assertions in the application

must be true and made under penalty of perjury. In the application, the borrower must demonstrate to the satisfaction of the Secretary that the requirements in paragraphs (c)(1) through (6) of this section have been met.

(1) *High school diploma or equivalent.* (i) In the case of a borrower requesting a discharge based on not having had a high school diploma and not having met the alternative eligibility requirements, the borrower must certify that the borrower (or the student on whose behalf a parent borrowed)—

(A) Received a disbursement of a loan, in whole or in part, on or after January 1, 1986, to attend a school; and

(B) Received a Direct Loan at that school and did not have a high school diploma or its recognized equivalent, and did not meet the alternative to graduation from high school eligibility requirements described in 34 CFR part 668 and section 484(d) of the Act applicable at the time of disbursement.

(ii) A borrower does not qualify for a false certification discharge under § 685.215(c)(1) if—

(A) The borrower was unable to provide the school with an official transcript or an official copy of the borrower's high school diploma or the borrower was home schooled and has no official transcript or high school diploma; and

(B) As an alternative to an official transcript or official copy of the borrower's high school diploma, the borrower submitted to the school a written attestation, under penalty of perjury, that the borrower had a high school diploma.

* * * * *

(d) *Discharge procedures.* (1) If the Secretary determines that a borrower's Direct Loan may be eligible for a discharge under this section, the Secretary provides the borrower the application described in paragraph (c) of this section, which explains the qualifications and procedures for obtaining a discharge. The Secretary also promptly suspends any efforts to collect from the borrower on any affected loan. The Secretary may continue to receive borrower payments.

(2) If the borrower fails to submit a completed application within 60 days of the date the Secretary suspended collection efforts, the Secretary resumes collection and grants forbearance of principal and interest for the period in which collection activity was suspended. The Secretary may capitalize any interest accrued and not paid during that period.

(3) If the borrower submits a completed application the Secretary determines whether to grant a request for discharge under this section by reviewing the application in light of information available from the Secretary's records and from other sources, including, but not limited to, the school, guaranty agencies, State authorities, and relevant accrediting associations.

* * * * *

■ 23. Section 685.300 is amended by:

■ a. Revising paragraph (b)(8).

■ b. Removing the word ''and'' at the end of paragraph (b)(10).

■ c. Redesignating paragraph (b)(11) as paragraph (b)(12).

■ d. Adding a new paragraph (b)(11).

The revision and addition read as follows:

§ 685.300 Agreements between an eligible school and the Secretary for participation in the Direct Loan Program.

* * * * *

(b) * * *

(8) Accept responsibility and financial liability stemming from its failure to perform its functions pursuant to the agreement;

* * * * *

(11) Accept responsibility and financial liability stemming from losses incurred by the Secretary for repayment of amounts discharged by the Secretary pursuant to §§ 685.206, 685.214, 685.215, and 685.216; and

* * * * *

■ 24. Section 685.304 is amended by:

■ a. Revising paragraphs (a)(3)(iii) and (a)(5).

■ b. Removing the word ''and'' at the end of paragraph (a)(6)(xii).

■ c. Redesignating paragraph (a)(6)(xiii) as paragraph (a)(6)(xvi) and adding paragraphs (a)(6)(xiii), (xiv), and (xv).

The revision and additions read as follows:

§ 685.304 Counseling borrowers.

(a) * * *

(3) * * *

(iii)(A) Online or by interactive electronic means, with the borrower acknowledging receipt of the information.

(B) If a standardized interactive electronic tool is used to provide entrance counseling to the borrower, the school must provide to the borrower any elements of the required information that are not addressed through the electronic tool:

(*1*) In person; or

(*2*) On a separate written or electronic document provided to the borrower.

* * * * *

(5) A school must ensure that an individual with expertise in the title IV programs is reasonably available shortly after the counseling to answer the student borrower's questions. As an alternative, in the case of a student borrower enrolled in a correspondence, distance education, or study-abroad program approved for credit at the home institution, the student borrower may be provided with written counseling materials before the loan proceeds are disbursed.

(6) * * *

(xiii) If the school requires borrowers to enter into a pre-dispute arbitration agreement, as defined in § 668.41(h)(2)(iii) of this chapter, or to sign a class action waiver, as defined in § 668.41(h)(2)(i) and (ii) of this chapter, the school must provide a written description of the school's dispute resolution process that the borrower has agreed to pursue as a condition of enrollment, including the name and contact information for the individual or office at the school that the borrower may contact if the borrower has a dispute relating to the borrower's Federal student loans or to the educational services for which the loans were provided;

(xiv) If the school requires borrowers to enter into a pre-dispute arbitration agreement, as defined in § 668.41(h)(2)(iii) of this chapter, to enroll in the institution, provides a written description of how and when the agreement applies, how the borrower enters into the arbitration process, and who to contact if the borrower has any questions;

(xv) If the school requires borrowers to sign a class-action waiver, as defined in § 668.41(2)(h)(i) and (ii) of this chapter, to enroll in the institution, explain how and when the waiver applies, alternative processes the borrower may pursue to seek redress, and who to contact if the borrower has any questions; and

* * * * *

■ 25. Section 685.308 is amended by revising paragraph (a) to read as follows:

§ 685.308 Remedial actions.

(a) The Secretary may require the repayment of funds and the purchase of loans by the school if the Secretary determines that the school is liable as a result of—

(1) The school's violation of a Federal statute or regulation;

(2) The school's negligent or willful false certification under § 685.215; or

(3) The school's actions that gave rise to a successful claim for which the Secretary discharged a loan, in whole or

in part, pursuant to §§ 685.206, 685.214, and 685.216.

* * * * *

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Part IV

Securities and Exchange Commission

17 CFR Parts 239, 270 and 274
Exchange-Traded Funds; Proposed Rule

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 239, 270, and 274

[Release Nos. 33–10515; IC–33140; File No. S7–15–18]

RIN 3235–AJ60

Exchange-Traded Funds

AGENCY: Securities and Exchange Commission.

ACTION: Proposed rule.

SUMMARY: The Securities and Exchange Commission (the ''Commission'') is proposing a new rule under the Investment Company Act of 1940 (the ''Investment Company Act'' or the ''Act'') that would permit exchange-traded funds (''ETFs'') that satisfy certain conditions to operate without the expense and delay of obtaining an exemptive order. In connection with the proposed exemptive rule, the Commission proposes to rescind certain exemptive orders that have been granted to ETFs and their sponsors. The Commission also is proposing certain disclosure amendments to Form N–1A and Form N–8B–2 to provide investors who purchase and sell ETF shares on the secondary market with additional information regarding ETF trading costs, regardless of whether such ETFs are structured as registered open-end management investment companies (''open-end funds'') or unit investment trusts (''UITs''). Finally, the Commission is proposing related amendments to Form N–CEN. The proposed rule and form amendments are designed to create a consistent, transparent, and efficient regulatory framework for ETFs and to facilitate greater competition and innovation among ETFs.

DATES: Comments should be received on or before October 1, 2018.

ADDRESSES: Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/proposed.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number S7–15–18 on the subject line.

Paper Comments

- Send paper comments to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number S7–15–18. This file number should be included on the subject line if email is used. To help us process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/proposed.shtml*). Comments are also available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. 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.

Studies, memoranda, or other substantive items may be added by the Commission or staff to the comment file during this rulemaking. A notification of the inclusion in the comment file of any such materials will be made available on the Commission's website. To ensure direct electronic receipt of such notifications, sign up through the ''Stay Connected'' option at *www.sec.gov* to receive notifications by email.

FOR FURTHER INFORMATION CONTACT: Zeena Abdul-Rahman (Senior Counsel), Joel Cavanaugh (Senior Counsel), John Foley (Senior Counsel), Jacob D. Krawitz (Branch Chief), Melissa S. Gainor (Senior Special Counsel), and Brian McLaughlin Johnson (Assistant Director), Investment Company Regulation Office, at (202) 551–6792, Sumeera Younis (Branch Chief) and Christian Sandoe (Assistant Director), Disclosure Review and Accounting Office, at (202) 551–6921, Division of Investment Management, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

SUPPLEMENTARY INFORMATION: The Commission is proposing for public comment 17 CFR 270.6c–11 (new rule 6c–11) under the Investment Company Act [15 U.S.C. 80a–1 *et seq.*]; amendments to Form N–1A [referenced in 17 CFR 274.11A] under the Investment Company Act and the Securities Act of 1933 [15 U.S.C. 77a *et seq.*] (''Securities Act''); and amendments to Forms N–8B–2 [referenced in 17 CFR 274.12] and N–CEN [referenced in 17 CFR 274.101] under the Investment Company Act.[1]

[1] Unless otherwise noted, all references to statutory sections are to the Investment Company Act, and all references to rules under the Investment Company Act are to title 17, part 270 of the Code of Federal Regulations [17 CFR part 270].

Table of Contents

I. Introduction

The Commission is proposing rule 6c–11 under the Investment Company Act to permit ETFs that satisfy certain conditions to operate without the expense and delay of obtaining an exemptive order from the Commission under the Act. This rule would modernize the regulatory framework for ETFs to reflect our 26 years of experience with these investment products. It is designed to create a consistent, transparent, and efficient regulatory framework for ETFs and to facilitate greater competition and innovation among ETFs.

The Commission approved the first ETF in 1992. Since then, ETFs registered with us have grown to $3.4 trillion in total net assets.[2] They now account for approximately 15% of total net assets managed by investment companies,[3] and are projected to continue to grow.[4] ETFs currently rely on exemptive orders, which permit them to operate as investment companies under the Act, subject to representations and conditions that have evolved over time.[5] We have granted over 300 of these orders over the last quarter century, resulting in differences in representations and conditions that have led to some variations in the regulatory structure for existing ETFs.[6]

Proposed rule 6c–11 would simplify this regulatory framework by eliminating conditions included within our exemptive orders that we no longer believe are necessary for our exemptive relief and removing historical distinctions between actively managed and index-based ETFs. In connection with the proposed rule, we also propose to rescind certain exemptive orders that have been granted to ETFs and their sponsors. As a result, proposed rule 6c–11 would level the playing field for ETFs that are organized as open-end funds and pursue the same or similar investment strategies.[7] The proposed rule also would assist the Commission with regulating ETFs, as funds covered by the rule would no longer be subject to the varying provisions of exemptive orders granted over time, and instead would be subject to a consistent regulatory framework. Furthermore, creating an efficient regulatory framework for ETFs would allow Commission staff and industry resources to focus the exemptive order process on products that do not fall within the scope of our proposed rule.

In addition, we are proposing certain disclosure amendments to provide additional information to investors who purchase and sell ETF shares in the secondary markets, and to provide investors who purchase UITs with the same disclosures that we propose to require of ETFs organized as open-end funds. The proposed amendments would include new disclosures regarding certain unique costs associated specifically with ETFs, such as the bid-ask spread and premiums and discounts from the ETF's net asset value (''NAV'').

Our proposal takes into account the comments we received in response to our 2008 ETF proposal, which was designed to codify the exemptive relief that had been issued to ETFs at that time.[8] Developments in the ETF industry since the 2008 proposal and interim Commission actions also have informed the parameters of proposed rule 6c–11 and the related disclosure amendments that we are proposing.[9]

A. Overview of Exchange-Traded Funds

ETFs are a type of exchange-traded product (''ETP'').[10] ETFs possess characteristics of both mutual funds, which issue redeemable securities, and closed-end funds, which generally issue shares that trade at market-determined prices on a national securities exchange and are not redeemable.[11] Because ETFs

[2] This figure is based on data obtained from Bloomberg. As of December 2017, there were 1,900 ETFs registered with the Commission. *See id.*

[3] ICI, 2018 Investment Company Fact Book (58th ed., 2018) (''2018 ICI Fact Book''), *available at https://www.ici.org/pdf/2018_factbook.pdf,* at 96. When the Commission first proposed a rule for ETFs in 2008, aggregate ETF assets were less than 7% of total net assets held by mutual funds. *See* Exchange-Traded Funds, Investment Company Act Release No. 28193 (Mar. 11, 2008) [73 FR 14618 (Mar. 18, 2008)] (''2008 ETF Proposing Release'').

[4] *See* Greg Tusar, *The evolution of the ETF industry,* Pension & Investments (Jan. 31, 2017), *available at http://www.pionline.com/article/20170131/ONLINE/170139973/the-evolution-of-the-etf-industry* (describing projections that ETF assets could double to $6 trillion by 2020).

[5] As the orders are subject to the terms and conditions set forth in the applications requesting exemptive relief, references in this release to ''exemptive relief'' or ''exemptive orders'' include the terms and conditions described in the related application. *See, e.g., infra* footnote 6.

[6] Since 2000, our ETF exemptive orders have provided relief for future ETFs. *See, e.g.,* Barclays Global Fund Advisors, Investment Company Act Release Nos. 24394 (Apr. 17, 2000) [65 FR 21215 (Apr. 20, 2000)] (notice) and 24451 (May 12, 2000) (order) and related application (''Barclays Global 2000''). This relief has allowed ETF sponsors to form ETFs without filing new applications to the extent that the new ETFs meet the terms and conditions set forth in the exemptive order. Applications granted before 2000, unless subsequently amended, did not include this relief.

[7] As discussed below, the scope of proposed rule 6c–11 does not include ETFs that: (i) Are organized as UITs; (ii) seek to exceed the performance of a market index by a specified multiple or to provide returns that have an inverse relationship to the performance of a market index, over a fixed period of time (''leveraged ETFs''); or (iii) are structured as a share class of a fund that issues multiple classes of shares representing interests in the same portfolio (''share class ETFs''). These ETFs would continue to operate pursuant to the terms of their exemptive orders. *See infra* sections II.A.1 (UIT ETFs), II.A.3 (leveraged ETFs), and II.E (share class ETFs).

[8] *See* 2008 ETF Proposing Release, *supra* footnote 3. Comment letters on the 2008 ETF Proposing Release are available at *http://www.sec.gov/comments/s7-07-08/s70708.shtml.*

[9] *See, e.g.,* Request for Comment on Exchange-Traded Products, Exchange Act Release No. 75165 (June 12, 2015) [80 FR 34729 (June 17, 2015)] (''2015 ETP Request for Comment''), at section I.A; Report of the Staffs of the CFTC and SEC to the Joint Advisory Committee on Emerging Regulatory Issues, *Findings Regarding the Market Events of May 6, 2010* (Sept. 30, 2010) (''Final May 6 Report''), *available at http://www.sec.gov/news/studies/2010/marketevents-report.pdf.* Comment letters on the 2015 ETP Request for Comment are available at *https://www.sec.gov/comments/s7-11-15/s71115.shtml.*

[10] ETFs are investment companies registered under the Investment Company Act. *See* 15 U.S.C. 80a–3(a)(1). Other types of ETPs are pooled investment vehicles with shares that trade on a securities exchange, but they are not ''investment companies'' under the Act because they do not invest primarily in securities. Such ETPs may invest primarily in assets other than securities, such as futures, currencies, or physical commodities (*e.g.,* precious metals). Still other ETPs are not pooled investment vehicles. For example, exchange-traded notes are senior, unsecured, unsubordinated debt securities that are linked to the performance of a market index and trade on securities exchanges.

[11] The Act defines ''redeemable security'' as any security that allows the holder to receive his or her proportionate share of the issuer's current net assets upon presentation to the issuer. 15 U.S.C. 80a–2(a)(32). While closed-end fund shares are not redeemable, certain closed-end funds may elect to repurchase their shares at periodic intervals pursuant to 17 CFR 270.23c–3 (rule 23c–3) under the Act (''interval funds''). Based on staff analysis, there were 39 interval funds, representing approximately $21 billion in assets, in 2017. Other closed-end funds may repurchase their shares in tender offers pursuant to 17 CFR 240.13e–4 (rule

Continued

have characteristics that distinguish them from the types of investment companies contemplated by the Act, they require exemptions from certain provisions of the Investment Company Act in order to operate. The Commission (and Commission staff under delegated authority) now routinely grants exemptive orders permitting ETFs to operate as investment companies under the Investment Company Act, generally subject to the provisions of the Act applicable to open-end funds (or UITs).[12] These exemptive orders reflect our determination that, based on the factual representations offered by the applicants and the conditions to which the applicants have agreed, the requested relief is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Investment Company Act.[13] The Commission also has approved the standards of national securities exchanges, under which ETF shares are listed and traded.[14]

As discussed above, ETFs have become an increasingly popular investment vehicle over the last 26 years. They also have become a popular trading tool, making up a significant portion of secondary market equities trading. During the first quarter of 2018, for example, trading in U.S.-listed ETFs made up approximately 18.75% of U.S. equity trading by share volume and 28.2% of U.S. equity trading by dollar volume.[15]

Investors can buy and hold shares of ETFs (sometimes as a core component of a portfolio) or trade them frequently as part of an active trading or hedging strategy.[16] ETF investors can sell ETF shares short, write options on them, and set market, limit, and stop-loss orders on them. Moreover, because certain costs are either absent in the ETF structure or are otherwise partially externalized, many ETFs have lower operating expenses than mutual funds.[17] ETFs also may offer certain tax efficiencies compared to other pooled investment vehicles because redemptions from ETFs are often made in kind (that is, by delivering certain assets from the ETF's portfolio, rather than in cash), thereby avoiding the need for the ETF to sell assets and potentially realize capital gains that are distributed to its shareholders.

ETFs today provide investors with a diverse set of investment options. While the first ETFs held portfolios of securities that replicated the component securities of broad-based domestic stock market indexes, some ETFs now track more specialized indexes, including international equity indexes, fixed-income indexes, or indexes focused on particular industry sectors such as telecommunications or healthcare.[18] Some ETFs seek to track highly customized or bespoke indexes, while others seek to provide a level of leveraged or inverse exposure to an index over a fixed period of time.[19] Investors also have the ability to invest in ETFs that do not track a particular index and are actively managed.[20]

B. Operation of Exchange-Traded Funds

An ETF issues shares that can be bought or sold throughout the day in the secondary market at a market-determined price. Like other investment companies, an ETF pools the assets of multiple investors and invests those assets according to its investment objective and principal investment strategies. Each share of an ETF represents an undivided interest in the underlying assets of the ETF. Similar to mutual funds, ETFs continuously offer their shares for sale.

Unlike mutual funds, however, ETFs do not sell or redeem individual shares. Instead, ''authorized participants'' that have contractual arrangements with the ETF (or its distributor) purchase and redeem ETF shares directly from the ETF in blocks called ''creation units.'' [21] An authorized participant may act as a principal for its own account when purchasing or redeeming creation units from the ETF. Authorized participants also may act as agent for others, such as market makers, proprietary trading firms, hedge funds or other institutional investors, and receive fees for processing creation units on their behalf.[22] Market makers, proprietary trading firms, and hedge funds provide additional liquidity to the ETF market through their trading activity. Institutional investors may engage in primary market transactions with an ETF through an authorized participant as a way to efficiently hedge a portion of their portfolio or balance sheet or to

13e–4) under the Securities Exchange Act of 1934 (the ''Exchange Act'').

[12] Historically, ETFs have been organized as open-end funds or UITs. *See* 15 U.S.C. 80a–5(a)(1) (defining the term ''open-end company'') and 15 U.S.C. 80a–4(2) (defining the term ''unit investment trust''). Some fund groups have multiple orders covering different types of ETFs (*e.g.,* one order covering ETFs organized as UITs and another covering ETFs organized as open-end funds or one order covering index-based ETFs and another covering actively managed ETFs).

[13] *See* 15 U.S.C. 80a–6(c).

[14] Additionally, ETFs regularly request relief from 17 CFR 242.101 and 242.102 (rules 101 and 102 of Regulation M); section 11(d)(1) of the Exchange Act and 17 CFR 240.11d1–2 (''rule 11d1–2'' under the Exchange Act); certain other rules under the Exchange Act (*i.e.,* 17 CFR 240.10b–10, 240.10b–17, 240.14e–5, 240.15c1–5, and 240.15c1–6 (rules 10b–10, 10b–17, 14e–5, 15c1–5, and 15c1–6)); and 17 CFR 242.200(g) (rule 200(g) of Regulation SHO). *See* 2015 ETP Request for Comment, *supra* footnote 9, at section I.D.2 (discussing the exemptive and no-action relief granted to ETPs under the Exchange Act and the listing process for ETP securities for trading on a national securities exchange).

[15] These estimates are based on trade and quote data from the New York Stock Exchange and Trade Reporting Facility data from FINRA.

[16] *See, e.g.,* Chris Dieterich, *Are You An ETF 'Trader' Or An ETF 'Investor'?,* Barrons (Aug. 8, 2017), *available at https://www.barrons.com/articles/are-you-an-etf-trader-or-an-etf-investor-1470673638;* Greenwich Associates, *Institutions Find New, Increasingly Strategic Uses for ETFs* (May 2012) (''More than one-in-five asset managers that use [ETFs] report employing ETFs for active exposures in domestic equities and commodities, and about 17% note using them for active exposures in international equities.''); Joe Renninson, *Institutional Investors Boost Ownership of ETFs,* Financial Times (Apr. 13, 2017), *available at https://www.ft.com/content/c70113ac-ab83-33ac-a624-d2d874533fb0?mhq5j=e7.*

[17] For instance, ETFs typically do not bear distribution or shareholder servicing fees. In addition, ETFs that transact on an in-kind basis can execute changes in the ETF's portfolio without incurring brokerage costs, leading to transaction cost savings.

[18] The Commission historically has referred to ETFs that have stated investment objectives of maintaining returns that correspond to the returns of a securities index as ''index-based'' ETFs. *See, e.g.,* Parker Global Strategies, LLC, *et al.,* Investment Company Act Release Nos. 32528 (Mar. 10, 2017) [82 FR 14043 (Mar. 16, 2017)] (notice) and 32595 (Apr. 5, 2017) (order) and related application (''Parker Global Strategies'').

[19] Inverse ETFs are often marketed as a way for investors to profit from, or at least hedge their exposure to, downward moving markets. *See infra* section II.A.3.

[20] An actively managed ETF's investment adviser, like an adviser to any actively managed mutual fund, generally selects securities consistent with the ETF's investment objectives and policies without trying to track the performance of a corresponding index. Actively managed ETFs represent approximately 1.3% of total ETF assets as of September 2017. Based on data obtained from the Market Information Data Analytics System (''MIDAS''), Bloomberg, and Morningstar Direct.

[21] Our exemptive orders typically contain a representation by the applicant that an authorized participant will be either: (a) A broker or other participant in the continuous net settlement system of the National Securities Clearing Corporation, a clearing agency registered with the Commission and affiliated with the Depository Trust Company (''DTC''), or (b) a DTC participant, which has executed a participant agreement with the ETF's distributor and transfer agent with respect to the creation and redemption of creation units. *See, e.g.,* Emerging Global Advisors, LLC, *et al.,* Investment Company Act Release Nos. 30382 (Feb. 13, 2013) [78 FR 11909 (Feb. 20, 2013)] (notice) and 30423 (Mar. 12, 2013) (order) and related application. Proposed rule 6c–11(a) would define ''authorized participant'' as a member or participant of a clearing agency registered with the Commission, which has a written agreement with the ETF or one of its service providers that allows the authorized participant to place orders for the purchase and redemption of creation units.

[22] *See* David J. Abner, *The ETF Handbook: How to Value and Trade Exchange Traded Funds,* 2nd ed. (2016) (''ETF Handbook'').

gain exposure to a strategy or asset class.[23]

An authorized participant that purchases a creation unit of ETF shares directly from the ETF deposits with the ETF a ''basket'' of securities and other assets identified by the ETF that day, and then receives the creation unit of ETF shares in return for those assets.[24] The basket is generally representative of the ETF's portfolio [25] and, together with a cash balancing amount, equal in value to the aggregate NAV of the ETF shares in the creation unit.[26] After purchasing a creation unit, the authorized participant may hold the individual ETF shares, or sell some or all of them in secondary market transactions.[27] Investors then purchase individual ETF shares in the secondary market. The redemption process is the reverse of the purchase process: The authorized participant redeems a creation unit of ETF shares for a basket of securities and other assets.

The combination of the creation and redemption process with secondary market trading in ETF shares provides arbitrage opportunities that are designed to help keep the market price of ETF shares at or close to the NAV per share of the ETF.[28] For example, if ETF shares are trading on national securities exchanges at a ''discount'' (a price below the NAV per share of the ETF), an authorized participant can purchase ETF shares in secondary market transactions and, after accumulating enough shares to compose a creation unit, redeem them from the ETF in exchange for the more valuable securities in the ETF's redemption basket. The authorized participant's purchase of an ETF's shares on the secondary market, combined with the sale of the ETF's basket assets, may create upward pressure on the price of the ETF shares, downward pressure on the price of the basket assets, or both, bringing the market price of ETF shares and the value of the ETF's portfolio holdings closer together.[29] Alternatively, if ETF shares are trading at a ''premium'' (a price above the NAV per share of the ETF), the transactions in the arbitrage process are reversed and, when arbitrage is working effectively, keep the market price of the ETF's shares close to its NAV.

Market participants also can engage in arbitrage activity without using the creation or redemption processes. For example, if a market participant believes that an ETF is overvalued relative to its underlying or reference assets (*i.e.,* trading at a premium), the market participant may sell ETF shares short and buy the underlying or reference assets, wait for the trading prices to move toward parity, and then close out the positions in both the ETF shares and the underlying or reference assets to realize a profit from the relative movement of their trading prices. Similarly, a market participant could buy ETF shares and sell the underlying or reference assets short in an attempt to profit when an ETF's shares are trading at a discount to the ETF's underlying or reference assets. As with the creation and redemption process, the trading of an ETF's shares and the ETF's underlying or reference assets may bring the prices of the ETF's shares and its portfolio assets closer together through market pressure.[30]

The arbitrage mechanism is important because it provides a means to maintain a close tie between market price and NAV per share of the ETF, thereby helping to ensure ETF investors are treated equitably when buying and selling fund shares. In granting relief under section 6(c) of the Act for ETFs to operate, the Commission has relied on this close tie between what retail investors pay (or receive) in the secondary market and the ETF's approximate NAV to find that the required exemptions are 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. Investors also have come to expect that an ETF's market price will maintain a close tie to the ETF's NAV per share, which may lead some investors to view ETFs more favorably than similar closed-end funds.[31] On the other hand, this expectation may lead investors to view ETFs as a less attractive investment option or cause them to sell ETF shares if market price and NAV per share diverge, particularly during periods of market stress.[32]

II. Discussion

Given the growth in the ETF market, ETFs' popularity among retail and institutional investors, and our long experience regulating this investment and trading vehicle, we believe that it is appropriate to propose a rule that would allow most ETFs to operate without first obtaining an exemptive order from the Commission under the Act. We believe that such a rule would create a consistent, transparent and efficient regulatory framework for the regulation of most ETFs and level the playing field for these market participants. Proposed

[23] *Id.*

[24] An ETF may impose fees in connection with the purchase or redemption of creation units that are intended to defray operational processing and brokerage costs to prevent possible shareholder dilution (''transaction fees'').

[25] The basket might not reflect a *pro rata* slice of an ETF's portfolio holdings. Subject to the terms of the applicable exemptive relief, an ETF may substitute other securities or cash in the basket for some (or all) of the ETF's portfolio holdings. Restrictions related to flexibility in baskets have varied over time. *See infra* section II.C.5.

[26] An open-end fund is required by law to redeem its securities on demand from shareholders at a price approximating their proportionate share of the fund's NAV at the time of redemption. *See* 15 U.S.C. 80a–22(d). Title 17 CFR 270.22c–1 (''rule 22c–1'') generally requires that funds calculate their NAV per share at least once daily Monday through Friday. *See* rule 22c–1(b)(1). Today, most funds calculate NAV per share as of the time the major U.S. stock exchanges close (typically at 4:00 p.m. Eastern Time). Under rule 22c–1, an investor who submits an order before the 4:00 p.m. pricing time receives that day's price, and an investor who submits an order after the pricing time receives the next day's price. *See also* 17 CFR 270.2a–4 (''rule 2a–4'') (defining ''current net asset value'').

[27] ETFs register offerings of shares under the Securities Act, and list their shares for trading under the Exchange Act. Depending on the facts and circumstances, authorized participants that purchase a creation unit and sell the shares may be deemed to be participants in a distribution, which could render them statutory underwriters and subject them to the prospectus delivery and liability provisions of the Securities Act. *See* 15 U.S.C. 77b(a)(11) (defining the term ''underwriter'').

[28] To date, the arbitrage mechanism has been dependent on daily portfolio transparency.

[29] As part of this arbitrage process, authorized participants are likely to hedge their intraday risk. For example, when ETF shares are trading at a discount to an estimated intraday NAV per share of the ETF, an authorized participant may short the securities composing the ETF's redemption basket. After the authorized participant returns a creation unit of ETF shares to the ETF in exchange for the ETF's baskets, the authorized participant can then use the basket assets to cover its short positions.

[30] Some studies have found the majority of all ETF-related trading activity takes place on the secondary market. *See, e.g.,* Rochelle Antoniewicz & Jane Heinrichs, *Understanding Exchange-Traded Funds: How ETFs Work,* ICI Research Perspective 20, No. 5 (Sept. 2014) (''Antoniewicz''), *available at https://www.ici.org/pdf/per20-05.pdf,* at 2 (''On most trading days, the vast majority of ETFs do not have any primary market activity—that is, they do not create or redeem shares.'').

[31] Scott W. Barnhart & Stuart Rosenstein, *Exchange-Traded Fund Introductions and Closed-End Fund Discounts and Volume,* 45 The Financial Review 4 (Nov. 2010) (within a year of the introduction of a similar ETF, the average discount widens significantly and volume falls significantly in U.S. domestic equity, international equity, and U.S. bond closed-end funds, which may indicate that closed-end funds lose some desirability when a substitute ETF becomes available). As of December 31, 2017, total net assets of ETFs were $3.4 trillion compared to $275 billion for closed-end funds. *See* 2018 ICI Fact Book, *supra* footnote 3.

[32] *See* Staff of the Office of Analytics and Research, Division of Trading and Markets, *Research Note: Equity Market Volatility on August 24, 2015* (Dec. 2015) (''August 24 Staff Report''), *available at https://www.sec.gov/marketstructure/research/equity_market_volatility.pdf* (discussing spikes in ETF trading volume on August 24, 2015 when U.S. equity markets experienced unusual price volatility). *See also infra* section II.B.2 (discussing intraday deviations between market price and NAV as well as contemporaneous deviations between market price and the intraday value of the ETF's portfolio).

rule 6c–11 includes several conditions designed to address the concerns underlying the relevant statutory provisions and to support a Commission finding that the exemptions necessary to allow ETFs to operate are in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. The proposed conditions are based upon the existing exemptive relief for ETFs, which we believe have served to support an efficient arbitrage mechanism, but reflect several modifications based on our experience regulating this product.

A. Scope of Proposed Rule 6c–11

Proposed rule 6c–11 would define an ETF as a registered open-end management investment company that: (i) Issues (and redeems) creation units to (and from) authorized participants in exchange for a basket and a cash balancing amount (if any); and (ii) issues shares that are listed on a national securities exchange and traded at market-determined prices.[33]

1. Organization as Open-End Funds

Proposed rule 6c–11 would be available only to ETFs that are organized as open-end funds. The vast majority of ETFs currently in operation are organized as open-end funds, although the earliest ETFs were organized as UITs (''UIT ETFs'').[34] These early UIT ETFs represent a significant amount of assets within the ETF industry.[35] For example, two of the largest ETFs by total net assets and estimated dollar trading volume (SPDR S&P 500 ETF Trust (SPY) and PowerShares QQQ Trust, Series 1 (QQQ)) are organized as UITs.

A UIT is an investment company organized under a trust indenture or similar instrument that issues redeemable securities, each of which represents an undivided interest in a unit of specified securities.[36] By statute, a UIT is unmanaged and its portfolio is fixed. Substitution of securities may take place only under certain pre-defined circumstances.[37] A UIT does not have a board of directors, corporate officers, or an investment adviser to render advice during the life of the trust. By contrast, ETFs organized as open-end funds are managed by investment advisers and, in addition to replicating an index, can be actively managed or use a ''sampling'' strategy to track an index.[38] Unlike an ETF structured as a UIT, an open-end fund ETF may participate in securities lending programs and has greater flexibility to reinvest dividends from portfolio securities.[39] ETFs structured as open-end funds also may invest in derivatives, which typically require a degree of management that is not provided for in the UIT structure.[40] As a result, we understand that most ETF sponsors now prefer the open-end fund structure over the UIT structure given the increased investment flexibility the open-end structure affords. Indeed, we have received very few exemptive applications for new UIT ETFs since 2002 and no new UIT ETFs have come to market in that time.[41]

The rule we proposed in 2008 would not have included UIT ETFs within its scope.[42] Comments on the 2008 ETF Proposing Release were mixed with regard to providing relief to UITs, with two commenters supporting the exclusion of UITs.[43] On the other hand, two commenters argued that the Commission should expand the rule to include UITs, contending that sponsors in the future may choose the UIT structure for some reason unforeseen today.[44] Some commenters also stated that existing UIT ETFs should be able to rely on the rule, which may provide broader relief than provided by their exemptive orders.[45]

While we acknowledge that excluding UIT ETFs would result in a segment of ETF assets that are outside the regulatory framework of proposed rule 6c–11, we do not believe there is a need to include ETF UITs within the scope of the proposed rule given the limited sponsor interest in developing ETFs organized as UITs. In addition, even if we were to include UIT ETFs within the scope of the rule, we believe that the unmanaged nature of the UIT structure would require conditions that differ from the conditions applicable to ETFs

[33] *See* proposed rule 6c–11(a) (defining ''exchange-traded fund''). Under the proposed rule, the term ''basket'' would be defined to mean the securities, assets, or other positions in exchange for which an ETF issues (or in return for which it redeems) creation units. The term ''exchange-traded fund'' thus would include ETFs that transact on an in-kind basis, on a cash basis, or both.

[34] *See, e.g.,* SPDR Trust, Series 1, Investment Company Act Release Nos. 18959 (Sept. 17, 1992) [57 FR 43996 (Sept. 23, 1992)] (notice) and 19055 (Oct. 26, 1992) (order) and related application (''SPDR'').

[35] As of Dec. 31, 2017, for example, the eight existing UIT ETFs had total assets of approximately $379 billion, representing approximately 11.3% of total assets invested in ETFs (based on data obtained from MIDAS, Bloomberg, and Morningstar Direct).

[36] *See* section 4(2) of the Act [15 U.S.C. 80a–4]. A UIT has a fixed life—a termination date for the trust is established when the trust is created.

[37] The exemptive relief granted to UIT ETFs does not provide relief from the portion of section 4(2) that requires that UIT securities represent an undivided interest in a unit of specified securities. Because a UIT must invest in ''specified securities,'' the investment strategies that a UIT ETF can pursue are limited. All UIT ETFs today seek to track the performance of an index by investing in the component securities of the index in the same approximate proportions as in the index (*i.e.,* ''replicating'' the index). The trustee of an UIT ETF may make adjustments to the ETF's portfolio only to reflect changes in the composition of the underlying index. *See* Actively Managed Exchange-Traded Funds, Investment Company Act Release No. 25258 (Nov. 8. 2001) [66 FR 57614 (Nov. 15, 2001)] (''2001 Concept Release''), at n.11.

[38] An ETF that uses a sampling strategy includes assets in its portfolio that are designed, in the aggregate, to reflect the underlying index's capitalization, industry, and fundamental investment characteristics, and to perform like the index. The ETF implements the strategy by acquiring a subset of the underlying index's component securities and may invest a portion of the ETF's portfolio in securities and other financial instruments (including derivatives) that are not included in the corresponding index if the adviser believes the investment will help the ETF track the underlying index. *See* 2008 ETF Proposing Release, *supra* footnote 3.

[39] UIT dividends are held in a non-interest bearing account and paid out quarterly. The inability to reinvest dividends can have a cash drag on the tracking performance of a UIT ETF. *See* A. Seddik Meziani, *Exchange-Traded Funds: Investment Practices and Tactical Approaches* (2016), at 22.

[40] *See* Use of Derivatives by Registered Investment Companies and Business Development Companies, Investment Company Act Release No. 31933 (Dec. 11, 2015) [80 FR 80883 (Dec. 28, 2015)] (''Derivatives Proposing Release''), at n.139.

[41] The Commission has received applications for ETFs structured as a UIT, but with features that are different from typical UIT-structured ETFs. *See* Application of Elkhorn Securities, LLC and Elkhorn Unit Trust (Mar. 6, 2017) (''Elkhorn Application''); Application of Precidian ADRs LLC (Aug. 1, 2014) (''Precidian ADR Application''). The Commission has not taken any action on the Elkhorn Application, and the Precidian ADR Application was withdrawn by the applicant. Two orders modifying relief for existing ETFs organized as UITs were issued in 2007. *See* NASDAQ–100 Trust, Series 1, *et al.,* Investment Company Act Release Nos. 27740 (Feb. 27, 2007) [72 FR 9594 (Mar. 2, 2007)] (notice) and 27753 (Mar. 20, 2007) (order) and related application; BLDRS Index Funds Trust, *et al.,* Investment Company Act Release Nos. 27745 (Feb. 28, 2007) [72 FR 9787 (Mar. 5, 2007)] (notice) and 27768 (Mar. 21, 2007) (order) and related application.

[42] *See* 2008 ETF Proposing Release, *supra* footnote 3, at text accompanying nn.63–67 (noting that the Commission had not received an exemptive application for a new ETF to be organized as a UIT since 2002 and, as a result, there did not appear to be a need to include UIT relief in the proposed rule).

[43] *See* Comment Letter of Xshares Advisors LLC (May 20, 2008) (''Xshares 2008 Comment Letter''); Comment Letter of the Investment Company Institute (May 19, 2008) (''ICI 2008 Comment Letter'').

[44] *See* Comment Letter of Katten Muchin Rosenman LLP (May 30, 2008) (''Katten 2008 Comment Letter''); Comment Letter of the Federal Regulation of Securities Committee, Section of Business Law, American Bar Association (May 29, 2008) (''ABA 2008 Comment Letter'').

[45] *See* Comment Letter of State Street Global Advisors (May 19, 2008) (''SSgA 2008 Comment Letter''); Comment Letter of NYSE Arca (May 29, 2008) (''NYSE Arca 2008 Comment Letter''); Katten 2008 Comment Letter.

organized as open-end funds, requiring a regulatory framework that would be different than our proposed structure for open-end ETFs. The exemptive relief that has been granted to UIT ETFs, for example, provides that the trustee will make adjustments to the ETF's portfolio only pursuant to the specifications set forth in the trust formation documents in order to track changes in the ETF's underlying indexes.[46] The trustee does not have discretion when making these portfolio adjustments.[47] In most cases, therefore, a UIT ETF uses baskets that correspond *pro rata* to the ETF's portfolio holdings.[48] The rule we are proposing would allow ETFs the flexibility to use baskets that differ from a *pro rata* representation of the ETF's portfolio if certain conditions are met.[49] Because the conditions we are proposing related to basket flexibility require ongoing management and board oversight, we do not believe that extending such basket flexibility to UIT ETFs would be appropriate given the unmanaged nature of a UIT.

Instead, we believe that UIT ETFs should continue to operate pursuant to their exemptive orders, which include terms and conditions that are appropriately tailored to address the unique features of a UIT.[50] The exemptive relief granted to UIT ETFs includes relief from sections of the Act that govern key aspects of a UIT's operations.[51] For example, because UITs are prohibited from paying fees beyond those necessary to cover the costs of administrative and bookkeeping services, UIT ETFs require exemptive relief from section 26(a)(2)(C) of the Act to allow the ETF to pay certain enumerated expenses.[52] However, because UITs are unmanaged and are not overseen by boards, the exemptive order for each UIT ETF contains its own list of permissible capped expenses that vary among the different UIT ETFs.[53]

To the extent that ETF sponsors develop unforeseen, novel UIT ETFs, we believe that the Commission should review such products as part of its exemptive process to determine whether the relief is necessary or appropriate in the public interest and consistent with the protection of investors. We therefore are not proposing to include ETFs structured as UITs within the scope of proposed rule 6c–11.[54]

We request comment on whether proposed rule 6c–11 should be available only to ETFs structured as open-end funds.

- Should the rule provide exemptive relief for both ETFs organized as open-end funds and ETFs organized as UITs? Are we correct that ETF sponsors will likely prefer the open-end structure to the UIT structure when forming ETFs in the future? If not, why?
- If UIT ETFs were included in the scope of the proposed rule, should they be subject to the same proposed conditions or should we tailor particular conditions in light of the unmanaged nature of a UIT? For example, how should the proposed rule address basket composition for UIT ETFs? Should UIT ETFs only be permitted to replicate their index, or should we allow them to engage in representative sampling on a *pro rata* basis? Should a UIT ETF only be permitted to substitute cash (instead of other securities) for particular basket assets? Should we allow a UIT ETF to substitute basket assets only in certain enumerated circumstances (*e.g.,* only when the basket asset is not eligible for trading by an authorized participant or is not available in sufficient quantity for delivery to or from the authorized participant)?
- If UIT ETFs were included within the scope of the rule, should we expressly limit the types of indexes that such ETFs may track given the unmanaged nature of the UIT structure and the potential for specialized or bespoke indexes to be inconsistent with a fixed portfolio? For example, should we provide that ETFs structured as UITs may only track broad-based securities indexes? Should we limit the derivatives holdings of UIT ETFs or restrict them from tracking indexes that include certain types of derivatives? If so, what types of derivatives should be permitted?
- If we were to include UIT ETFs within the scope of rule 6c–11, should we provide an exemption from section 26(a)(2)(C), consistent with our exemptive orders, to permit the payment of certain expenses associated with the creation and maintenance of the ETF? If so, should we limit the amount of expenses that may be reimbursed? What should the limit be, and why? Should we limit the reimbursement to no more than 20 basis points of the ETF's NAV per share on an annualized basis, consistent with some of the exemptive orders granted to UIT ETFs? Should this limit be higher (*e.g.,* 30 basis points) or lower (*e.g.,* 10 basis points)? Should the rule enumerate the expenses that may be reimbursed? For example, should the rule permit the reimbursement of any or all of the following: (i) Annual index licensing fees; (ii) annual federal and state fees for the registration of newly issued creation units; and (iii) expenses of the sponsor relating to the development, printing, and distribution of marketing materials? Are there other expenses that should be permissible reimbursements under such an exemption?
- Our exemptive orders for UIT ETFs also include relief from section 14(a) of the Act, which provides that no registered investment company may make an initial public offering of its securities unless it has a net worth of at least $100,000 or is assured, via private subscriptions, of issuing at least $100,000 in securities in the offering.[55] If UIT ETFs were included within the scope of the rule, would they need relief from section 14(a) of the Act consistent with our prior exemptive relief? If so, what conditions should we consider as part of the rule? Alternatively, should we consider amending rule 14a–3 under the Act, which provides an exemption from section 14(a) for UITs that invest in ''eligible trust securities?'' [56] If so, how should we define ''eligible trust securities''? For example, should equity securities be added to the definition of ''eligible trust securities''? Should we

[46] *See, e.g.,* SPDR, *supra* footnote 34.

[47] *See id.*

[48] *See id.* (permitting baskets accepted by UIT ETF for purchases of creation units to include the cash equivalent of a component security of the underlying index only where: (i) The trustee determines that the index security is likely to be unavailable or available in insufficient quantity; or (ii) a particular investor is restricted from investing or transacting in such index security).

[49] *See infra* section II.C.5.

[50] Unlike the exemptive relief we have granted to certain ETFs organized as open-end funds (*see supra* footnote 6), the relief we have granted to ETFs organized as UITs does not provide relief for future ETFs formed pursuant to the same order.

[51] *See, e.g.,* SPDR, *supra* footnote 34.

[52] Section 26(a)(2)(C) of the Act requires that the trust indenture for a UIT prohibit payments to the depositor or to any affiliated person thereof, except payments for performing bookkeeping and other administrative services of a character normally performed by the trustee or custodian itself. 15 U.S.C. 80a–26(a)(2)(C).

[53] *See, e.g.,* NASDAQ–100 Trust, Series 1, Investment Company Act Release Nos. 23668 (Jan. 27, 1999) [64 FR 5082 (Feb. 2, 1999)] (notice) and 23702 (Feb. 22, 1999) (order) and related application (exemption from section 26(a)(2)(C) to permit UIT to reimburse the sponsor up to a maximum of 20 basis points) (''NASDAQ 100''); Midcap SPDR Trust, Series 1, Investment Company Act Release Nos. 20797 (Dec. 23, 1994) [60 FR 163 (Jan. 3, 1995)] (notice) and 20844 (Jan. 18, 1995) (order) and related application (30 basis points).

[54] While we do not propose to include ETFs organized as UITs within the scope of proposed rule 6c–11, we are proposing amendments to Form N–8B–2 to require them to provide certain additional disclosures regarding trading costs. *See infra* section II.I.

[55] *See* NASDAQ 100, *supra* footnote 53.

[56] Eligible trust securities under rule 14a–3 include corporate debt securities (including nonconvertible preferred stock), government and municipal securities, and units of a previously issued series of a UIT. The term does not include equity securities. *See* rule 14a–3(b).

include other types of securities within that definition? For example, should we include FLEX options within the definition? [57]

- Are there any other exemptions we should consider for UIT ETFs?
- If we were to include UIT ETFs in rule 6c–11, are there any specific disclosures that should be required, other than the ones proposed herein?
- If we do not include UIT ETFs within the scope of the rule, should we nonetheless require them to comply with any of the rule's requirements for ETFs organized as open-end funds?

2. Index-Based ETFs and Actively Managed ETFs

Proposed rule 6c–11 would provide exemptions for both index-based ETFs and actively managed ETFs, but would not by its terms establish different requirements based on whether an ETF's investment objective is to seek returns that correspond to the returns of an index. We believe that index-based and actively managed ETFs that comply with the proposed rule's conditions function similarly with respect to operational matters, despite different investment objectives or strategies, and do not present significantly different concerns under the provisions of the Act from which the proposed rule grants relief. For example, both index-based and actively managed ETFs register under the Act, issue and redeem shares in creation unit sizes in exchange for baskets of assets, list on national securities exchanges, and allow investors to trade ETF shares throughout the day at market-determined prices in the secondary market.

The distinction between index-based ETFs and actively managed ETFs in our current exemptive orders is largely a product of ETFs' historical evolution. The Commission did not approve the first actively managed ETF until nearly 15 years after index-based ETFs were introduced.[58] As discussed in a 2001 concept release on actively managed ETFs, the Commission was initially concerned that actively managed ETFs would not be able (or willing) to provide portfolio transparency, potentially hindering the arbitrage mechanism deemed critical to the operation of an ETF.[59] Actively managed ETFs were novel at the time of the 2008 ETF Proposing Release, and the Commission solicited comment on whether a proposed ETF rule should specifically include actively managed ETFs.[60] Six commenters supported this approach,[61] while a few commenters questioned whether it was premature to allow actively managed ETFs to operate using the rule.[62]

The actively managed ETF market has grown considerably since 2008. There are now over 200 actively managed ETFs with approximately $45.8 billion in assets.[63] The Commission has observed how actively managed ETFs operate during this time, and has not identified any operational issues that suggest additional conditions for actively managed ETFs are warranted. As noted below, we believe that the arbitrage mechanism for existing actively managed ETFs has worked effectively with small deviations between market price and NAV per share.[64]

We believe that permitting index-based and actively managed open-end ETFs to operate under the proposed rule subject to the same conditions would provide a level playing field among those market participants. Furthermore, we believe that it would be unreasonable to create a meaningful distinction within the rule between index-based and actively managed ETFs given the evolution of indexes over the last decade. The proliferation of highly customized, often methodologically complicated, indexes has blurred the distinction between such products.[65] At the same time, ETF industry practices in areas such as portfolio transparency have converged between these types of funds.[66] We therefore believe that eliminating the regulatory distinction between index-based ETFs and actively managed ETFs would help to provide a more consistent and transparent regulatory framework for ETFs organized as open-end funds. This approach also would be consistent with our regulation of other types of open-end funds, which does not distinguish between actively managed and index-based strategies.

The rule we proposed in 2008 similarly would not have distinguished between index-based ETFs and actively managed ETFs, except in one respect—it would have permitted an index-based ETF to disclose daily the composition of its index in lieu of disclosing its portfolio holdings.[67] However, we believe that distinguishing between index-based ETFs and actively managed ETFs in this manner is no longer necessary given that all ETFs that could rely on the proposed rule currently provide full portfolio transparency.[68]

We request comment on whether proposed rule 6c–11 should provide

[57] FLexible EXchange options (''FLEX options'') are a type of customized equity or index option contracts. Some traditional UITs have exemptive relief from section 14(a) to invest in FLEX options with expiration dates that coincide with UIT's maturity date. *See e.g.,* Olden Lane Securities LLC, *et al.,* Investment Company Act Release Nos. 32589 (April 3, 2017) [82 FR 17048 (April 7, 2017)] (notice) and 32619 (May 1, 2017) (order) and related application.

[58] *See, e.g.,* WisdomTree Trust, *et al.,* Investment Company Act Release Nos. 28147 (Feb. 6, 2008) [73 FR 7776 (Feb. 11, 2008)] (notice) and 28174 (Feb. 27, 2008) (order) and related application (''2008 WisdomTree Trust''); Barclays Global Fund Advisors, *et al.,* Investment Company Act Release Nos. 28146 (Feb. 6, 2008) [73 FR 7771 (Feb. 11, 2008)] (notice) and 28173 (Feb. 27, 2008) (order) and related application (''Barclays Global 2008''). Approximately 100 exemptive orders have been issued since 2008 for actively managed, transparent ETFs.

[59] *See* 2001 Concept Release, *supra* footnote 37, at n.31 and accompanying and following text. Comment letters to the 2001 Concept Release are available at *http://www.sec.gov/rules/concept/s72001.shtml.*

[60] *See* 2008 ETF Proposing Release, *supra* footnote 3, at section III.A.2.

[61] *See e.g.,* Comment Letter of the Vanguard Group, Inc. (June 19, 2008) (''Vanguard 2008 Comment Letter''); Xshares 2008 Comment Letter; Comment Letter of Barclays Global Fund Advisors (May 16, 2008) (''BGFA 2008 Comment Letter''); ICI 2008 Comment Letter; SSgA 2008 Comment Letter; Comment Letter of Mutual Fund Directors Forum (May 21, 2008).

[62] *See* Comment Letter of Brown & Associates LLC (May 19, 2008); Katten 2008 Comment Letter.

[63] These estimates are based on data obtained from MIDAS, Bloomberg and Morningstar Direct as of December 31, 2017.

[64] *See infra* section II.B.2.

[65] *See, e.g.,* John Waggoner, *Smart-beta ETFs Take in Billions in New Assets,* Investment News (Oct. 11, 2017), *available at http://www.investmentnews.com/article/20171011/FREE/171019982/smart-beta-etfs-take-in-billions-in-new-assets*); Brendan Conway, *New Trend: The ''Bespoke'' ETF,* Barron's (Jan. 17, 2014), *available at http://www.barrons.com/articles/new-trend-the-aposbespokeapos-etf-1389970766.*

[66] All ETFs that could rely on the proposed rule currently provide full portfolio transparency as a matter of market practice, although only actively managed ETFs and some index-based ETFs with affiliated index providers are required to do so pursuant to their exemptive orders. *See infra* section II.C.4. *See also, e.g.,* Guggenheim Funds Investment Advisors, LLC, *et al.,* Investment Company Act Release Nos. 30560 (June 14, 2013) [78 FR 37614 (June 21, 2013)] (notice) and 30598 (July 10, 2013) (order) and related application. Earlier relief granted to ETFs with affiliated index providers did not require full portfolio transparency, but included conditions that were intended to address potential conflicts of interest. *See, e.g.,* HealthShares Inc., *et al.,* Investment Company Act Release Nos. 27916 (July 27, 2007) [72 FR 42447 (Aug. 2, 2007)] (notice) and 27930 (Aug. 20, 2007) (order) and related application; WisdomTree Investments, Inc., *et al.,* Investment Company Act Release Nos. 27324 (May 18, 2006) [71 FR 29995 (May 24, 2006)] (notice) and 27391 (June 12, 2006) (order) and related application (''2006 WisdomTree Investments'').

[67] For these purposes, an index-based ETF was defined as an ETF that has a stated investment objective of obtaining returns that correspond to the returns of a securities index (whose provider discloses on its internet website the identities and weightings of the component securities and other assets of that index). *See* 2008 ETF Proposing Release, *supra* footnote 3. *See also infra* section II.C.4 (discussing proposed condition regarding portfolio transparency).

[68] *See* 2015 ETP Request for Comment, *supra* footnote 9.

exemptions to index-based ETFs and actively managed ETFs subject to the same conditions.

- Should the rule maintain the historical distinction between index-based ETFs and actively managed ETFs? Do investors find this distinction meaningful?
- If the rule maintains the distinction, what conditions of the rule should differ between index-based and actively managed ETFs? For example, some applications for index-based ETFs include a representation that the ETF will invest at least 80% of its assets, exclusive of collateral held from securities lending, in the component securities of its underlying index.[69] Should the rule include a similar condition?
- Should the proposed rule include requirements relating to index-based ETFs with an affiliated index provider? If so, what requirements and why? For example, should ETFs with affiliated index providers be required to adopt additional policies and procedures designed to further limit information sharing between portfolio management staff and index management staff? How should we define ''index provider'' for these purposes?
- Are there operational differences between index-based and actively managed ETFs that should be addressed in the proposed rule?

3. Leveraged ETFs

Although the proposed rule would not distinguish between actively managed ETFs and index-based ETFs in general, it would take a different approach with respect to leveraged ETFs, which are a type of index-based ETF that presents unique considerations.[70] ''Leveraged ETFs'' refers to ETFs that seek, directly or indirectly, to provide returns that exceed the performance of a market index by a specified multiple or to provide returns that have an inverse relationship to the performance of a market index, over a fixed period of time.[71] A leveraged ETF seeks to amplify the returns of its underlying index or to profit from a decline in the value of its underlying index. It also typically seeks to deliver the targeted return over a short period of time, such as a day. This means that investors holding shares over periods longer than the targeted period may experience performance that is different, and at times substantially different, from the targeted returns. Leveraged ETFs seek to achieve their targeted returns by using financial derivatives. These funds are sometimes referred to as trading tools because they can be used by investors to hedge against or profit from short-term market movements without using margin.[72]

The strategy that leveraged ETFs pursue requires them to rebalance their portfolios on a daily basis in order to maintain a constant leverage ratio. This daily reset, and the effects of compounding,[73] can result in performance that differs significantly from some investors' expectations of how index investing generally works.[74] This effect can be more pronounced in volatile markets.[75] As a result, buy-and-hold investors in a leveraged ETF with an intermediate or long-term time horizon—who may not evaluate their portfolios frequently—may experience large and unexpected losses.[76]

Leveraged ETFs, and their use of derivatives, also may raise issues under section 18 that we are evaluating as part of our broader consideration of the use of derivatives by registered funds and business development companies.[77] In

[69] There are some variations in this representation for index-based funds that invest in fixed-income securities and foreign securities. *See, e.g.,* Destra Exchange-Traded Fund Trust, *et al.,* Investment Company Act Release Nos. 33048 (Mar. 14, 2018) [83 FR 12208 (Mar. 20, 2018)] (notice) and 33071 (Apr. 10, 2018) (order) and related application (''Each Fund . . . will invest at least 80% of its assets, exclusive of collateral held from securities lending, in Component Securities of its respective Underlying Index, or in the case of Fixed Income Funds, in the Component Securities of its respective Underlying Index and [to-be-announced transactions] representing Component Securities, and in the case of Foreign Funds, in Component Securities and depositary receipts representing foreign securities such as [American Depositary Receipts and Global Depositary Receipts] representing such Component Securities (or, in the case of Foreign Funds tracking Underlying Indexes for which Depositary Receipts are themselves Component Securities, underlying stocks in respect of such Depositary Receipts.'') (internal footnotes omitted).

[70] We use the term ''leveraged ETFs'' in this release to refer to ETFs that pursue leveraged strategies (*i.e.,* those that seek to provide returns that exceed the performance of a market index by a specified multiple over a period of time) and inverse strategies (*i.e.,* those that seek to provide returns that have an inverse relationship to, or provide returns that are an inverse multiple of, the performance of a market index over a fixed period of time). At the end of December 2017, 187 ETFs employed leveraged or inverse investment strategies. All of these ETFs are structured as open-end funds. In total, these ETFs had total net assets of $35.26 billion or approximately 1% of all ETF assets. *See infra* footnote 427 and following text.

[71] *See* proposed rule 6c–11(c)(4); *see also* Item C.3.c. of Form N–CEN (requiring funds to identify if they seek to achieve performance results that are a multiple of an index or other benchmark, the inverse of an index or other benchmark, or a multiple of the inverse of an index or other benchmark).

[72] *See* ETF Handbook, *supra* footnote 22, at 266.

[73] For example, as a result of compounding, leveraged ETFs can outperform a simple multiple of its index's returns over several days of consistently positive returns, or underperform a simple multiple of its index's returns over several days of volatile returns.

[74] *See* Office of Investor Education and Advocacy, SEC, *Leveraged and Inverse ETFs: Specialized Products with Extra Risks for Buy-and-Hold Investors* Investor Alert and Bulletins (Aug. 1, 2009), *available at http://www.sec.gov/investor/pubs/leveragedetfs-alert.htm*; FINRA, *Non-Traditional ETFs: FINRA Reminds Firms of Sales Practice Obligations Relating to Leveraged and Inverse Exchange-Traded Funds,* Regulatory Notice 09–31 (June 2009), *available at http://www.finra.org/sites/default/files/NoticeDocument/p118952.pdf* (''FINRA Regulatory Notice 09–31'') (providing an example of a four-month period where a specified index gained 2%, while an ETF seeking to deliver twice the daily return of that index fell 6%, and the related ETF seeking to deliver twice the inverse of the index's daily return fell 26%).

[75] *See* FINRA Regulatory Notice 09–31, *supra* footnote 74 (''Using a two-day example, if the index goes from 100 to close at 101 on the first day and back down to close at 100 on the next day, the two-day return of an inverse ETF will be different than if the index had moved up to close at 110 the first day but then back down to close at 100 on the next day. In the first case with low volatility, the inverse ETF loses 0.02 percent; but in the more volatile scenario the inverse ETF loses 1.82 percent. The effects of mathematical compounding can grow significantly over time, leading to scenarios such as those noted above.'').

[76] *See id.* (reminding member firms of their sales practice obligations relating to leveraged ETFs and noting that leveraged ETFs are typically not suitable for retail investors who plan to hold these products for more than one trading session). *See also, e.g., SEC* v. *Hallas,* No. 1:17-cv-2999 (S.D.N.Y. Sept. 27, 2017); FINRA News Release, *FINRA Sanctions Oppenheimer & Co. $2.9 Million for Unsuitable Sales of Non-Traditional ETFs and Related Supervisory Failures* (June 8, 2016), *available at http://www.finra.org/newsroom/2016/finra-sanctions-oppenheimer-co-29-million-unsuitable-sales-non-traditional-etfs.* The Commission also settled an enforcement action against an investment adviser under section 206(4) of the Investment Advisers Act of 1940 (the ''Advisers Act'') and rule 206(4)–7, finding the adviser violated these provisions by failing to adequately implement written compliance policies that were designed to ensure that recommendations of single inverse ETFs to non-discretionary advisory clients were suitable for each individual client. *See In Re Morgan Stanley Smith Barney, LLC,* Investment Advisers Act Release No. 4649 (Feb. 14, 2017) (settled action), *available at https://www.sec.gov/litigation/admin/2017/ia-4649.pdf.*

[77] The staff has not supported new exemptive relief for leveraged ETFs since 2009. The orders issued to current leveraged ETF sponsors prior to the staff moratorium, as amended over time, relate to leveraged ETFs that seek investment results of up to 300% of the return (or inverse of the return) of the underlying index. Rydex ETF Trust, *et al.,* Investment Company Act Release Nos. 27703 (Feb. 20, 2007) [72 FR 8810 (Feb. 27, 2007)] (notice) and 27754 (Mar. 20, 2007) (order) and related application; Rafferty Asset Management, LLC, *et al.,* Investment Company Act Release Nos. 28379 (Sept. 12, 2008) [73 FR 54179 (Sept. 18, 2008)] (notice) and 28434 (Oct. 6, 2008) (order) and related application. *See also* ProShares Trust, *et al.,* Investment Company Act Release Nos. 28696 (Apr. 14, 2009) [74 FR 18265 Apr. 21, 2009)] (notice) and 28724 (May 12, 2009) (order) and related application (amending the applicant's prior order) (''ProShares''); Rafferty Asset Management, LLC, *et al.,* Investment Company Act Release Nos. 28889 (Aug. 27, 2009) [74 FR 45495 (Sept. 2, 2009)] (notice) and 28905 (Sept. 22, 2009) (order) and related application (amending the applicant's prior order) (''Rafferty'').

2015, for example, we proposed new 17 CFR 270.18f–4 (''rule 18f–4'' under the Act). Proposed rule 18f–4 was designed to address the investor protection purposes and concerns underlying section 18 of the Act and to provide an updated and more comprehensive approach to the regulation of funds' use of derivatives transactions.[78]

In light of our ongoing consideration, including the potential staff recommendation of a re-proposal on funds' use of derivatives, we do not believe it is appropriate to permit additional leveraged ETF sponsors to form leveraged ETFs and operate under our proposed rule at this time.[79] Accordingly, we propose to include a condition that would prevent leveraged ETFs from relying on proposed rule 6c–11.[80] ETFs that seek to provide returns that exceed the performance (or inverse performance) of a market index by a specified multiple over a fixed period could not operate under our proposed rule.

The daily or other periodic reset, and more particularly the effects of compounding, are what distinguish a leveraged ETF strategy from other strategies pursued by ETFs. The proposed condition relating to leveraged ETFs thus includes a temporal element (*i.e.,* ''over a fixed period of time'') in order to specifically capture ETFs that seek to deliver the leveraged or inverse return of a market index over a fixed period of time, daily or otherwise.[81] In addition, the proposed rule's use of the term ''multiple'' includes leverage that is not evenly divisible by 100, such as a fund that seeks to provide a return equal to 150% of the performance of an index.[82] Finally, we believe it is important to specify that an ETF may not *indirectly* seek to provide returns that exceed the performance of a market index by a specified multiple or to provide returns that have an inverse relationship to the performance of a market index over a fixed period of time in order to prevent a fund from circumventing this condition, such as by embedding inverse leverage in the underlying index.

We request comment on excluding leveraged ETFs from the scope of funds that may rely on the proposed rule.

- Do commenters agree that it is appropriate for proposed rule 6c–11 to include a condition that an ETF may not seek, directly or indirectly, to provide returns that exceed the performance of a market index by a specified multiple, or to provide returns that have an inverse relationship to the performance of a market index, over a fixed period of time?
- Alternatively, do commenters believe that the structure and operation of leveraged ETFs do not raise issues that warrant our excluding them from a rule of general applicability related to the structure and operations of ETFs? If so, are there any conditions specific to leveraged ETFs that should be part of the rule? For example, should we permit leveraged ETFs to operate in reliance on the rule but prohibit a leveraged ETF that exceeds a specific multiple of the performance, or inverse performance, of a market index? If so, what multiple should we use? For example, ETFs currently may not seek investment results over 300% of the return (or inverse of the return) of the underlying index. Should we maintain the status quo with respect to the maximum amount of leveraged market exposure that leveraged ETFs may obtain (*i.e.,* 300%)? Should we limit ETFs to a higher or lower multiplier? If so, what multiplier and why?
- Does the proposed rule's use of ''a fixed period of time'' effectively describe the daily reset mechanism in leveraged ETFs? Are there other descriptions we should use? Could an ETF seek to provide returns that are a multiple, or inverse, of an index without this limitation? For example, would such an ETF be able to operate without the daily (or other periodic) reset? Would such an ETF raise the same investor protection issues as the leveraged ETFs that we are proposing to exclude from relying on proposed rule 6c–11? Would they raise other investor protection issues? If so, what issues and why?
- Does the proposed rule prevent an ETF from circumventing this limitation by embedding leverage in an index or through any other means? If not, should we consider other conditions or limitations, and if so, what? For example, should the rule provide that an ETF may not ''obtain'' or ''provide'' leveraged exposure, rather than stating that an ETF may not ''seek'' to provide leveraged exposure as proposed? Alternatively, should we define leveraged ETFs as funds currently do in their applications (*i.e.,* to achieve its investment objective by corresponding to a specified multiple of the performance (either 125%, 150% or 200%), or the inverse performance, or the inverse multiple (either 125%, 150% or 200% of the opposite) of the performance of a particular securities index)?[83]
- Proposed rule 6c–11 does not seek to address any concerns raised under section 18 of the Act by leveraged ETFs. Do commenters agree that this is appropriate? Should we consider additional conditions in rule 6c–11 for leveraged ETFs designed to address concerns raised under section 18 or other investor protection concerns raised by their strategies? If so, what conditions? Should we provide any relief to these ETFs under section 18 of the Act?
- What types of investors purchase shares of leveraged ETFs? What is the proportion of volume from retail versus institutional trading? How do these different types of investors utilize leveraged ETFs? What is the typical holding period of leveraged ETFs by each type of investor?
- What types of intermediaries are active with leveraged ETF investments? Are the current suitability requirements for intermediaries effective with respect to leveraged ETFs? What specific methods, if any, are intermediaries using to meet their suitability obligations for these products? Should we propose as part of a future rulemaking that leveraged ETFs be subject to additional requirements, particularly for retail investors?[84]

[78] *See* Derivatives Proposing Release, *supra* footnote 40. Section 18 of the Act limits a fund's ability to obtain leverage or issue senior securities. 15 U.S.C. 80a–18.

[79] *See supra* footnote 77. As discussed in more detail in section II.G below, we are not proposing here to rescind the existing leverage ETF orders. Existing leveraged ETF sponsors would continue to operate under their exemptive orders. Existing leveraged ETFs, however, would be subject to the proposed amendments to Form N–1A discussed below.

[80] Proposed rule 6c–11(c)(4).

[81] The current exemptive orders that allow leveraged ETFs contemplate a daily reset, because the orders relate to ETFs that pursue daily investment objectives. *See supra* footnote 77. For example, one application describes its leveraged ETFs as ''seek[ing] to provide daily investment results, before fees and expenses, that correspond to 300% of the daily performance, or 300% of the inverse (opposite) daily performance, of its Underlying Index.'' *See* Rafferty, *supra* footnote 77. Another describes its leveraged ETFs as ''attempt[ing], on a daily basis, to achieve its investment objective by corresponding to a specified multiple of the performance (either 125%, 150% or 200%), or the inverse performance, or the inverse multiple (either 125%, 150% or 200% of the opposite) of the performance of a particular securities index.'' *See* ProShares, *supra* footnote 77.

[82] Similarly, an ''inverse ETF'' includes both inverse strategies (*i.e.,* −100% of an index's performance) and leveraged inverse strategies (*e.g.,* −125% or −200% of an index's performance).

[83] *See supra* footnote 81.

[84] *See, e.g.,* NASD, *Structured Products: NASD Provides Guidance Concerning the Sale of Structured Products,* Notice to Members (September 2005), *available at http://www.complinet.com/file_store/pdf/rulebooks/nasd_0559ntm.pdf*; *see also* FINRA, *Complex Products: Heightened Supervision of Complex Products,* Regulatory Notice 12–03 (January 2012), *available at http://www.finra.org/sites/default/files/NoticeDocument/p125397.pdf.*

• The Commission understands that leveraged ETFs typically provide enhanced disclosure of the risks of investing in the ETF.[85] Do investors understand leveraged ETFs better today than they did when Commission staff and FINRA jointly issued an investor alert expressing the concern that individual investors may be confused about the performance objectives of leveraged ETFs? [86] For example, are investors more likely to be aware that leveraged ETFs are typically designed to achieve their stated performance objectives on a periodic basis (*e.g.,* daily)? Do investors understand that leveraged ETFs may not achieve those performance objectives over the long-term? [87]

• Leveraged ETFs typically include charts in their disclosures that explain the potential impact of compounding to an investor's returns. Should we amend Form N–1A to require leveraged ETFs to include such a chart to better explain the impact of compounding? Are there other disclosures that we should require leveraged ETFs to provide? If so, what are they?

• Should we propose rules governing leveraged ETF marketing materials to address concerns that leveraged ETFs may be marketed to investors that do not have an appropriate risk tolerance to invest in these products or that lack understanding of leveraged ETFs' strategies and risks? For example, should we require leveraged ETFs to include prescribed cautionary disclosures regarding these strategies and risks?

B. Exemptive Relief Under Proposed Rule 6c–11

Proposed rule 6c–11 would provide ETFs within the scope of the rule with exemptions from certain provisions of the Act that are necessary to allow ETFs to operate. These exemptions are generally consistent with the relief we have given to ETFs under our exemptive orders.[88] Proposed rule 6c–11 would permit an ETF that meets the conditions of the rule to: (i) Redeem shares only in creation unit aggregations; (ii) permit ETF shares to be purchased and sold at market prices rather than at NAV per share; (iii) engage in in-kind transactions with certain affiliates; and (iv) in certain limited circumstances, pay authorized participants the proceeds from the redemption of shares in more than seven days. As discussed below in section II.C, the exemptions would be subject to certain conditions that are designed to address the concerns underlying the relevant statutory provisions and to support a Commission finding that the exemptions are in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.[89]

1. Treatment of ETF Shares as ''Redeemable Securities''

Under proposed rule 6c–11, an ETF, as defined in the rule, would be considered to issue a ''redeemable security'' within the meaning of section 2(a)(32) of the Act.[90] As discussed above, ETFs have features that distinguish them from both traditional open-end and closed-end funds. A defining feature of open-end funds is that they offer redeemable securities, which allow the holder to receive his or her proportionate share of the fund's NAV per share upon presentation of the security to the issuer. Although individual ETF shares cannot be redeemed, except in limited circumstances,[91] they can be redeemed in creation unit aggregations.[92] Therefore, we believe that ETF shares are most appropriately classified under the proposed rule as redeemable securities within the meaning of section 2(a)(32),[93] and that ETFs should be regulated as open-end funds within the meaning of section 5(a)(1) of the Act.[94]

The arbitrage mechanism that is central to the operation of an ETF (and the conditions in our relief designed to facilitate an effective arbitrage mechanism) serves to keep the market price of ETF shares at or close to the ETF's NAV per share. As a result, even though only authorized participants may redeem creation units directly from the ETF at NAV per share, investors are able to sell their ETF shares on the secondary market at or close to NAV, similar to investors in an open-end fund that redeem their shares directly from the fund at NAV per share.[95] The shares of closed-end funds, on the other hand, generally trade on the secondary market at a discount or premium to NAV.

Our exemptive orders have provided exemptions from sections 2(a)(32) and 5(a)(1) of the Act so that ETFs may register under the Act as open-end funds while issuing shares redeemable in creation units only. Unlike our exemptive orders, however, the proposed rule would not provide an exemption from the definition of ''redeemable security'' in section 2(a)(32) or from the definition ''open-end company'' in section 5(a)(1). We believe that it is more appropriate for the proposed rule to address these questions of status by classifying ETF shares as ''redeemable securities.'' Thus,

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[85] This understanding is based on Commission staff review of registration statements filed with the Commission and ETF websites.

[86] *See supra* footnote 74.

[87] *See e.g.,* Paolo Guasoni and Eberhard Mayerhofer, Leveraged Funds: Robust Replication and Performance Evaluation (2017) (''Leveraged and inverse exchange-traded funds seek daily returns equal to fixed multiples of indexes' returns. Trading costs implied by frequent adjustments of funds' portfolios create a tension between tracking error, reflecting short-term correlation with the index, and excess return, the long-term deviation from the leveraged index's performance.''); Lu Lei, Jun Wang, and Ge Zhang, *Long-term performance of leveraged ETFs,* 21 Financial Services Review 1 (2012) (''Overall our results caution against the use of leveraged ETFs as long-term investment substitutes for long or short positions of the benchmark indices.'').

[88] Our exemptive orders also provide relief allowing certain types of funds to invest in ETFs beyond the limits of section 12(d)(1) of the Act. We are not addressing this relief at this time. *See infra* section II.G. However, we are proposing to rescind the master-feeder relief that we previously granted to ETFs that do not rely on the relief as of the date of this proposal (June 28, 2018). We also propose to grandfather existing master-feeder arrangements involving ETF feeder funds, but prevent the formation of new ones, by amending relevant exemptive orders. *See infra* section II.F.

[89] *See* 15 U.S.C. 80a–6(c).

[90] Proposed rule 6c–11(b)(1).

[91] *See infra* section II.C.1 (discussing circumstances where ETF shares can be individually redeemed).

[92] *See* proposed rule 6c–11(a) (defining an exchange-traded fund, in part, as a registered open-end management company that issues and redeems its shares in creation units). The proposed rule would define ''creation unit'' to mean a specified number of ETF shares that the ETF will issue to (or redeem from) an authorized participant in exchange for the deposit (or delivery) of a basket and a cash balancing amount (if any). *See* proposed definition of ''creation unit'' in rule 6c–11(a).

[93] If ETF shares were not classified as redeemable securities within the meaning of section 2(a)(32) of the Act, an ETF would be subject to the provisions of the Act applicable to closed-end funds. *See* 15 U.S.C. 80a–5(a)(2) (defining a ''closed-end company'' as any management company other than an open-end company).

[94] 15 U.S.C. 80a–5(a)(1) (defining ''open-end company''); 15 U.S.C. 80a–2(a)(32) (defining ''redeemable security'').

[95] *See* Robert Engle & Debojyoti Sarkar, *Premiums-Discounts and Exchange Traded Funds,* 13 Journal of Derivatives 4 (Summer 2006) (''Engle Article'') (observing that premiums and discounts for domestic ETFs are generally small and highly transient, and that while premiums and discounts are larger and more persistent in international ETFs, they are smaller and less persistent than the premiums and discounts of international closed-end funds); *but see, e.g.,* Bradley Kay, *Has the ETF Arbitrage Mechanism Failed?,* Morningstar (Mar. 11, 2009), *available at http://news.morningstar.com/articlenet/article.aspx?id=283302* (stating that market prices for ETFs may deviate significantly from NAV during periods of market stress); Chris Dieterich, *Greece ETF Pacing for Record Tumble on Huge Volume: Here's What You Need to Know,* Barron's (June 29, 2015), *available at https://www.barrons.com/articles/greece-etf-pacing-for-record-tumble-on-huge-volume-heres-what-you-need-to-know-1435597369* (noting that ETFs tied to Greek and Egyptian stocks traded at significant discounts to NAV when the exchanges on which the underlying stocks traded were closed).

any ETF operating in compliance with the rule's conditions and requirements would meet the definition of open-end company.[96]

ETFs operating in reliance on the proposed rule would be subject to the requirements imposed under the Act and our rules that apply to all open-end funds.[97] We note that our approach is substantially similar to the 2008 proposal, which was generally supported by commenters.[98] In addition, in our view the rules under the Exchange Act that apply to redeemable securities issued by an open-end fund would apply to ETFs relying on the proposed rule.[99] Thus, proposed rule 6c–11 would result in ETFs relying on proposed rule 6c–11 becoming eligible for the ''redeemable securities'' exceptions in 12 CFR 242.101(c)(4) and 242.102(d)(4) (''rules 101(c)(4) and 102(d)(4) of Regulation M'') and 12 CFR 240.10b–17(c) (''rule 10b–17(c) under the Exchange Act'') in connection with secondary market transactions in ETF shares and the creation or redemption of creation units. Similarly, we would view ETFs relying on rule 6c–11 as within the ''registered open-end investment company'' exemption in rule 11d1–2 under the Exchange Act.[100]

We request comment on this aspect of the proposed rule.

- Are there differences between ETFs and other open-end funds that would justify not applying certain open-end fund provisions of the Act or our rules to ETFs? For example, we adopted tailored liquidity risk management program requirements for ETFs under 17 CFR 270.22e–4 (''rule 22e–4'').[101] Should we consider tailored requirements for ETFs in connection with other provisions?
- As we discussed above, ETFs relying on proposed rule 6c–11 would be able to rely on the ''redeemable securities'' exceptions in rules 101(c)(4) and 102(d)(4) of Regulation M and rule 10b–17(c) under the Exchange Act and the ''registered open-end investment company'' exemption in rule 11d1–2 under the Exchange Act. Should the Commission exempt ETFs relying on proposed rule 6c–11 from any other rules under the Exchange Act?[102] If so, which rules and why? For example, ETFs typically request relief from Exchange Act section 11(d)(1) and rule 11d1–2 thereunder; and 17 CFR 240.10b–10, 240.15c1–5, and 240.15c1–6 (rules 10b–10, 15c1–5, and 15c1–6 under Exchange Act). Should the Commission provide relief from these provisions under the Exchange Act? If so, what conditions should apply to such relief, if any, and why? For example, ETFs currently rely on relief that is conditioned on: minimum creation unit sizes;[103] dissemination of the Intraday Indicative Value (''IIV'');[104] restrictions on the payment of certain cash compensation or economic incentives;[105] minimum levels of diversification in the ETF's basket;[106] and whether the ETF is managed to track an index.[107] Should we eliminate or modify any or all of these conditions? We requested comment on exchange listing standards for ETFs and other ETPs in 2015.[108] Do commenters have updated views on those requests for comment?

2. Trading of ETF Shares at Market-Determined Prices

Section 22(d) of the Act, among other things, prohibits investment companies, their principal underwriters, and dealers from selling a redeemable security to the public except at a current public offering price described in the prospectus.[109] Rule 22c–1 generally requires that a dealer selling, redeeming, or repurchasing a redeemable security do so only at a price based on its NAV.[110] Together, section 22(d) and rule 22c–1 are designed to: (i) Prevent dilution caused by certain riskless trading practices of principal underwriters and dealers; (ii) prevent unjust discrimination or preferential treatment among investors purchasing and redeeming fund shares; and (iii) preserve an orderly distribution of investment company shares.[111] ETFs seeking to register under the Act obtain exemptions from these provisions because investors may purchase and sell individual ETF shares from and to dealers on the secondary market at market-determined prices (*i.e.,* at prices other than those described in the prospectus or based on NAV). Consistent with our prior exemptive orders, proposed rule 6c–11 would provide exemptions from these provisions.[112]

As discussed above, only authorized participants can purchase and redeem shares directly from an ETF at NAV per share and only in creation unit aggregations. Because authorized participants (and other market participants transacting through an authorized participant) can take advantage of disparities between the market price of ETF shares and NAV per share, they may be in a different position than investors who buy and sell individual ETF shares only on the secondary market.[113] However, if the arbitrage mechanism is functioning effectively, entities taking advantage of these disparities in market price and NAV per share move the market price to a level at or close to the NAV per share of the ETF. The proposed rule would provide exemptions from section 22(d) and rule 22c–1 because we believe this

[96] Section 5(a)(1) defines an ''open-end company'' as ''a management company which is offering for sale or has outstanding any redeemable security of which it is the issuer.'' 15 U.S.C. 80a–5(a)(1).

[97] *See, e.g.,* 15 U.S.C. 80a–22; 17 CFR 270.22c–1.

[98] *See* 2008 ETF Proposing Release, *supra* footnote 3. *See also* ICI 2008 Comment Letter; Xshares 2008 Comment Letter.

[99] *See, e.g.,* 17 CFR 240.15c3–1. *See also* Securities Transaction Settlement Cycle, Exchange Act Release No. 80295 (Mar. 22, 2017) [82 FR 15564 (Mar. 29, 2017)] (''T+2 Adopting Release'') (shortening the standard settlement cycle for most broker-dealer securities transactions to two business days).

[100] *Cf.* Securities Industry Association, SEC Staff No-Action Letter (Nov. 21, 2005) (treating certain equity index-based ETFs as registered open-end investment companies for purposes of rule 11d1–2).

[101] *See* Investment Company Liquidity Risk Management Programs, Investment Company Act Release No. 32315 (Oct. 13, 2016) [81 FR 82142 (Nov. 18, 2016)] (''LRM Adopting Release''), at sections II.A. and II.J.

[102] *See, e.g., supra* footnote 14.

[103] *See, e.g.,* Letter from James A. Brigagliano, Deputy Director, Division of Trading and Markets, to W. John McGuire, Morgan, Lewis & Bockius LLP re: U.S. One Trust Actively-Managed Exchange Traded Fund of Exchange Traded Funds, dated May 4, 2010 (conditioning relief under Exchange Act Section 11(d)(1) on the ETFs continuously redeeming, at NAV, creation unit aggregations of 50,000 shares valued at a minimum of $1.25 million).

[104] *Id.* (representing that the ETFs would disseminate the IIV every 15 seconds throughout the trading day).

[105] *See, e.g.,* Letter from Catherine McGuire, Chief Counsel, Division of Market Regulation to Securities Industry Association, dated Nov. 21, 2005, at n.3 and accompanying text.

[106] *Id.* (defining, in part, a ''qualifying ETF'' as consisting of a basket of twenty or more component securities with no one component security constituting more than 25% of the total value of the ETF).

[107] *Id.*

[108] 2015 ETP Request for Comment, *supra* footnote 9, at n.106 and accompanying and following text.

[109] 15 U.S.C. 80a–22(d).

[110] *See* 17 CFR 270.22c–1.

[111] *See generally* Mutual Fund Distribution Fees; Confirmations, Investment Company Act Release No. 29367 (July 21, 2010) [75 FR 47064 (Aug. 4, 2010)] (discussing legislative history of section 22(d)).

[112] *See* proposed rule 6c-11(b)(2). The reference in the proposed rule to ''repurchases . . . at market-determined prices'' refers to secondary market transactions with dealers. Thus, the rule would not allow an ETF to repurchase shares from an investor at market-determined prices.

[113] *See, e.g.,* Comment Letter of Barclays Global Investors on 2001 Concept Release (Jan. 11, 2002) (''[D]uring periods of market volatility . . . it is not unreasonable to assume that some retail investors would buy or sell ETF shares at secondary market prices moving in the opposite direction of a fund's NAV.'').

arbitrage mechanism—and the conditions in this rule designed to promote a properly functioning arbitrage mechanism—have adequately addressed, over the significant operating history of ETFs, the potential concerns regarding shareholder dilution and unjust discrimination that these provisions were designed to address.

We proposed the same exemptions in 2008 and commenters who addressed this aspect of the 2008 ETF Proposing Release supported the Commission's approach.[114] Commenters on the 2015 ETP Request for Comment also addressed the existing arbitrage mechanism, generally arguing that it is effective and efficient in ensuring that an ETF's market price does not vary substantially from its NAV per share.[115] On the other hand, one commenter questioned the efficacy of the arbitrage mechanism, particularly at the close of trading when bid-ask spreads tend to widen.[116] One commenter asserted that the arbitrage mechanism does not work well for ETFs holding securities that do not trade during U.S. market hours.[117] Another commenter argued that even if the arbitrage mechanism corrects price mismatches between market price and NAV per share, it does so by creating an unfair windfall for authorized participants who can capitalize on information asymmetries and operational advantages to extract value from the market.[118]

The arbitrage mechanism is the foundation for why retail and other secondary market investors generally can buy and sell ETF shares at prices that are at or close to the prices at which authorized participants are able to buy and redeem shares directly from the ETF at NAV. In the Commission's experience, the deviation between the market price of ETFs and NAV per share, each calculated as of the close of trading each day, generally has been relatively small.[119] For example, during 2016–2017, the closing price of ETFs based on U.S. equity indexes were within 1% of NAV for 97.9% of trading days and within 1% of NAV for actively managed ETFs investing in U.S. equities for 98.5% of trading days. The absolute weighted average of the daily difference between the NAV and market price during a six-month period ending in December 2017 was 0.014% for ETFs based on U.S. equities indexes and 0.074% for actively managed ETFs investing in U.S. equities.[120]

Other types of ETFs have had a somewhat higher deviation between NAV per share and market price. During 2016–2017, the closing price for index-based and actively managed ETFs investing in international equities, for example, were within 1% of NAV for 87.4% and 86.8% of trading days, respectively. Similarly, the absolute weighted average of the daily difference between the NAV and market price during a six-month period ending in December 2017 for index-based and actively managed ETFs investing in U.S. fixed-income securities were 0.067% and 0.068%, respectively. The absolute weighted average of daily difference between NAV per share and market price during the six-month period studied was 0.206% for ETFs based on international equities indexes and 0.390% for actively managed ETFs investing in international equities.[121]

These numbers represent only broad averages with respect to end-of-day differences, however, and intraday deviations between market price and NAV per share may be greater under certain circumstances. These figures also do not reflect intraday deviations between market prices and the contemporaneous value of the ETF's portfolio.[122] However, one academic paper has shown that deviations between intraday market prices and estimated intraday values for domestic ETFs also were generally small.[123]

The Commission and its staff have observed the operation of the arbitrage mechanism during periods of market stress when the deviation between intraday market prices and the next-calculated NAV per share significantly widened for short periods of time. During periods of extraordinary volatility in the underlying ETF holdings, it may be difficult for authorized participants or market makers to confidently ascribe precise values to an ETF's holdings, thereby making it more difficult to effectively hedge their positions.[124] These market participants may widen their quoted spreads in ETF shares or, in certain cases, may elect not to transact in or quote ETF shares, rather than risk loss.[125]

Market makers may have already exhibited this behavior in periods of extraordinary volatility.[126] For example,

[114] *See* ICI 2008 Comment Letter; Xshares 2008 Comment Letter.

[115] *See, e.g.,* Comment Letter of KCG Holdings, Inc. on 2015 ETP Request for Comment (Aug. 17, 2015); Comment Letter of Vanguard on 2015 ETP Request for Comment (Aug. 17, 2015); Comment Letter of Charles Schwab & Co., Inc. and Charles Schwab Investment Management, Inc. on 2015 ETP Request for Comment (Aug. 17, 2015) (''Schwab ETP Comment Letter'') (noting that it had not identified any significant systemic differences in efficiency across various ETF products, regardless of ETF's investment strategy).

[116] *See* Comment Letter of ETF Consultants.com, Inc. on 2015 ETP Request for Comment (Aug. 17, 2015); *see also infra* section II.H regarding bid-ask spreads.

[117] *See* Comment Letter of James J. Angel, Ph.D., CFA on 2015 ETP Request for Comment (Aug. 17, 2015).

[118] *See* Comment Letter of Occupy the SEC on 2015 ETP Request for Comment (Aug. 21, 2015).

[119] Figures in this section represent an analysis by Commission staff of market data obtained from Bloomberg Professional Services and Morningstar. In preparing this analysis, staff used the market price of each ETF as of the close of trading each day.

[120] An ETF can trade at a premium or discount to its NAV per share on any given day. When taking an average over many days, premiums (which have a positive difference) and discounts (which have a negative difference) may offset each other. Therefore, to calculate deviation from NAV, we use the absolute value of premiums and discounts when calculating weighted average differences to prevent such offsetting.

[121] International equity ETFs can provide exposure to markets that do not overlap with U.S. trading hours. In these circumstances, the deviation between NAV per share and market price may be attributable in large part to obtaining exposure to those markets when they are closed.

[122] Most funds calculate NAV per share once per day as of the time the major U.S. stock exchanges close. *See supra* footnote 26.

[123] Engle Article, *supra* footnote 95. For domestic ETFs, the study showed intraday average daily premium of 0.25 basis points with an average standard deviation of 11.8 basis points. For international ETFs, the respective figures were 23.7 basis points and an average standard deviation of 64.8 basis points. The intraday premium was measured every minute as the percentage difference between: (i) The average of the bid and the ask of the ETF shares; and (ii) the intraday indicative value (IIV) of the ETF's portfolio. *See infra* sections II.C.3 and II.C.6 for a discussion of the IIV and the potential problems associated with using the IIV as a tool to measure the current value of the ETF's portfolio on an ongoing basis.

[124] *See generally* Itzhak Ben-David, *et al., Exchange Traded Funds (ETFS),* National Bureau of Econ., Working Paper No. 22829 (Nov. 2016), *available at http://www.nber.org/papers/w22829* (''Ben-David'') (''Because of sparse liquidity in some exchanges [on the morning of August 24, 2015], some of the arbitrage programs diagnosed unreliable price data and withdrew from the market, leading to a positive feedback loop.'').

[125] *See also* Milan Borkovec, *et al., Liquidity and Price Discovery in Exchange-Traded Funds: One of Several Possible Lessons from the Flash Crash,* 1 The Journal of Index Investing 2 (2010) (''Borkovec'') (reporting that liquidity of ETFs declined dramatically during the ''Flash Crash,'' causing spreads to widen significantly).

[126] *See* Ben-David, *supra* footnote 124 (''ETF market makers and [authorized participants] arguably withdrew from the market after a trading pause in the futures market, which they used to hedge their exposure in volatile trading sessions.'') (internal citations omitted). Many ETFs disclose the risk that ETF shares will trade at a premium or discount, particularly during times of market disruptions, in their prospectuses as part of their principal risk disclosure. *See, e.g.,* iShares Trust rule 485(b) Registration Statement (Nov. 1, 2017), *available at https://www.sec.gov/Archives/edgar/data/1100663/000119312517327588/d486424d485bpos.htm* (''Market Trading Risk: The Fund faces numerous market trading risks, including the potential lack of an active market for Fund shares, losses from trading in secondary markets, periods of high volatility and disruptions in the creation/redemption process. ANY OF

Continued

on May 6, 2010, the prices of many U.S.-based equity products experienced a significant decline and recovery, and many of the securities that experienced the greatest price changes were equity-based ETFs.[127] Significant price volatility on the morning of August 24, 2015 triggered limit up-limit down pauses in many equity securities, including many ETFs.[128] In both instances, certain ETFs saw larger intraday premiums/discounts and wider bid-ask spreads for portions of the trading day.[129] Deviations between market price and NAV per share were closed after relatively short periods, however, as the arbitrage mechanism resumed its effectiveness.[130]

Accordingly, we recognize that under certain circumstances, including during periods of market stress, the arbitrage mechanism may work less effectively for a period of time. We also recognize that secondary market investors who trade in ETF shares during these periods may be harmed by trading at a price that is not close to the NAV per share of the ETF (or the contemporaneous value of the ETF's portfolio). On balance, however, we believe these investors are more likely to weigh the potential benefits of ETFs (*e.g.,* low cost and intraday trading) against any potential for market price deviations when deciding whether to utilize ETFs.[131] Further, we believe that the conditions we are proposing as part of rule 6c–11, along with other recent actions that are designed to promote an effective arbitrage mechanism,[132] would continue to result in a sufficiently close alignment between an ETF's market price and NAV per share in most circumstances, and provide an appropriate basis for the exemptive relief we are proposing. We particularly find this to be the case given the benefits ETFs offer investors, as discussed above.

Furthermore, to the extent that there are instances where bid-ask spreads widen, or premiums and discounts persist, the proposed rule and disclosure amendments would require ETFs to disclose certain information on their website.[133] We believe that it is important for investors to be informed where costs may increase beyond what they would reasonably expect. Our exemptive orders have required ETFs' websites to disclose, among other things, the ETF's NAV per share for the prior business day, the market closing price or the midpoint of the bid-ask spread at the time of the calculation of NAV, and a calculation of the premium or discount of the market closing price or midpoint of the bid-ask spread against NAV per share.[134] However, the proposed rule and disclosure amendments would require ETFs to disclose additional information on their websites that is not currently required under our exemptive orders.[135]

In particular, as discussed in section II.C.6, we are proposing to require ETFs to disclose on their websites the median bid-ask spread for the ETF's most recent fiscal year and certain historical information about the extent and frequency of an ETF's premiums and discounts. This would allow investors to be more aware of this risk when deciding whether to invest in ETFs generally or in a particular ETF. Our proposed amendments to Form N–1A would require additional disclosure regarding ETF trading information and related costs, including information relating to high-end (95th percentile) spread costs.[136] We also request comment below on whether there are other ways to calculate premiums and discounts, or other metrics we should consider, to better inform investors about an ETF's history of deviations between intraday market prices and (i) the next-calculated NAV; or (ii) the contemporaneous value of the ETF's portfolio.[137]

We request comment on the proposed exemptions from section 22(d) of the Act and rule 22c–1 thereunder.

- Is the proposed relief sufficient to facilitate transactions in ETF shares on the secondary market?
- Will the proposed conditions (discussed below) promote the arbitrage mechanism and support the Commission granting this relief? Are there other conditions we should consider?
- Under what circumstances could a premium or discount for an ETF develop or persist? For example, when would a premium or discount develop due to a break-down in the arbitrage mechanism? Are there instances where a premium or discount may develop or persist because of price discovery, such as when the underlying markets for the ETF's component securities are closed? Are there instances where a premium or discount may develop or persist because of transaction costs relating to the ETF's basket securities? How can these circumstances be distinguished from one another? Should we consider any changes to our proposal to account for these different circumstances?
- Would the arbitrage mechanism contemplated by the proposed rule keep ETF market prices at or close to NAV per share under normal market conditions? How should this be measured? For example, is it appropriate to assess premiums and discounts solely by comparing ETF market prices to the ETF's NAV, which typically is calculated at the end of the day? Should intraday calculations play a larger role when assessing premiums and discounts? Should we, for example, assess the efficiency of the arbitrage mechanism by comparing the mean/median of the market prices on a given trading day against the end of day NAV? Alternatively, should we compare the mean/median of the market price on a given trading day against an intraday

THESE FACTORS, AMONG OTHERS, MAY LEAD TO THE FUND'S SHARES TRADING AT A PREMIUM OR DISCOUNT TO NAV.'').

[127] *See* Final May 6 Report, *supra* footnote 9, at n.36 and accompanying text (noting that ETFs accounted for approximately 70% of all securities with trades broken pursuant to the clearly erroneous execution rules on May 6).

[128] *See* August 24 Staff Report, *supra* footnote 32 (noting that ETFs as a class accounted for almost all of the 1,279 trading halts on August 24, 2015, but 80% of ETFs did not experience a single trading halt).

[129] *See* Borkovec, *supra* footnote 125; Ben-David, *supra* footnote 124.

[130] *See* Borkovec, *supra* footnote 125, at 40; *see also* Ananth Madhavan, *Exchange-Traded Funds, Market Structure, and the Flash Crash,* 68 Financial Analysts Journal 20 (2012) (''Madhavan Article'').

[131] The Commission has taken steps to address disruptions in the arbitrage mechanism. For example, the Commission approved changes to the limit up-limit down rules following the market events on August 24, 2015. *See* Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Clarify the Operation of the Regulation NMS Plan to Address Extraordinary Market Volatility, Exchange Release No. 78435 (July 28, 2016) [81 FR 51239 (Aug. 3, 2016)]; Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Extend the Effective Date of SR–FINRA–2016–028, Exchange Release No.78660 (Aug. 24, 2016) [81 FR 59676 (Aug. 30, 2016)].

[132] For example, rule 22e–4 under the Act requires ETFs to consider certain additional factors that address the relationship between the liquidity of the ETF's portfolio and the arbitrage mechanism in assessing, managing, and periodically reviewing its liquidity risk. *See* LRM Adopting Release, *supra* footnote 101. We have taken these requirements into consideration in developing the conditions in this proposal.

[133] *See infra* section II.C.6.

[134] *See, e.g.,* Fidelity Commonwealth Trust, Investment Company Act Release Nos. 32166 (June 29, 2016) [81 FR 44063 July 6, 2016)] (notice) and 32191 (July 26, 2016) (order) and related application; Claymore Exchange-Traded Fund Trust, Investment Company Act Release Nos. 27469 (Aug. 28, 2006) [71 FR 51869 (Aug. 31, 2006)] (notice) and 27483 (Sept. 18, 2006) (order) and related application.

[135] *See infra* footnote 278 and accompanying and following text (noting that, currently, Form N–1A provides an ETF with the option to omit certain historical information regarding premiums and discounts from its prospectus and annual report if the disclosure is provided on its website).

[136] *See infra* section II.H.

[137] *See infra* section II.C.6.

measure of the value of an ETF's portfolio?

3. Affiliated Transactions

Section 17(a) of the Act generally prohibits an affiliated person of a registered investment company, or an affiliated person of such person, from selling any security or other property to or purchasing any security from the company.[138] Purchases and redemptions of ETF creation units are typically effected in kind, and section 17(a) prohibits these in-kind purchases and redemptions by affiliated persons of the ETF. An affiliated person of an ETF includes, among others: (i) Any person directly or indirectly owning, controlling, or holding with power to vote, 5% or more of the outstanding voting securities of the ETF; (ii) any person 5% or more of whose outstanding voting securities are directly or indirectly owned, controlled, or held with power to vote by the ETF; and (iii) any person directly or indirectly controlling, controlled by, or under common control with the ETF.[139]

ETF applicants have requested, and we have granted, exemptive relief from section 17(a) of the Act for: (i) Persons affiliated with the ETF based on their ownership of 5% or more of the ETF's outstanding securities (''first-tier affiliates''); and (ii) affiliated persons of the first-tier affiliates or persons who own 5% or more of the outstanding securities of one or more funds advised by the ETF's investment adviser (''second-tier affiliates'').[140] In seeking this relief, applicants have stated that first- and second-tier affiliates are not treated differently from non-affiliates when engaging in purchases and redemptions of creation units.[141] All purchases and redemptions of creation units are at an ETF's next-calculated NAV pursuant to rule 22c–1. Additionally, the securities deposited or delivered upon redemption are valued in the same manner, using the same standards, as those securities are valued for purposes of calculating the ETF's NAV per share.

Proposed rule 6c–11 similarly would provide exemptions from sections 17(a)(1) and (a)(2) of the Act with regard to the deposit and receipt of baskets to a person who is an affiliated person of an ETF (or who is an affiliated person of such a person) solely by reason of: (i) Holding with the power to vote 5% or more of an ETF's shares; or (ii) holding with the power to vote 5% or more of any investment company that is an affiliated person of the ETF.[142] We believe that this relief is necessary to facilitate the efficient functioning of the arbitrage mechanism. Without it, an authorized participant or other market participant that becomes an affiliated person of the ETF due to its holdings would be prevented from engaging in arbitrage using an in-kind basket. This, in turn, could have the adverse effect of limiting the pool of market participants that could engage in arbitrage. Ultimately, it could result in the deviation between market price and NAV per share widening in cases where there are very few authorized participants or other market participants actively engaged in transactions with the ETF. The arbitrage mechanism for newly launched ETFs could be particularly challenged without this relief because every purchaser of a creation unit would be considered an affiliated person of the ETF so long as there are fewer than twenty creation units outstanding. We also believe that this relief is appropriate because all purchases and redemptions of creation units are at an ETF's next-calculated NAV, and the securities deposited or delivered upon redemption would be valued in the same manner, using the same standards, as those securities are valued for purposes of calculating the ETF's NAV.

The exemption in proposed rule 6c–11(b)(3) is similar to the section 17(a) exemption we proposed in 2008, although the relief would be subject to certain additional conditions related to custom baskets.[143] Commenters who addressed the proposed relief in 2008 supported it.[144] Several commenters, however, requested that the relief be expanded to cover additional types of affiliated relationships, such as broker-dealers that are affiliated with the ETF's adviser.[145] These commenters noted that any Commission concern of undue influence by the affiliate would be addressed by the federal securities laws and regulations that prohibit manipulative practices and misuse of nonpublic information, and that ETFs would benefit from an increase in entities eligible to transact with the ETF.[146] An increase in the number of authorized participants could also help to reduce the potential for an ETF to be reliant on one or more particular authorized participants.[147]

While we acknowledge that an increase in entities eligible to transact with an ETF could facilitate the arbitrage mechanism and reduce concentration risk, we preliminarily do not believe that it is appropriate to expand the scope of affiliated persons covered by the exemption at the same time that we are permitting additional flexibility with respect to custom baskets. The proposed rule would allow an ETF to utilize custom baskets if certain conditions are met, increasing the possibility that affiliates and non-affiliates could be treated differently in connection with an ETF's receipt or delivery of baskets.[148] We believe that the conditions related to the issuance or acceptance of custom baskets in proposed rule 6c–11 would provide appropriate protections against overreaching and similar abusive practices when an ETF exchanges a custom basket with an affiliate; however, limiting the types of affiliates that are permitted to rely on this exemption would serve as an additional protection against potential disparate treatment in connection with an ETF's receipt or delivery of baskets.

We request comment on this aspect of the proposed rule.

- Without an exemption from section 17(a) of the Act, would ETFs or authorized participants bear any costs that they do not incur today?
- As discussed above, the exemptive relief from section 17(a) of the Act that we are proposing would apply only to

[138] 15 U.S.C. 80a–17(a).

[139] 15 U.S.C. 80a–2(a)(3)(A), (B) and (C). A control relationship is presumed when one person owns more than 25% of another person's outstanding voting securities. 15 U.S.C. 80a–2(a)(9).

[140] *See, e.g.,* Barclays Global 2000, *supra* footnote 6 (''Because purchases and redemptions of Creation Units may be 'in-kind' rather than cash transactions, section 17(a) may prohibit affiliated persons of an [ETF] from purchasing or redeeming Creation Units.'').

[141] *See e.g.,* Barclays Global 2008, *supra* footnote 58.

[142] *See* proposed rule 6c–11(b)(3).

[143] *See id.* To utilize custom baskets, proposed rule 6c–11(c)(3) would require an ETF to adopt and implement written policies and procedures that: (i) Set forth detailed parameters for the construction and acceptance of custom baskets that are in the best interests of the ETF and its shareholders, including the process for any revisions to, or deviations from, those parameters; and (ii) specify the titles or roles of the employees of the ETF's investment adviser who are required to review each custom basket for compliance with those parameters.

[144] *See, e.g.,* Comment Letter of Barclays Capital Inc. (May 8, 2008); ICI 2008 Comment Letter; SSgA 2008 Comment Letter.

[145] *See, e.g.,* ICI 2008 Comment Letter; BGFA 2008 Comment Letter.

[146] *See, e.g.,* ICI 2008 Comment Letter; ABA 2008 Comment Letter.

[147] Item E.2.a. of Form N–CEN requires ETFs to provide certain identifying information regarding its authorized participants. *See* Investment Company Reporting Modernization Adopting Release, Investment Company Act Release No. 32314 (Oct. 13, 2016) [81 FR 81870 (Nov. 18, 2016)] (''Reporting Modernization Adopting Release'') (''[C]ollecting information concerning these entities on an annual basis will allow [the Commission] to understand and better assess the size, capacity, and concentration of the authorized participant framework and also inform the public about certain characteristics of the ETF primary markets.'').

[148] *See* proposed rule 6c–11(c)(3).

in-kind purchases and redemptions of creation units, and only to persons affiliated with the ETF (or affiliates of those persons) by reason of holding the power to vote 5% or more of the ETF's shares or holding the power to vote 5% or more of any investment company that is affiliated with the ETF. Should the relief extend to parties that are affiliated persons of an ETF for other reasons, or to non-creation unit transactions, such as portfolio transactions? For example, should a broker-dealer that is affiliated with the ETF's adviser be allowed to transact in kind with the ETF? If so, should the proposed rule include any additional conditions to minimize potential risks of overreaching for this type of affiliated person? How would expanding the scope of the exemption in this manner interact with the proposed conditions regarding basket flexibility?

4. Additional Time for Delivering Redemption Proceeds

Section 22(e) of the Act generally prohibits a registered open-end management investment company from postponing the date of satisfaction of redemption requests for more than seven days after the tender of a security for redemption.[149] This prohibition can cause operational difficulties for ETFs that hold foreign investments and exchange in-kind baskets for creation units. For example, local market delivery cycles for transferring foreign investments to redeeming investors, together with local market holiday schedules, can sometimes require a delivery process in excess of seven days. These ETFs have previously requested, and we have granted, relief from section 22(e) so that they may satisfy redemptions up to a specified maximum number of days (depending upon the local markets), as disclosed in the ETF's prospectus or statement of additional information (''SAI''). Other than in the disclosed situations, these ETFs satisfy redemptions within seven days.[150]

Section 22(e) was designed to prevent unreasonable delays in the actual payment of redemption proceeds.[151] Proposed rule 6c–11 would provide an exemption from section 22(e) of the Act because we believe that the limited nature of the exemption addresses the concerns underlying this section of the Act. As proposed, rule 6c–11 would grant relief from section 22(e) to permit an ETF to delay satisfaction of a redemption request for more than seven days if a local market holiday, or series of consecutive holidays, the extended delivery cycles for transferring foreign investments to redeeming authorized participants, or the combination thereof prevents timely delivery of the foreign investment included in the ETF's basket.[152] To rely on this exemption, an ETF would be required to deliver foreign investments as soon as practicable, but in no event later than 15 days after the tender to the ETF.[153] This proposed exemption thus would permit a delay in the delivery of foreign investments only if the foreign investment is being transferred in kind as part of the basket.[154]

The exemption would permit a delay only to the extent that additional time for settlement is actually required, when a local market holiday, or series of consecutive holidays, or the extended delivery cycles for transferring foreign investments to redeeming authorized participants prevents timely delivery of the foreign investment included in the ETF's basket. To the extent that settlement times continue to shorten, the ''as soon as practicable'' language embedded in the exemption is designed to minimize any unnecessary settlement delays.[155] If a foreign investment settles in less than 15 days, the ETF would be required to deliver it pursuant to the standard settlement time of the local market where the investment trades.

In addition, given the continued movement toward shorter settlement times in markets around the world, we believe that the relief from section 22(e) in the proposed rule does not need to be permanent. Accordingly, we propose to include a sunset provision in the proposed rule relating to the relief from section 22(e). Absent further action by the Commission, the exemption from section 22(e) for postponement of delivering redemption proceeds would expire ten years from the rule's effective date. We believe that technological innovation and changes in market infrastructures and operations will lead to further shortening of settlement cycles, although these developments may be gradual. Therefore, we believe it is appropriate for the relief from section 22(e) to be limited in duration to ten years.[156]

In 2008, we proposed a similar exemption for postponement of delivering redemption proceeds. However, that exemption would have allowed up to 12 days to deliver redemption proceeds without an offsetting requirement to deliver as soon as practicable and without a sunset provision.[157] Commenters on the 2008 proposal agreed that the specified delay in satisfying redemption requests seemed reasonable because it was for a limited period of time and disclosed to investors.[158] However, one commenter suggested increasing the period of time for settlement beyond 12 days consistent with the terms of exemptive orders that had been issued to some ETFs.[159] Since 2012, numerous applicants for exemptive relief have indicated that payment or satisfaction of redemption requests may take as long as 15 days after a redemption request is received, and we have issued orders permitting delayed delivery of settlement proceeds for up to 15 days.[160] We believe an extended

[149] 15 U.S.C. 80a–22(e).

[150] *See, e.g.,* Parker Global Strategies, *supra* footnote 18.

[151] *See Investment Trusts and Investment Companies: Hearings on S. 3580 Before a Subcomm. of the Senate Comm. on Banking and Currency,* 76th Cong., 3d Sess. 291–293 (statements of David Schenker).

[152] Proposed rule 6c–11(b)(4). This relief from the requirements of section 22(e) would not affect any obligations arising under rule 15c6–1 under the Exchange Act, which requires that most securities transactions be settled within two business days of the trade date. 17 CFR 240.15c6–1.

[153] Proposed rule 6c–11(b)(4).

[154] While mutual funds also may invest in foreign investments that require a delivery process in excess of seven days, mutual funds typically deliver redemption proceeds in cash, rather than in kind. Mutual funds, ETFs that redeem in cash, and ETFs that substitute cash in lieu of a particular foreign investment in a basket do not require an exemption from section 22(e) of the Act.

[155] Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Italy, Ireland, the Netherlands, Latvia, Lichtenstein, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain (certain fixed-income trades only), Sweden, Switzerland, and the United Kingdom moved to a T+2 settlement cycle by the end of 2014, while Australia and New Zealand transitioned to a T+2 settlement cycle in 2016. *See* Amendments to Securities Transaction Settlement Cycle, Exchange Act Release No. 78962 (Sept. 28, 2016) [81 FR 69240 (Oct. 5, 2016)], at n.134. Like the United States, Mexico, Canada, Peru and Argentina moved to a T+2 settlement cycle in September 2017. *See* T+2 Adopting Release, *supra* footnote 99. *See also* Annie Massa, *Your Trades Will Soon Spend Less Time Stuck in Market's Plumbing,* Bloomberg Markets (Aug. 31, 2017), *available at https://www.bloomberg.com/news/articles/2017-08-31/your-trades-will-soon-spend-less-time-stuck-in-market-s-plumbing.* There are many securities that trade over the counter (OTC) in certain foreign markets with agreed-upon settlement timeframes between the parties that could extend beyond the settlement timeframes of central securities depositories.

[156] ETFs that invest in foreign investments from jurisdictions that continue to require more than seven days to deliver redemption proceeds would have the option of redeeming in cash rather than in-kind once the exemptive relief sunsets. Such ETFs also could request targeted exemptive relief from section 22(e) from the Commission.

[157] *See* 2008 ETF Proposing Release, *supra* footnote 3.

[158] *See, e.g.,* Katten 2008 Comment Letter; Xshares 2008 Comment Letter.

[159] Katten 2008 Comment Letter (recommending up to 14 days).

[160] *See, e.g.,* Legg Mason ETF Trust, Investment Company Act Release Nos. 30237 (Oct. 22, 2012)

settlement period in these circumstances of 15 days, with the requirement that delivery nevertheless be made as soon as practicable, is reasonable in light of the limited nature and duration of the exemption.

The exemption we proposed in 2008 would have required an ETF to disclose in its registration statement the foreign holidays that it expects may prevent timely delivery of foreign securities, and the maximum number of days that it anticipates it will need to deliver the foreign securities.[161] We are not proposing a similar requirement for several reasons. First, we do not believe this disclosure is relevant to investors who purchase ETF shares on the secondary market, because the settlement of these investors' ETF trades would be unaffected by the potential delay. Only authorized participants engaged in redemption transactions with the ETF (and market participants that use the authorized participants as their agents for transacting with the ETF) would be affected. We believe that information regarding these potential delays is typically covered in the agreement governing the relationship between the ETF and the authorized participant (an ''authorized participant agreement'') and would likely be shared by the authorized participant with other market participants, as necessary.[162] Therefore, authorized participants already have information regarding potential delays. Second, given that these delays are typically covered by the authorized participant agreement, we do not believe it is necessary to require ETFs to provide registration statement disclosures.

The proposed rule would define ''foreign investment'' as any security, asset or other position of the ETF issued by a foreign issuer (as defined by rule 3b–4 under the Exchange Act) for which there is no established U.S. public trading market (as that term is used in Regulation S–K under the Securities Act).[163] This definition differs from the one we proposed in 2008 in that it references rule 3b–4 rather than enumerating the types of foreign entities that are considered issuers of foreign investments.[164] We believe this approach is appropriate because it creates consistency with a long-accepted definition under Exchange Act rules.[165] The reference to whether the investment has an ''established U.S. public trading market'' is designed to make the relief unavailable to an ETF that could trade the investment in its basket on a U.S. market, thereby avoiding the settlement delay that is the basis for the relief.[166] In addition, this definition is not limited to ''foreign securities,'' but also would include other investments that may not be considered securities. Although these other investments may not be securities, they may present the same challenges for timely settlement as foreign securities if they are transferred in kind. This approach is consistent with the terms of some recent exemptive orders that provide relief from section 22(e) for the delivery of foreign investments that may not be securities.[167]

We request comment on this aspect of the proposed rule.

- Is this relief necessary, particularly given that many non-U.S. jurisdictions have shorter settlement periods today than when we began granting this relief to ETFs? We specifically request comment regarding how frequently ETFs rely on this exemption. Should we permit the delayed delivery of settlement proceeds for up to 15 days? Is this period too long or too short? Should the rule refer to the applicable local market's settlement cycle without specifying a number of days? Should we require that the ETF deliver foreign investments as soon as practicable, as proposed, in order to minimize unnecessary settlement delays?
- Should we include a sunset provision for this relief as proposed? Is the duration of the proposed sunset provision appropriate? Should it be longer or shorter?
- Is the proposed definition of ''foreign investment'' appropriate for identifying investments that may routinely settle more than seven days after a redemption request? For example, are there circumstances where a U.S. entity could be subject to delays due to local market restrictions? Should we utilize a definition found elsewhere in rules and regulations set forth under the Exchange Act, the Investment Company Act, or other securities laws (*e.g.,* the definition of ''foreign security'' set forth in rule 15a–6 under the Exchange Act, or the definition of ''foreign assets'' set forth in rule 17f–5 under the Investment Company Act)? Alternatively, should we utilize the definition of ''foreign security'' set forth in the 2008 ETF Proposing Release, or utilize an entirely new definition? If recommending an alternate definition, please explain the specific types of investments that would be better captured or that would be excluded by that definition.
- Should the rule also provide relief if an ETF has foreign investments in its portfolio (and not in a particular basket)? If so, why? Should the rule permit the delayed delivery of the entire basket (instead of the specific foreign investments in a basket) if the basket is composed substantially of foreign investments subject to potential delays in the delivery of settlement proceeds?
- Are we correct that information regarding potential delays in the delivery of settlement proceeds for foreign investments typically is covered in the authorized participant agreement? If so, are we also correct that authorized participants acting as agents typically would share this information with their customers if it is a part of the redemption process?
- Should the rule require disclosure in an ETF's Statement of Additional Information of the foreign holidays an ETF expects may prevent timely delivery of the foreign investments and the maximum number of days it anticipates it would need to deliver the foreign investments as required by current exemptive orders? For example, should we require ETFs relying on this exemption to include a more general statement in their prospectus or SAI that the ETF may take up to 15 days to deliver settlement proceeds for certain foreign investments affected by foreign holidays, rather than the more specific statement of each holiday an ETF expects may prevent timely delivery of the investments that is currently required? Should these disclosures be included in an ETF's sales literature or

[77 FR 65425 (Oct. 26, 2012)] (notice) and 30265 (Nov. 16, 2012) (order) and related application (''Legg Mason'').

[161] *See* 2008 ETF Proposing Release, *supra* footnote 3.

[162] For example, an authorized participant acting as an agent typically would share this information with its customer if it is a necessary part of the creation or redemption process.

[163] *See* proposed rule 6c–11(a); *see also* rule 201(a) of Regulation S–K [17 CFR 229.201(a)] (describing how a registrant should identify its principal United States market or markets); rule 3b–4 of the Exchange Act [17 CFR 240.3b–4].

[164] The 2008 proposal defined ''foreign security'' as any security issued by a government or political subdivision of a foreign country, or corporation or other organization incorporated or organized under the laws of any foreign country and for which there is no established U.S. public trading market. *See* 2008 ETF Proposing Release, *supra* footnote 3.

[165] Rule 3b-4 under the Exchange Act was adopted in 1967. *See* Adoption of Rules Relating to Foreign Securities, Exchange Act Release No. 8066 (Apr. 28, 1967) [32 FR 7848 (May 30, 1967)].

[166] The rule does not rely on registration status because an unregistered large foreign private issuer may have an active U.S. market for its securities, in which case the ETF should be able to meet redemption requests in a timely manner. *See* Termination of a Foreign Private Issuer's Registration of a Class of Securities Under Section 12(g) and Duty to File Reports Under Section 13(a) or 15(d) of the Securities Exchange Act of 1934, Exchange Act Release No. 55540 (Mar. 27, 2007) [72 FR 16934 (Apr. 5, 2007)].

[167] *See, e.g.,* Redwood Investment Management, LLC, *et al.,* Investment Company Act Release Nos. 33076A (Apr. 26, 2018) [83 FR 19367 (May 2, 2018)] (notice) and 33100 (May 21, 2018) (order) and related application.

on its website? Alternatively, should we require ETFs to provide a written notice of the foreign holidays an ETF expects may prevent timely delivery of the foreign investments to authorized participants as a condition to rule 6c–11? If so, how often should this information be updated?

• Do secondary market investors or others use information regarding delays in the delivery of foreign investments?

C. Conditions for Reliance on Proposed Rule 6c–11

Proposed rule 6c–11 would require ETFs to comply with certain conditions that would allow them to operate within the scope of the Act, and that are designed to protect investors and to be consistent with the purposes fairly intended by the policy and provisions of the Act. These conditions are generally consistent with the conditions we have imposed under our exemptive orders, which we believe have effectively accommodated the unique structural and operational features of ETFs while maintaining appropriate protections for ETF investors. The conditions also reflect certain changes to the conditions imposed under our exemptive orders that, based on 26 years of experience regulating ETFs, we believe will improve the overall regulatory framework for these products.

1. Issuance and Redemption of Shares

Proposed rule 6c–11 would include several requirements in the paragraph defining ''exchange-traded fund,'' including a requirement that the ETF issue (and redeem) creation units to (and from) authorized participants in exchange for baskets and a cash balancing amount (if any).[168] As such, the proposed rule would seek to preserve the existing structure, reflected in our ETF exemptive orders, whereby only an authorized participant of an ETF may purchase creation units from (or sell creation units to) the ETF. This requirement is designed to preserve an orderly creation unit issuance and redemption process between ETFs and authorized participants. An orderly creation unit issuance and redemption process is of central importance to the arbitrage mechanism, which forms the basis for several of the proposed rule's exemptive provisions.

The proposed rule would define an authorized participant as a member or participant of a clearing agency registered with the Commission, which has a written agreement with the ETF or one of its service providers that allows the authorized participant to place orders for the purchase and redemption of creation units.[169] This definition differs from the definition of ''authorized participant'' we recently adopted in connection with Form N–CEN, which, in relevant part, defines the term as a broker-dealer that is also a member of a clearing agency registered with the Commission or a DTC Participant and has a written agreement with the ETF or one of its service providers that allows the authorized participant to place orders to purchase and redeem creation units of the ETF.[170] Our proposed definition also differs from the definition of authorized participant in our ETF exemptive orders and Form N–CEN, because it does not include a specific reference to an authorized participant's participation in DTC since DTC is itself a clearing agency.[171] We believe the definition that we are proposing remains largely consistent with our existing exemptive relief, while eliminating unnecessary terms. As discussed further below, we are proposing a corresponding amendment to Form N–CEN.[172]

The proposed rule would define the term ''creation unit'' to mean a specified number of ETF shares that the ETF will issue to (or redeem from) an authorized participant in exchange for the deposit (or delivery) of a basket and a cash balancing amount (if any).[173] In their exemptive applications, ETFs have stated that they would establish a specific creation unit size (*i.e.,* a minimum number of shares).[174] Creation unit aggregations may differ among ETFs based on an ETF's investment strategy, the type and availability of the assets in the basket, and the types of authorized participants (and other market participants) that are expected to engage in creation and redemption transactions with the ETF. For example, an ETF tracking a narrowly focused niche strategy may establish a smaller creation unit size than an ETF tracking a broad-based index, such as the S&P 500, in order to facilitate arbitrage. Accordingly, we do not believe it is necessary to mandate a particular maximum or minimum creation unit size for all types of ETFs. This approach is consistent with our 2008 proposal, and commenters who addressed this aspect of the 2008 proposal generally supported it.[175]

While we believe that creation unit sizes are an important component in effective arbitrage, we do not propose to expressly require, as we proposed in 2008, that an ETF establish creation unit sizes reasonably designed to facilitate arbitrage.[176] Commenters on this aspect of the 2008 proposal generally believed that the proposed standard was too vague and that an ETF would not have an incentive to establish creation unit sizes that would be too large or too small to facilitate effective arbitrage.[177] Some commenters also questioned the description of arbitrage embedded within the 2008 definition of creation unit on the basis that the definition did not capture all forms of arbitrage.[178]

As we noted in the 2008 proposal, a large creation unit size could reduce the willingness or ability of authorized participants (and other market participants) to engage in creation unit purchases or redemptions.[179] Impeding the ability of authorized participants to purchase and redeem ETF shares could disrupt arbitrage pricing discipline, which could lead to more frequent occurrences of premiums or discounts to NAV per share of the ETF. Conversely, a small creation unit size could discourage market making and render creation units irrelevant because the ETF could issue and redeem ETF shares much like a mutual fund.[180] We agree with the view that ETFs are not likely to have an incentive to set very large or very small creation unit sizes that could disrupt the arbitrage

[168] *See* proposed rule 6c–11(a). *See also infra* section II.C.5 (discussing definitions of baskets and cash balancing amount).

[169] Proposed rule 6c–11(a).

[170] *See* Instruction to Item E.2 of Form N–CEN. *See also* Reporting Modernization Adopting Release, *supra* footnote 147.

[171] *See, e.g.,* Legg Mason, *supra* footnote 160. The 2008 proposal would not have defined the term ''authorized participant'' because this term was not used in the definition of an ETF. *See* 2008 ETF Proposing Release, *supra* footnote 3 (defining ETF to mean, in relevant part, a registered open-end management company that issues (or redeems) creation units in exchange for the deposit (or delivery) of basket assets).

[172] *See infra* section II.J.

[173] Proposed rule 6c–11(a).

[174] *See, e.g.,* Legg Mason, *supra* footnote 160.

[175] *See* 2008 ETF Proposing Release, *supra* footnote 3; *see also, e.g.,* Comment Letter of James J. Angel (May 16, 2008); Comment Letter of Chapman and Cutler LLP (May 19, 2008) (''Chapman 2008 Comment Letter'').

[176] *See* 2008 ETF Proposing Release, *supra* footnote 3 (describing arbitrage, for these purposes, as ''the purchase (or redemption) of shares from the ETF with an offsetting sale (or purchase) of shares on a national securities exchange at as nearly the same time as practicable for the purpose of taking advantage of a difference in the Intraday Value and the [market price] of the shares.'').

[177] *See, e.g.,* Vanguard 2008 Comment Letter; BGFA 2008 Comment Letter. *But see* Xshares 2008 Comment Letter (''The proposal to 'establish creation unit sizes the number of which is reasonably designed to facilitate arbitrage' seems to describe the process that we apply when determining the basket size and is appropriate, as is the definition of arbitrage.'').

[178] *See* ICI 2008 Comment Letter; Katten 2008 Comment Letter.

[179] *See* 2008 Proposing Release, *supra* footnote 3.

[180] *See id.*

mechanism and that an ETF would establish a size that is appropriate for market demand given its investment strategies and objectives. Moreover, we believe that the conditions in the proposed rule designed to promote effective arbitrage are better suited for that purpose than conditions related to creation unit size.

An ETF generally would issue and redeem shares only in creation unit size aggregations under the proposed rule. However, the proposed rule would permit an ETF to sell or redeem individual shares on the day of consummation of a reorganization, merger, conversion or liquidation.[181] In a merger, for example, an acquired ETF typically transfers substantially all of its assets to a surviving ETF in exchange for interests in the surviving ETF. We understand that, under these limited circumstances, a surviving ETF may need to issue shares, not necessarily in creation unit aggregations, to shareholders of the acquired ETF without utilizing authorized participants. Similarly, an ETF may need to issue individual shares in connection with a reorganization, conversion, or liquidation. We also understand that the redemptions that take place in connection with these transactions are generally intended to facilitate the transactions themselves and compensate individual shareholders that may be exiting the reorganized, merged, converted or liquidated ETF—activities likely to involve small cash amounts and to be outside the scope of an authorized participant's expected role of transacting in creation units. We believe that permitting ETFs to conduct redemptions with investors other than authorized participants in these limited circumstances is operationally necessary to facilitate reorganizations, mergers, conversions or liquidations. Permitting ETFs to transact with other investors in these limited circumstances also is consistent with prior exemptive relief, which permits ETF shares to be individually redeemable in connection with the termination of an ETF.[182]

An additional issue related to the issuance and redemption of ETF shares is the extent to which an ETF may directly or indirectly suspend these processes. An ETF that suspends the issuance or redemption of creation units indefinitely could cause a breakdown of the arbitrage mechanism, resulting in significant deviations between market price and NAV per share. Such deviations may be harmful to investors that purchase shares at market prices above NAV per share and/or sell shares at market prices below NAV per share. An ETF may suspend the redemption of creation units only in accordance with section 22(e) of the Act,[183] and an ETF may charge transaction fees on creation unit redemptions only in accordance with 17 CFR 270.22c–2 (''rule 22c–2'').[184] In addition, we believe an ETF generally may suspend the issuance of creation units only for a limited time and only due to extraordinary circumstances, such as when the markets on which the ETF's portfolio holdings are traded are closed for a limited period of time.[185] We also believe that an ETF could not set transaction fees so high as to effectively suspend the issuance of creation units.

We request comment on this requirement.

- Should we require, as proposed, that an ETF issue (and redeem) creation units to (and from) authorized participants in exchange for baskets and a cash balancing amount if any? Are there alternative formulations that we should consider? Does this provision facilitate the arbitrage mechanism?
- Should we define ''authorized participant'' as proposed? Should other criteria apply? For example, should the definition require authorized participants to be registered broker-dealers?
- Instead of amending the definition of ''authorized participant'' in Form N–CEN as proposed below in order to correspond with proposed rule 6c–11, should we use the existing Form N–CEN ''authorized participant'' definition for rule 6c–11? Should we have the same definition of ''authorized participant'' for both rule 6c–11 and Form N–CEN? Would different definitions cause confusion or operational difficulties?
- Do commenters agree with our understanding that ETFs are not likely to have an incentive to set very large or very small creation unit sizes that could disrupt the arbitrage mechanism?
- Should we establish requirements for creation unit sizes and/or dollar amounts? Alternatively, should we establish a standard for how ETFs must establish creation unit sizes? If so, what standard should be established? Do differently sized creation units present different operational challenges? If so, please explain these challenges, and provide data to support such a view.
- Would institutional investors engage in more create/redeem transactions with an ETF, through an authorized participant, if the ETF established a smaller creation unit size? If so, what are the costs and benefits of this result? Would it impact the efficiency of the ETF's arbitrage mechanism? If so, how?
- Should we permit an ETF to sell or redeem individual shares on the day of consummation of a reorganization, merger, conversion or liquidation as proposed? Should we define any or all of the terms ''reorganization,'' ''merger,'' ''conversion'' and ''liquidation'' for purposes of this condition? If so, how should those terms be defined? For example, as an alternative, should we consider the definition for ''merger'' in 17 CFR 270.17a–8 (''rule 17a–8'' under the Act)?[186] Are there other circumstances or transactions that should be included within this provision? For example, should we specify in this provision that shares may be issued other than in creation unit size aggregations as part of a dividend reinvestment program? Is any additional relief needed to conduct these transactions? Should the relief be limited to the day of consummation of the transaction, as proposed? Should the relief be limited in time at all? Should more time be provided? If so, how much time?
- Do commenters generally agree that an ETF may suspend creations only in limited circumstances? Do commenters generally agree that an ETF could not set transaction fees so high as to effectively suspend the issuance of

[181] *See* proposed rule 6c–11(c)(5).

[182] *See, e.g.,* Application of FFCM, LLC, *et al.* (June 12, 2017), at n.23 (''Therefore, in the event of a termination, the Board in its discretion could determine to permit the Shares to be individually redeemable. In such circumstances, the Fund might elect to pay cash redemptions to all shareholders, with an 'in-kind' election for shareholders owning in excess of a certain stated minimum amount.'').

[183] Section 22(e) of the Act permits open-end funds to suspend redemptions and postpone payment for redemptions already tendered for any period during which the New York Stock Exchange is closed (other than customary weekend and holiday closings) and in three additional situations if the Commission has made certain determinations. *See* LRM Adopting Release, *supra* footnote 101, at n.36.

[184] *See supra* footnote 24 and accompanying text. Rule 22c–2 limits redemption fees to no more than 2% of the value of shares redeemed. *See* rule 22c–2(a)(1)(i). In other contexts, the Commission has limited redemption fees paid by redeeming shareholders, as well as swing pricing NAV adjustments, to no more than 2%. *See* Investment Company Swing Pricing, Investment Company Act Release No. 32316 (Oct. 13, 2016) [81 FR 82084 (Nov. 18, 2016)] (describing liquidity fees under rule 2a–7 and the swing factor upper limit under rule 22c–1).

[185] *See* Comment Letter of BlackRock on 2015 ETP Request for Comment (Aug. 11, 2015) (noting that suspensions of creations are rare, but an ETF could suspend creations when it is unable to increase its exposure to underlying assets, such as when a non-U.S. market suspends capital inflows).

[186] *See* rule 17a–8(b)(1) (defining ''merger'' as the ''merger, consolidation, or purchase or sale of substantially all of the assets between a registered investment company (or a series thereof) and another company'').

creation units? Is any additional guidance needed? Should we consider including provisions in rule 6c–11 that would permit ETFs to suspend creations or redemptions in particular circumstances?

2. Listing on a National Securities Exchange

Proposed rule 6c–11 defines ''exchange-traded fund,'' in part, to mean a fund that issues shares that are listed on a national securities exchange and traded at market-determined prices.[187] Exchange-listing is one of the fundamental characteristics that distinguishes an ETF from other types of open-end funds (and UITs) and is one reason that ETFs need certain exemptions from the Act and the rules thereunder. The Commission has premised all of its previous exemptive orders on an ETF listing its shares for trading on a national securities exchange.[188] Listing on an exchange provides an organized and continuous trading market for the ETF shares at market-determined prices. Trading on an exchange also is important to a functioning arbitrage mechanism. We proposed a similar condition in 2008 that would have required ETF shares to be approved for listing and trading on a national securities exchange.[189] Commenters on the 2008 proposal generally agreed that listing on an exchange would provide an organized and continuous trading market for the ETF shares.[190]

The proposed definition would require that the ETF's shares be traded at market-determined prices. Like other exchange-traded equity securities, however, we understand that there may be instances where ETF shares simply may not trade for a given period due to a lack of market interest.[191] This proposed requirement is not designed to establish a minimum level of trading volume for ETFs necessary in order to rely on the rule, but rather to distinguish ETFs from other products that are listed on exchanges, but trade at NAV-based prices (*i.e.,* exchange-traded managed funds).[192]

An ETF that is delisted from a national securities exchange would not meet the definition of ''exchange-traded fund,'' and would no longer be eligible to rely on the proposed rule. Such a fund thus would be required to meet individual redemption requests within seven days pursuant to section 22(e) of the Act or liquidate.[193] We requested comment in the 2008 proposal on whether the rule should include an exception for ETF shares that are delisted for a short time or suspended from listing.[194] Commenters generally did not support such an exception, asserting that it would be difficult for the Commission to identify all of the circumstances in which such an exception would be appropriate, and recommended that ETFs seek individual exemptive relief from the listing requirement under these circumstances.[195] We are not aware of any ETF requesting an order that omits the requirement that its shares be listed on an exchange. Therefore, we do not propose to include an exemption for ETFs whose shares are suspended or delisted.

We request comment on this requirement.

- Should the rule make allowance for shares that are delisted for a short time, or for halts or suspensions in trading? If so, how would the arbitrage mechanism function in these circumstances?

3. Intraday Indicative Value

Exchange listing standards include a requirement that an intraday estimate of an ETF's NAV per share (an ''intraday indicative value'' or ''IIV'') be widely disseminated at least every 15 seconds during regular trading hours (60 seconds for international ETFs).[196] Our orders also require the dissemination of the IIV, and ETFs have stated in their exemptive applications that an ETF's IIV is useful to investors because it allows them to determine (by comparing the IIV to the market value of the ETF's shares) whether and to what extent the ETF's shares are trading at a premium or discount.[197] We are not proposing, however, to require the dissemination of an ETF's IIV as a condition of the proposed rule. We understand that market makers today typically calculate their own intraday value of an ETF's portfolio with proprietary algorithms that use an ETF's daily portfolio disclosure and available pricing information about the assets held in the ETF's portfolio.[198] We further understand that they generally use the IIV, if at all, as a secondary or tertiary check on the value that their proprietary algorithms generate.[199]

We believe that the IIV is no longer used by market participants when conducting arbitrage trading. In today's fast-moving markets, 15 seconds is likely too long for purposes of efficient market making and could result in poor execution.[200] An ETF's current value changes every time the value of any underlying component of the ETF portfolio changes. Therefore, the IIV for a more frequently traded component security might not effectively take into account the full trading activity for that security, despite being available every 15 seconds. In particularly volatile

[187] Proposed rule 6c–11(a). For purposes of the rule, a ''national securities exchange'' would be defined as an exchange that is registered with the Commission under section 6 of the Exchange Act.

[188] *See, e.g.,* PowerShares Capital Management LLC, *et al.,* Investment Company Act Release Nos. 28140 (Feb. 1, 2008) [73 FR 7328 (Feb. 7, 2008)] (notice) and 28171 (Feb. 27, 2008) (order) and related application (''PowerShares'').

[189] *See* 2008 ETF Proposing Release, *supra* footnote 3.

[190] *See, e.g.,* NYSE Arca 2008 Comment Letter; SSgA 2008 Comment Letter.

[191] Based on staff analysis of data obtained from Bloomberg, approximately 5% of ETFs do not trade on the secondary market on a given trading day.

[192] Proposed rule 6c–11 would not apply to exchange-traded managed funds (ETMFs), which are not ETFs, but rather hybrids between mutual funds and ETFs. Unlike ETFs, secondary market transactions in ETMFs do not occur at a market-determined price. Rather, they occur at the next-determined NAV plus or minus a market-determined premium or discount that may vary during the trading day. *See* Eaton Vance Management, *et al.,* Investment Company Act Release Nos. 31333 (Nov. 6, 2014) [79 FR 67471 (Nov. 13, 2014)] (notice) and 31362 (Dec. 2, 2014) (order) and related application.

[193] Indeed, an ETF that does not comply with the provisions of the rule would be required to comply with the Investment Company Act in all respects unless it was relying on other relief.

[194] *See* 2008 ETF Proposing Release, *supra* footnote 3, at text following n.94.

[195] BGFA 2008 Comment Letter; ICI 2008 Comment Letter.

[196] *See, e.g.,* NYSE Arca Equities Rule 5.2–E(j)(3), Commentary .01(c) (stating that the IIV may be based upon ''current information regarding the required deposit of securities and cash amount to permit creation of new shares of the series or upon the index value''); *see also supra* footnote 14 and accompanying text. The IIV is also sometimes referred to as the ''iNAV'' (indicative net asset value) or the ''PIV'' (portfolio indicative value).

[197] *See, e.g.,* 2006 WisdomTree Investments, *supra* footnote 66.

[198] David J. Abner, *The ETF Handbook: How to Value and Trade Exchange Traded Funds* (2010), at 90 (''Since stock trading now takes place in microseconds, a lot can happen between two separate 15-second quotes. Professional traders are not using the published IIVs as a basis for trading. Most, if not all, desks that are trading ETFs are calculating their own [NAV of the ETF] based on real time quotes . . . that they are generating within their own systems.'').

[199] *See, e.g.,* Spruce ETF Trust, *et al.,* Investment Company Act Release Nos. 31301 (Oct. 21, 2014) [79 FR 63964 (Oct. 27, 2014)] (notice) and 31337 (Nov. 14, 2017) (order permitting withdrawal of application) and related application (withdrawn).

[200] *See, e.g.,* Gary Gastineau, *How to Minimize Your Cost of Trading ETFs, ETF.com* (June 22, 2009), *available at http://www.etf.com/publications/journalofindexes/joi-articles/6042-how-to-minimize-your-cost-of-trading-etfs.html,* at Figure 2 and related discussion. *See also* Comment Letter of ICI on NASDAQ proposed rule change relating to iNAV pegged orders for ETFs, File No. SR–NASDAQ–2012–117 (Nov. 8, 2012), at 4 (''Professional equity traders operate at speeds calculated in fractions of a second. In such markets, 15 seconds can be an eternity, and establishing an order price based on data that is nearly 15 seconds old could result in poor execution.'').

markets, the dissemination lag of the IIV may not reflect the actual value of the ETF.[201]

The IIV also may not reflect the actual value of an ETF that holds securities that do not trade frequently. For example, the IIV can be stale or inaccurate for ETFs with foreign securities or less liquid debt instruments. For such ETFs, there may be a difference in value between the IIV, which is constructed using the last available market quotations or stale prices, and the ETF's NAV, which uses fair value when market quotations are not readily available.[202] Moreover, because there currently are no uniform methodology requirements, the IIV can be calculated in different, and potentially inconsistent, ways.

Several commenters to the 2008 ETF Proposing Release, which would have included an IIV dissemination requirement, agreed that market professionals no longer rely on the exchange-published IIV.[203] Commenters on the 2015 ETP Request for Comment also stated that the IIV is not always reliable, and in some cases is misleading, particularly when the underlying holdings are less liquid, or, in the case of certain international ETFs, not traded during the same hours as the ETF shares.[204]

As discussed below, we are proposing that rule 6c–11 condition its relief on the daily disclosure of portfolio holdings. We believe that this disclosure would promote the availability of information to market participants to support their ability to calculate an estimated intraday value of the ETF's portfolio holdings using their own methodologies. Therefore, the proposed rule would not include a requirement for IIV dissemination.

We request comment on this aspect of our proposal.

- Should proposed rule 6c–11 condition relief on dissemination of the IIV? If so, who should be required to disseminate the IIV? The national securities exchange on which the ETF is listed? Other entities?
- Are we correct in our understanding that market participants today typically calculate their own intraday values of an ETF portfolio by utilizing proprietary algorithms?
- Do market participants use the published IIV for any purpose, whether or not related to its original purpose of facilitating arbitrage? For example, do some market participants use the IIV as a secondary or tertiary check on their internal calculations of an ETF's intraday value?
- Do retail investors use or rely on the IIV, and if so, how? Do they use the IIV for international and fixed-income ETFs, and if so, how? Is there a risk that this information could be misleading in certain circumstances? Would omitting the IIV have a disparate impact on retail investors as opposed to more sophisticated market participants?
- Do the published IIVs provide an accurate indication of the value of ETFs' underlying holdings? Does the answer vary depending on the type of the ETF's underlying holdings? If we were to include a requirement to disseminate the IIV, should and can changes be made to improve its accuracy? For example, should we require that the IIV be disseminated at more frequent intervals? If so, how frequently (*e.g.,* every second, every five seconds)? Should we require that the IIV be disseminated for all ETFs or only specific types of ETFs?
- If we were to include an IIV requirement, should we establish a uniform method for calculation of the IIV for all ETFs relying on the rule? If so, what should that method take into account? How should fair valued securities be treated? Alternatively, should we prescribe methodologies for ETFs based on the types of portfolio holdings?
- If the IIV is no longer required pursuant to exemptive relief or regulation, would ETFs continue to publish this information? If so, should we require ETFs that voluntarily disseminate the IIV to follow certain prescribed methodologies? For example, should we require that these ETFs disseminate the IIV more frequently? If so, how frequently?

4. Portfolio Holdings

As discussed above, since the first exemptive order for an ETF, the Commission has relied on the existence of an arbitrage mechanism to keep the market prices of ETF shares at or close to the NAV per share of the ETF.[205] One mechanism that facilitates the arbitrage mechanism is daily portfolio transparency. Portfolio transparency provides authorized participants and other market participants with an important tool to facilitate valuing the ETF's portfolio on an intraday basis, which, in turn, would enable them to assess whether arbitrage opportunities exist. It also provides information necessary to hedge the ETF's portfolio. The ability to hedge is important because market makers generally trade to provide liquidity, balance supply and demand, and profit from arbitrage opportunities (without seeking to profit from taking a directional position in a security).[206] Without the ability to hedge, market makers may widen spreads or be reluctant to make markets because doing so may require taking on greater market risk than the firm is willing to bear. For this reason, to facilitate the ability of market makers to make markets in ETF shares, our exemptive orders have historically required ETFs to provide a certain degree of daily transparency.[207] Furthermore, Commission staff has observed that all ETFs that could rely on the proposed rule currently provide full transparency as a matter of industry market practice.

[201] *See Understanding iNAV, ETF.com, available at http://www.etf.com/etf-education-center/21028-understanding-inav.html http://www.etf.com/etf-education-center/21028-understanding-inav.html?nopaging=1*; Gary Gastineau, Exchange-Traded Funds Manual, 2nd Ed. (2010), at 200–202.

[202] Section 2(a)(41)(B) of the Act defines ''value'' as: ''(i) with respect to securities for which market quotations are readily available, the market value of such securities; and (ii) with respect to other securities and assets, fair value as determined in good faith by the board of directors.'' This definition also is used in rule 2a–4 under the Act as the required basis for computing a fund's current NAV per share. With daily portfolio disclosure, market participants can estimate fair value on their own for the holdings of current ETFs. 15 U.S.C. 80a–2(a)(41)(B).

[203] *See* BGFA 2008 Comment Letter; Xshares 2008 Comment Letter.

[204] *See* Schwab ETP Comment Letter, *supra* footnote 115, at 7 (''[A]s the ETF marketplace has expanded into such markets as fixed income, precious metals, and foreign securities the published data points can be potentially misleading when the reference asset the ETF is covering is not open for pricing or transactions . . . [t]he requirement for publication of the IIV every 15 seconds seems antiquated in the evolving electronic trading world in which we are currently immersed. Trading now occurs in micro and nano seconds and the lag between the published IIV value and real time quoting and trading has essentially made the calculation of limited worth even when the reference asset is open for pricing.''); Comment Letter of Eaton Vance Corp. to Request for Comment on Exchange-Traded Products (File No. S7–11–15) (Aug. 17, 2015) (stating that the IIV is ''frequently highly misleading'' as an indicator of current fund value and investor trading costs); *see also* John Spence, *ETFs Unfairly Blamed in Recent Market Drama,* USA Today (June 27, 2013), *available at https://www.usatoday.com/story/money/personalfinance/2013/06/27/etfs-criticism-investing/2464741/* (''[I]t's meaningless to compare the share price of any international equity ETF with a stale NAV based on stock prices that are several hours old.'').

[205] *See supra* section I.B.

[206] *See* Stanislav Dolgopolov, *Regulating Merchants of Liquidity: Market Making From Crowded Floors to High Frequency Trading,* 18 U. of Penn Journal of Business Law 3 (2016), at 652 (''[T]he distinguishing feature of a market maker is being 'pretty well always even.'").

[207] Exemptive orders for actively managed ETFs and recent orders for index-based ETFs with an affiliated index provider have required full portfolio transparency. Exemptive orders for index-based ETFs with an unaffiliated index provider have required publication of the ETF's baskets.

a. Transparency of Portfolio Holdings

Proposed rule 6c–11 would require an ETF to disclose prominently on its website, which is publicly available and free of charge, the portfolio holdings that will form the basis for each calculation of NAV per share.[208] The portfolio holdings disclosure must be made each business day before the opening of regular trading on the primary listing exchange of the ETF's shares and before the ETF starts accepting orders for the purchase or redemption of creation units.[209] For portfolio transparency to facilitate effective arbitrage, authorized participants or other market participants buying or selling ETF shares, whether on the secondary market or in a primary transaction, should have access to portfolio composition information at the time of the transaction. The proposed rule's timing requirements, therefore, are designed to prevent an ETF from disclosing its portfolio holdings only after the beginning of trading or after the ETF has begun accepting orders for the next business day.

In addition, the proposed rule would require the portfolio holdings that form the basis for the ETF's NAV calculation to be the ETF's portfolio holdings as of the close of business on the prior business day.[210] Changes in an ETF's holdings of portfolio securities would therefore be reflected on a T+1 basis. This condition is consistent with current ETF practices and enables an ETF to disclose at the beginning of the business day the portfolio that will form the basis for the next NAV calculation, helping to facilitate the efficient functioning of the arbitrage process.[211]

We believe that portfolio transparency is an effective means to facilitate the arbitrage mechanism. As noted above in our discussion of the IIV, authorized participants and other market participants today calculate the value of an ETF's net assets with proprietary algorithms that use an ETF's daily portfolio disclosure and available pricing information about the assets held in the ETF's portfolio on an ongoing basis during the course of the trading day. This information allows market participants to identify instances where an arbitrage opportunity exists and to effectively hedge their positions.

The 2008 proposal would have required actively managed ETFs to disclose the identities and weightings of the portfolio securities and other assets held by the ETF on the ETF's website each business day (*i.e.* full portfolio transparency). By contrast, index-based ETFs would have been required to have a stated investment objective of obtaining returns that correspond to the returns of a securities index, whose provider discloses on its website the identities and weightings of the component securities and other assets of the index (*i.e.* index transparency).[212] Commenters on that proposal generally concurred with the importance of transparency to the arbitrage mechanism and supported including a transparency requirement in the proposed rule.[213] Some commenters, however, asserted that index transparency may not be effective for ETFs whose portfolios sample an index or include holdings in proportions that are different from those in the index.[214] These commenters urged the Commission to consider alternative approaches, including permitting index-based ETFs to disseminate the identities and weightings of the securities in the basket, if the basket is a representative sample of the portfolio.[215]

We are proposing to require full transparency for all ETFs under this rule rather than proposing alternative transparency requirements for index-based ETFs or actively managed ETFs.[216] We generally agree with commenters on the 2008 proposal that portfolio transparency provides more detailed information than the index alone when an index-based ETF utilizes sampling techniques or holds derivatives or other instruments and, as noted above, all ETFs that could rely on the proposed rule already provide full portfolio transparency as a matter of market practice. Full portfolio transparency also may be useful for investors when they are determining the efficacy of an index-based ETF tracking a particular index because performance of two ETFs tracking the same index can differ based on sampling practices.[217] Similarly, where the primary information used to support the arbitrage mechanism is information about holdings, full portfolio transparency may be more helpful to market makers modelling ETFs that seek to track highly customized or bespoke indexes.

We seek comment on the portfolio transparency condition of the proposed rule.

- Should the rule include other transparency options? For example, should we have different transparency requirements for index-based ETFs and actively managed ETFs, similar to those proposed in 2008? Would disclosure of an index's constituents alone provide detailed enough information to allow market participants to effectively hedge the ETF's portfolio when an index-based ETF utilizes sampling techniques or holds derivatives or other instruments? Do index providers make information about index constituents easily accessible today? Are there other alternatives we should consider? For example, would disclosure of an ETF's basket provide a basis for effective hedging? In setting forth an option, please explain how your proposed level of transparency would allow effective arbitrage.

[208] Proposed rule 6c–11(c)(1)(i)(A). *See also* proposed rule 6c–11(a) (defining the term ''portfolio holdings'' to mean the securities, assets, or other positions held by the ETF). For purposes of this proposed requirement, as well as other requirements to disclose information on a publicly available website under proposed rule 6c–11, we believe that an ETF should not establish restrictive terms of use that would effectively make the disclosures unavailable to the public or otherwise difficult to locate. For example, the proposed required website disclosure should be easily accessible on the website, presented without encumbrance by user name, password, or other access constraints, and should not be subject to usage restrictions on access, retrieval, distribution or reuse. We also would encourage ETFs to consider whether there are technological means to make the disclosures more accessible. For example, today, ETFs could include the portfolio holdings information in a downloadable or machine-readable format, such as comma-delimited or similar format.

[209] For these purposes, ''business day'' is defined as any day the ETF is open for business, including any day when it satisfies redemption requests as required by section 22(e) of the Act. *See* proposed rule 6c–11(a).

[210] *See* proposed rule 6c–11(c)(2). Pursuant to this condition, an ETF would not be permitted to reflect portfolio changes on a T+0 basis, notwithstanding the ability to do so under rule 2a–4 under the Act.

[211] *See, e.g.,* Morgan Stanley ETF Trust, *et al.,* Investment Company Act Release Nos. 32484 (Feb. 21, 2017) [82 FR 11956 (Feb. 27, 2017)] (notice) and 32539 (Mar. 21, 2017) (order) and related application (''Morgan Stanley'').

[212] In the event the ETF tracks multiple indexes, the 2008 ETF Proposing Release would have permitted an ETF to provide full transparency like actively managed funds. *See* 2008 ETF Proposing Release, *supra* footnote 3.

[213] *See, e.g.,* BGFA 2008 Comment Letter.

[214] *See, e.g.,* ICI 2008 Comment Letter. *See also* Vanguard 2008 Comment Letter (opposing index transparency (as well as daily portfolio holdings disclosure) for index-based ETFs, voicing concerns about front running in the context of index-based ETFs).

[215] Commenters asserted that compliance with the index transparency requirement we proposed in 2008 would be difficult for ETFs that have licensing rights to an index that may preclude them from publicly disclosing the components of the index. *See, e.g.,* NYSE Arca 2008 Comment Letter; Comment Letter of Russell Investments (Aug. 27, 2008). Today, Commission staff, through conversations with ETF industry participants, understands the preference for this basket transparency approach to be significantly lessened.

[216] *See supra* section II.A.2.

[217] *See, e.g.,* Ben Johnson, *Assessing the Total Cost of ETF Ownership,* Morningstar Advisor (Apr. 12, 2017), *available at http://beta.morningstar.com/articles/802211/assessing-the-total-cost-of-etf-ownership.html.*

• Are there any circumstances that would prevent an index-based ETF from disclosing its portfolio holdings?
• Are we correct that all ETFs that could rely on the proposed rule currently provide full transparency as a matter of market practice?
• Would publicly available website disclosure of portfolio holdings be an effective way to convey this information? If not, what other means of disclosure should the rule require or permit? For example, should we allow ETFs to comply with the transparency condition by transmitting a portfolio composition file or ''PCF'' to a central clearing facility? Would this method provide information to enough market participants to facilitate the arbitrage mechanism? Would it give fair and equal access to all market participants? Should we require ETFs to provide daily portfolio holdings information to the Commission through other means, such as filing on EDGAR?
• Should proposed rule 6c–11 define ''publicly available'' for purposes of the website disclosure requirements? If so, what definition should we use? For example, should the rule require that all information publicly posted on a website pursuant to rule 6c–11 be and remain freely and persistently available and easily accessible by the general public on the ETF's website and that the information must be presented in an easily accessible manner, without encumbrance, and must not be subject to any restrictions, including restrictions on access, retrieval, distribution and reuse?
• Should we require ETFs to reflect changes in portfolio holdings no earlier than a T+1 basis as proposed? Is this condition necessary?
• Should we define ''business day'' as proposed or are there alternative definitions we should consider? Do commenters believe that ETFs are likely to calculate NAV per share more than once each business day in the future? If so, would a ''business day'' standard cause compliance challenges with the portfolio holdings disclosure requirements?
• Should the rule require that portfolio holdings disclosure be provided before the opening of regular trading on the primary listing exchange of the ETF's shares and before the ETF starts accepting orders for the purchase or redemption of creation units? Alternatively, should the rule exclude timing requirements? Are there operational issues that would make compliance with the timing requirements challenging or costly?
• Should we consider exemptions for ETFs with non-transparent or partially transparent portfolios as part of proposed rule 6c–11? Would a rule of general applicability be the appropriate means to provide an exemption for ETFs using a novel arbitrage mechanism?

b. Disclosure of Securities, Assets or Other Investment Positions

The proposed rule would require ETFs to disclose on their websites all portfolio holdings that will form the basis for the ETF's next calculation of NAV per share. Under the proposed rule, the term ''portfolio holdings'' is defined to mean an ETF's securities, assets, or other positions.[218] As a result, an ETF would be required to disclose its cash holdings, as well as holdings that are not securities or assets, including short positions or written options.[219] We believe that this approach would provide more consistent and comprehensive information regarding an ETF's portfolio holdings compared to other means of disclosure, allowing market participants to fairly and effectively value the entirety of the ETF's portfolio holdings. We believe this, in turn, would facilitate the arbitrage mechanism by allowing authorized participants and other market participants to more effectively hedge their exposure to a particular ETF.

In order to standardize the manner in which portfolio holdings are presented on the ETF's website, the proposed rule would require that portfolio holdings information be presented and contain information regarding description, amount, value and/or unrealized gain/loss (as applicable) in the manner prescribed within 17 CFR 210.12–12, 210.12–12A, 210.12–13, 210.12–13A, 210.12–13B, 210.12–13C, and 210.12–13D (''Article 12 of Regulation S–X''), which sets forth the form and content of fund financial statements.[220] This framework should be efficient for such disclosure because ETFs already comply with it for financial reporting purposes and track the relevant information for daily NAV calculations. Based on a staff review of ETF websites, there is currently little consistency regarding how portfolio holdings information is presented, particularly with respect to derivatives. We believe that this inconsistency may lead to investor confusion.[221]

The proposed rule would not require disclosure of intraday changes in the portfolio holdings of the ETF or advance disclosure of portfolio trades because changes in holdings would not affect the composition of the ETF's portfolio that serves as a basis for NAV calculation until the next business day.[222] The selective disclosure of nonpublic information regarding intraday changes in portfolio holdings and advance disclosure of portfolio trades, however, could result in the front-running of an ETF's trades, causing the ETF to pay more to obtain a security. We have stated that registered investment companies' compliance policies and procedures required by 17 CFR 38a–1 (''rule 38a–1'' under the Act) should address potential misuses of nonpublic information, including the disclosure to third parties of material information about a fund's portfolio, its trading strategies, or pending transactions, and the purchase or sale of fund shares by advisory personnel based on material, nonpublic information about the fund's portfolio.[223] ETFs are also required to describe their policies and procedures on portfolio security disclosure in the Statement of Additional Information and post such policies and procedures

[218] *See* proposed rule 6c–11(a).

[219] Under the proposed rule, for example, an ETF would have to disclose that it entered into a written call option, under which it would sacrifice potential gains that would result from the price of the reference asset increasing above the price at which the call may be exercised (*i.e.,* the strike price). Unless the ETF discloses the presence of these and similar liabilities, authorized participants and other investors may not be able to fully evaluate the portfolio's exposure.

[220] *See* 17 CFR 210.12–12, 210.12–12A, 210.12–13, 210.12–13A, 210.12–13B, 210.12–13C, and 210.12–13D. For investments in securities, securities sold short, and other investments, this would include the name of issuer and title of issue (as prescribed within the S–X schedules including any related footnotes on the description columns), balance held at close of period, number of shares, principal amount of bonds, and value of each item at close of period. For derivatives, this would include the description (as prescribed within the S–X schedules including any related footnotes), number of contracts, value, expiration date (as applicable), unrealized appreciation/depreciation (as applicable), and amount and description of currency to be purchased and to be sold (as applicable).

[221] We recognize that the generic listing standards for actively managed ETFs also currently require website disclosure of the ticker, CUSIP, description of the holding, and percentage of net assets for each portfolio holding. *See* NYSE Arca Rule 8.600–E(c)(2); Nasdaq Rule 5735(c)(2); Cboe BZX Rule 14.11(i)(3)(B).

[222] *See supra* footnote 208. None of our exemptive orders has required advance disclosure of intraday changes in the portfolio of the ETF or advance disclosure of portfolio trades. Instead, our orders have required ETFs to use the prior business day's portfolio holdings.

[223] Compliance Programs of Investment Companies and Investment Advisers, Investment Company Act Release No. 26299 (Dec. 17, 2003) [68 FR 74714 (Dec. 24, 2003)] (''Rule 38a–1 Adopting Release''). ETFs typically disclose (and would be required to disclose pursuant to proposed rule 6c–11) portfolio holdings information with greater frequency than other open-end funds, which are generally required to publicly disclose holdings on a quarterly basis.

on their websites.[224] As we noted in the release adopting these disclosures, a fund or investment adviser that discloses the fund's portfolio securities may only do so consistent with the antifraud provisions of the federal securities laws and the adviser's fiduciary duties.[225] Moreover, divulging nonpublic portfolio holdings to selected third parties is permissible only when the fund has legitimate business purposes for doing so and the recipients are subject to a duty of confidentiality, including a duty not to trade on the nonpublic information.[226]

We seek comment on this aspect of the proposed rule.

- Should we require ETFs to present the description, amount, value and unrealized gain/loss in the manner prescribed within Article 12 of Regulation S–X? Would such a presentation be more or less effective in disclosing portfolio holdings information than current website disclosure practices for ETFs? Do investors use current portfolio holding disclosures? Do current disclosure practices regarding portfolio holdings result in investor confusion? For example, do investors find the lack of consistency around the presentation of derivatives holdings confusing?
- Should we consider excluding any of the requirements in Article 12 of Regulation S–X? For example, is information regarding unrealized gain and loss useful for all ETFs? Should we only require that disclosure for ETFs that transact with authorized participants on a cash basis? Will disclosure of non-securities investment positions and assets permit investors, particularly authorized participants and other market participants engaged in arbitrage activities, to assess the full scope of the ETF's portfolio holdings?
- Is there any additional or alternative holdings information that we should require ETFs to disclose on their websites? For example, should we require daily disclosure regarding the ticker, CUSIP, or other identifier; sub-categories of holdings; and the percentage of net assets for each holding?
- Should ETFs be required to disclose all liabilities as part of their portfolio holding disclosure? For example, would disclosure of bank borrowings allow authorized participants and other market participants to evaluate the impact of leverage from these types of borrowings on the ETF's portfolio? How would the arbitrage mechanism work without this disclosure?
- Would the presentation requirements facilitate clear and uniform disclosure? Are there alternative presentation requirements we should consider? If so, what would those requirements be?
- The proposed rule would not require disclosure of intraday changes in the portfolio holdings of the ETF or advance disclosure of portfolio trades because changes in holdings would not affect the composition of the ETF's portfolio that serves as a basis for NAV calculation until the next business day. Should we require ETFs to disclose intraday changes in the portfolio or require advance disclosure of portfolio trades? Would such disclosure requirements improve transparency in a meaningful way? Would such disclosure requirements be costly to implement? Would an ETF or its investors suffer any harm if such information were disclosed? If so, how?
- Should we require ETFs to maintain portfolio holdings disclosure on their websites for periods longer than one day? If so, for how long (*e.g.,* 30 days)?
- ETFs trade in both portfolio assets (*e.g.,* when rebalancing) and creation units (when transacting with authorized participants). Does this raise any execution issues for ETFs? For example, how do ETFs prevent certain counterparties from receiving preferential treatment?[227] Are the policies and procedures noted above adequate to protect nonpublic information from misuse by authorized participants and other market participants that have access to ETF sensitive trade data? For example, how do ETFs ensure that authorized participants are not trading ahead of ETF rebalancing trades or other changes to its portfolio? Are there other requirements that we should adopt to protect ETFs and their investors? For example, should an ETF be required to maintain communications (including electronic communications) with its authorized participants?
- ETFs currently are not subject to Regulation FD, which prohibits the selective disclosure of information by publicly traded companies and other issuers.[228] Should we amend Regulation FD to apply to ETFs given that any information that is selectively disclosed may be immediately used to trade ETF shares (or the ETF's portfolio holdings) on the secondary market and given the proposed relief from section 17(a) for affiliated transactions?[229]

5. Baskets

Proposed rule 6c–11 would require each ETF relying on the rule to adopt and implement written policies and procedures governing the construction of baskets and the process that would be used for the acceptance of baskets.[230] In addition, the proposed rule would provide an ETF with the flexibility to use ''custom baskets'' if the ETF has adopted written policies and procedures setting forth detailed parameters for the construction and acceptance of custom baskets that are in the best interests of the ETF and its shareholders. The proposed rule also would require an ETF to disclose prominently on its website, which is publicly available and free of charge, information regarding a published basket that will apply to orders for the purchase or redemption of creation units each business day.[231] We believe that the conditions we are proposing related to baskets would provide ETFs with the ability to customize baskets in circumstances that would benefit the ETF and its investors, while at the same time putting in place protections against the potential for authorized participants to overreach by dictating the composition of baskets to the detriment of other ETF investors.[232]

[224] *See* Items 9(d) and 16(f) of Form N–1A; *see also* Disclosure Regarding Market Timing and Selective Disclosure of Portfolio Holdings, Investment Company Act Release No. 26418 (Apr. 20, 2004) [69 FR 22299 (Apr. 23, 2004)] (''Disclosure of Portfolio Holdings Release''), at section II.C.

[225] *See* Disclosure of Portfolio Holdings Release, *supra* footnote 224, at section II.C.

[226] *Id.*

[227] *See, e.g.,* Interpretive Release Concerning the Scope of Section 28(e) of the Securities Exchange Act of 1934 and Related Matters, Exchange Act Release No. 34–23170 (Apr. 28, 1986), at section V (discussing obligation of money manager to obtain best execution of client transactions).

[228] 17 CFR 243.

[229] Regulation FD does not apply to investment companies, other than closed-end funds. The releases proposing and adopting Regulation FD do not specifically discuss ETFs. *See* Selective Disclosure and Insider Trading, Investment Company Act Release No. 24209 (Dec. 20, 1999) [64 FR 72590 (Dec. 28, 1999)] (proposing release), at paragraph preceding n.54 (''Investment companies that are continually offering their securities to the public already are required to update their prospectuses to disclose material changes subsequent to the effective date of the registration statement or any post-effective amendment, and are not permitted to sell, redeem, or repurchase their securities except at a price based on their securities' net asset value. While we believe that Regulation FD would offer little additional protection to investors in these types of investment companies and therefore they should be excluded from its coverage, these considerations do not apply in the case of closed-end investment companies.''). *See also* Selective Disclosure and Insider Trading, Investment Company Act Release No. 24599 (Aug. 15, 2000) [65 FR 51716 (Aug. 24, 2000)] (adopting release).

[230] *See* proposed rule 6c–11(c)(3). The proposed rule would define ''basket'' to mean the securities, assets or other positions in exchange for which an ETF issues (or in return for which it redeems) creation units. *See* proposed rule 6c–11(a).

[231] *See* proposed rule 6c–11(c)(1)(i)(B).

[232] *See, e.g.,* proposed rule 6c–11(c)(2).

a. Basket Flexibility

Where an ETF uses in-kind creations and redemptions, the composition of the basket is an important aspect of the efficient functioning of the arbitrage mechanism.[233] Basket composition affects the costs of assembling and delivering the baskets that will be exchanged for creation units as well as the costs of liquidating basket securities when redeeming creation units. For example, the number of positions included in a basket, as well as the difficulty and cost of trading those positions, will affect the cost of basket transactions. A basket with hundreds of relatively small positions may prove less efficient than a basket with fewer positions.

Basket composition also is important to ETF portfolio management. Each in-kind creation or redemption increases or decreases positions in the ETF's portfolio. Managing the composition of a basket allows the ETF to add certain instruments to its portfolio during the creation process (by including those securities in the basket that it will accept in exchange for a creation unit), or, conversely, to remove certain portfolio holdings during the redemption process (by including them in a redemption basket while not accepting them in the creation unit). This can be an efficient way for a portfolio manager to execute changes in the ETF's portfolio because the manager can make the changes without incurring the additional expenses of trades in the market. When an ETF does not have flexibility to manage basket composition, however, it may result in undesired changes to the portfolio, such as the loss of desirable bonds when paying redemptions in kind.

The exemptive relief we have provided ETFs relating to baskets has evolved over time. Our earliest ETF orders for index-based ETFs organized as UITs provided that in-kind purchases of creation units were to be made using a basket of securities substantially similar to the composition and weighting of the ETF's underlying index.[234] Given the unmanaged nature of the UIT structure, a UIT ETF's basket generally reflected a *pro rata* representation of the ETF's portfolio.[235]

Early orders for ETFs organized as open-end funds included few explicit restrictions on baskets, and these orders did not expressly limit ETFs' baskets to a *pro rata* representation of the ETF's portfolio holdings.[236] Since approximately 2006, however, as the ETF industry grew and the Commission gained more experience with ETFs, our exemptive orders have placed tighter restrictions on ETFs' composition of baskets.[237] These orders expressly require that the ETF's basket generally correspond *pro rata* to its portfolio holdings, while identifying certain limited circumstances under which an ETF may use a non-*pro rata* basket.[238] Our recent exemptive orders, for example, permit ETFs to use baskets that do not correspond *pro rata* to the ETF's portfolio holdings when it is impossible to break up bonds beyond certain minimum sizes needed for transfer and settlement or where rounding is necessary to eliminate fractional shares.[239] The orders have allowed baskets to deviate from a *pro rata* representation where the basket includes positions that cannot be transferred in kind, such as ''to be announced'' transactions (''TBA transactions''), short positions, and derivatives.[240] We have also permitted index-based ETFs to use non-*pro rata* baskets where the ETF has determined to use representative sampling of its portfolio to create its basket,[241] and for temporary periods to replicate changes in the ETF's portfolio holdings as a result of the rebalancing of the ETF's securities market index.

Our recent exemptive orders also have permitted ETFs to specifically substitute cash for some or all of the securities in the ETF's basket in certain limited circumstances, including where the basket includes securities that are not eligible for trading due to local trading restrictions or are not available in sufficient quantity for purchases of creation units.[242] In addition, while most existing ETFs typically engage in creation and redemption transactions on an in-kind basis, we have permitted ETFs to use an all-cash basket.[243] Due to the limited transferability of certain financial instruments, some ETFs operate on a cash-only basis under their exemptive orders.[244]

The requirement that baskets correspond *pro rata* to the ETF's portfolio holdings, and the increasingly limited exceptions to the *pro rata* requirement, were designed to address the risk that an authorized participant could take advantage of its relationship with the ETF and pressure the ETF to construct a basket to be used only for that authorized participant and that favors the authorized participant to the detriment of the ETF's shareholders. For example, because ETFs rely on authorized participants to maintain the secondary market by promoting an effective arbitrage mechanism, an authorized participant holding less liquid or less desirable securities potentially could pressure an ETF into accepting those securities in its basket in exchange for liquid ETF shares (*i.e.,* dumping). An authorized participant also could pressure the ETF into including in its basket certain desirable securities in exchange for ETF shares tendered for redemption (*i.e.,* cherry-

[233] *See supra* section I.B.

[234] *See, e.g.,* SPDR, *supra* footnote 34.

[235] *See supra* section II.A.1. A UIT ETF could substitute cash for basket assets in certain limited circumstances. *See, e.g.,* SPDR, *supra* footnote 34.

[236] *See* WEBs Index Fund, Inc., *et al.,* Investment Company Act Release Nos. 23860 (June 7, 1999) [64 FR 31658 (June 11, 1999)] (notice) and 23890 (July 6, 1999) (order) and related application.

[237] *See, e.g.,* 2006 WisdomTree Investments, *supra* footnote 66; *see also infra* footnote 245 and accompanying paragraph.

[238] *See* 2006 WisdomTree Investments, *supra* footnote 66 (''[I]n limited circumstances and only when doing so would be in the best interest of a Fund as determined by the Advisor or Subadvisor, each Fund may designate Deposit Securities that may not be an exact pro rata reflection of such Fund's Portfolio Securities. For example, a Fund might designate a non-*pro rata* basket of Deposit Securities if one or more Portfolio Securities were not readily available, or in order to facilitate or reduce the costs associated with a rebalancing of a Fund's portfolio in response to changes in its Underlying Index.'').

[239] *See, e.g.,* Nationwide Fund Advisors, *et al.,* Investment Company Act Release Nos. 32727 (July 6, 2017) [82 FR 32214 (July 12, 2017)] (notice) and 32771 (Aug. 1, 2017) (order) and related application.

[240] *Id.* In the TBA market, lenders enter into forward contracts to sell agency mortgage-backed securities and agree to deliver such securities on a settlement date in the future. The specific agency mortgage-backed securities that will be delivered in the future may not yet be created at the time the forward contract is entered into. The purchaser will contract to acquire a specified dollar amount of mortgage-backed securities, which may be satisfied when the seller delivers one or more mortgage-backed securities pools at settlement. *See* LRM Adopting Release, *supra* footnote 101, at n.381.

[241] *See* Morgan Stanley, *supra* footnote 211. In this context, representative sampling means that the ETF's baskets do not reflect a *pro rata* representation of the ETF's portfolio but contain assets from the ETF's portfolio that have been determined by the ETF to constitute a representative sample of the portfolio. *See id.* Our exemptive orders have expressly limited the circumstances under which the ETF may use representative sampling to select its basket assets: (i) The sample must be designed to generate performance that is highly correlated to the performance of the ETF's portfolio; (ii) the sample must consist entirely of instruments that are already included in the ETF's portfolio; and (iii) the sample must be the same for all authorized participants on a given business day. *See id.*

[242] *See, e.g.,* J.P. Morgan Exchange-Traded Fund Trust, *et al.,* Investment Company Act Release Nos. 30898 (Jan. 30, 2014) [79 FR 6941 (Feb. 5, 2014)] (notice) and 30927 (Feb. 25, 2014) (order) and related application. These orders also generally require an ETF to use the same basket for both purchases and redemptions on a particular business day, subject to certain exceptions. *See, e.g., id.*

[243] *See, e.g.,* 2006 WisdomTree Investments, *supra* footnote 66.

[244] *See, e.g.,* ProShares Trust, *et al.,* Investment Company Act Release Nos. 27975 (Sept. 21, 2007) [72 FR 55257 (Sept. 28, 2007)] (notice) and 28014 (Oct. 17, 2007) (order) and related application.

picking). In either case, the ETF's other investors would be disadvantaged and would be left holding shares of an ETF with a less liquid or less desirable portfolio of securities. These abuses also could occur when a liquidity provider or other market participant engages in primary market transactions with the ETF by using an authorized participant as an agent.[245]

Based on our experience with ETFs, however, we recognize that there are many circumstances, in addition to the specific circumstances enumerated in our orders, where allowing baskets to differ from a *pro rata* representation or allowing the use of different baskets for different authorized participants could benefit the ETF and its shareholders. For instance, ETFs without basket flexibility typically are required to include a greater number of individual securities within their baskets when transacting in kind, making it more difficult and costly for authorized participants and other market participants to assemble or liquidate baskets.[246] This could result in wider bid-ask spreads and potentially less efficient arbitrage. In such circumstances, these ETFs may be at a competitive disadvantage to ETFs with greater basket flexibility. As a result, these differing conditions and requirements for basket composition in our exemptive orders may have created a disadvantage for newer ETFs that are subject to our more recent, stringent restrictions on baskets.

Moreover, we believe that certain exceptions to a *pro rata* basket requirement may help ETFs operate more efficiently. For example, a lack of basket flexibility may cause some ETFs, particularly fixed-income ETFs, to satisfy redemption requests entirely in cash in order to avoid losing hard-to-find securities and to preserve the ETF's ability to achieve its investment objectives.[247] ETFs that meet redemptions in cash may be required to maintain larger cash positions to meet redemption obligations, potentially resulting in cash drag on the ETF's performance. The use of cash baskets also may be less tax-efficient than using in-kind baskets to satisfy redemptions, and may result in additional transaction costs for the purchase and sale of portfolio holdings.[248]

We believe it is appropriate, therefore, to provide additional basket flexibility, subject to conditions designed to address concerns regarding the potential risk of overreaching. Additional basket flexibility potentially could benefit ETF investors through more efficient arbitrage and narrower bid-ask spreads, among other benefits.[249] Further, we believe that permitting the same level of basket flexibility for all ETFs relying on the rule would give a consistent structure to ETFs relying on the rule and would remove a barrier to entry for new ETFs.

As proposed, rule 6c–11 would require all ETFs relying on the rule to adopt and implement written policies and procedures that govern the construction of baskets and the process that will be used for the acceptance of baskets.[250] These policies and procedures would be required to cover the methodology that the ETF would use to construct baskets. For example, the policies and procedures should detail the circumstances when the basket may omit positions that are not operationally feasible to transfer in kind. The policies and procedures should detail when the ETF would use representative sampling of its portfolio to create its basket, and how the ETF would sample in those circumstances.[251] The policies and procedures also should detail how the ETF would replicate changes in the ETF's portfolio holdings as a result of the rebalancing or reconstitution of the ETF's securities market index, if applicable.

In addition to requiring that ETFs relying on the proposed rule adopt and implement policies and procedures regarding the composition of baskets, the proposed rule defines two particular types of baskets as ''custom baskets,'' which are subject to additional conditions designed to protect ETF investors. First, baskets that are composed of a non-representative selection of the ETF's portfolio holdings would be defined as custom baskets.[252] A non-representative selection of the ETF's portfolio holdings would include, but not be limited to, baskets that do not reflect: (i) A *pro rata* representation of the ETF's portfolio holdings; [253] (ii) a representative sampling of the ETF's portfolio holdings; or (iii) changes due to a rebalancing or reconstitution of the ETF's securities market index, if applicable.

Second, different baskets used in transactions on the same business day are defined as custom baskets under the proposed rule.[254] For example, if an ETF exchanges a basket with an authorized participant that reflects a representative sampling of the ETF's portfolio holdings and a different basket with either the same or another authorized participant that represents a different representative sampling, both baskets would be custom baskets. Similarly, if an ETF substitutes cash in lieu of a portion of basket assets for a single authorized participant, that basket would be a custom basket.

We believe the use of custom baskets presents an increased risk that the ETF may be subject to improper pressure by an authorized participant to create specific baskets that favor that authorized participant. For example, using a custom basket could give authorized participants more opportunities for cherry-picking, dumping, or other abuses, including the potential for manipulative trading in the underlying portfolio securities. The proposed rule includes heightened process requirements for ETFs that use custom baskets as a means to protect against these risks. We believe that requiring an ETF that relies on the proposed rule to adopt basket policies and procedures that include specified

[245] *See supra* footnote 22 and accompanying text.

[246] *See* Schwab ETP Comment Letter, *supra* footnote 115, at n.10 (''[W]e looked at the daily National Securities Clearing Corporation Portfolio Composition Files for three Fixed-Income ETFs that each seek to track the Barclays U.S. Aggregate Bond Index. The first ETF is subject to the *pro rata* requirement and on the August 7, 2015 trade date that ETF included 1,486 securities in its creation basket. The second and third ETFs are not subject to the *pro rata* requirement. In striking contrast, on the same trade date these two ETFs included only 64 and 56 securities in their creation baskets, respectively.'').

[247] As discussed above, many ETFs, including fixed-income ETFs, are permitted under their exemptive orders to satisfy redemptions entirely in cash where the ETF holds thinly traded securities, among other circumstances. *See, e.g.,* Pacific Investment Management Company LLC *et al.,* Investment Company Act Release Nos. 28723 (May 11, 2009) [74 FR 22772 (May 14, 2009)] (notice) and 28752 (June 1, 2009) (order) and related application.

[248] In-kind redemptions allow ETFs to avoid taxable events that arise when selling securities for cash within the ETF.

[249] *See infra* footnote 438 and accompanying paragraph; *see also infra* footnote 444 and accompanying text.

[250] *See* proposed rule 6c–11(c)(3). We note that ETFs already may have policies and procedures governing the construction of baskets in order to comply with the representations and conditions of their exemptive orders. These policies and procedures, however, would not have been subject to the requirements we are proposing for custom basket policies and procedures, which we discuss below.

[251] *See supra* footnote 38 for a discussion of sampling.

[252] *See* proposed rule 6c–11(a) (defining ''custom baskets'' to include baskets that are composed of a non-representative selection of the ETF's portfolio holdings).

[253] A basket that is a *pro rata* representation of the ETF's portfolio holdings, except for minor deviations when it is not operationally feasible to include a particular instrument within the basket, generally would not be considered a ''custom basket.''

[254] *See* proposed rule 6c–11(a) (defining ''custom baskets'' to include different baskets used in transactions on the same business day).

requirements is an appropriately tailored means to address concerns that authorized participants may overreach. Furthermore, we believe that the consistent implementation of custom basket policies and procedures would discipline the basket process and would act as a safeguard against potential cherry picking or dumping of unwanted securities by authorized participants.[255]

Under the proposed rule, an ETF using custom baskets must adopt policies and procedures that: (i) Set forth detailed parameters for the construction and acceptance of custom baskets that are in the best interests of the ETF and its shareholders, including the process for any revisions to, or deviation from, those parameters; and (ii) specify the titles or roles of the employees of the ETF's investment adviser who are required to review each custom basket for compliance with those parameters (''custom basket policies and procedures'').[256] Effective custom basket policies and procedures should provide specific parameters regarding the methodology and process that the ETF would use to construct or accept each custom basket. An ETF's custom basket policies and procedures should describe the ETF's approach for testing compliance with the custom basket policies and procedures and assessing (including through back testing or other periodic reviews) whether the parameters continue to result in custom baskets that are in the best interests of the ETF and its shareholders. The custom basket policies and procedures should be consistently applied and must establish a process that the ETF will adhere to if it wishes to make any revisions to, or deviate from, the parameters. In addition, ETFs should consider adopting reasonable controls designed to prevent inappropriate differential treatment among authorized participants.

As part of the custom basket policies and procedures, an ETF must specify the titles or roles of employees of the ETF's investment adviser who are required to review each custom basket for compliance with the parameters set forth in those policies and procedures. An ETF may want to consider whether employees outside of portfolio management should review the components of custom baskets before approving a creation or redemption. Finally, as discussed in more detail below in section II.D, the ETF would be required to create a record stating that each custom basket complies with the ETF's custom basket policies and procedures.[257]

We believe that the ETF's investment adviser is in the best position to design and administer the custom basket policies and procedures and to establish parameters that are in the best interests of the ETF and its shareholders.[258] The ETF's adviser (and personnel) would be familiar with the ETF's portfolio holdings and would be able to assess whether the process and methodology used to construct or accept a custom basket would be in the best interests of the ETF and its shareholders and whether a particular custom basket complies with the parameters set forth in the custom basket policies and procedures. We believe that these requirements would allow an ETF to establish a tailored framework for the utilization of custom baskets, while also requiring the ETF to put into place safeguards against abusive practices related to basket composition. Custom basket policies and procedures designed and utilized in the best interests of an ETF and its shareholders may help the ETF manage its portfolio more efficiently, facilitate the arbitrage mechanism for the ETF, provide liquidity in markets for the ETF's shares and/or the ETF's underlying portfolio holdings, or provide other benefits to the ETF.

In addition, ETFs currently are required by rule 38a–1 under the Act to adopt, implement and periodically review written policies and procedures reasonably designed to prevent violations of the federal securities laws.[259] An ETF's compliance policies and procedures should be appropriately tailored to reflect its particular compliance risks. An ETF's basket policies and procedures (including its custom basket policies and procedures), therefore, should be covered by the ETF's compliance program and other requirements under rule 38a–1.[260] For example, an ETF would be required to preserve the basket policies and procedures pursuant to the requirements of rule 38a–1(d)(1). We believe that the ETF's board of directors' oversight of the ETF's compliance policies and procedures, as well as their general oversight of the ETF, would provide an additional layer of protection for an ETF's use of custom baskets.

Our 2008 proposal did not expressly contemplate that an ETF would be permitted to substitute other securities in lieu of other basket assets.[261] Instead, the proposal noted that in some circumstances it may not be practicable, convenient or operationally possible for the ETF to operate on an in-kind basis, and indicated that a fund could substitute cash for some or all of the securities in the basket.[262] Commenters on this aspect of the 2008 proposal agreed with the definition of basket and did not recommend any modifications.[263]

Under proposed rule 6c–11, however, an ETF would be permitted to construct baskets using cash, securities, or other positions, provided that the ETF has satisfied the appropriate policies and procedures requirement (*i.e.,* the standard requirement or the heightened requirement for custom baskets). As noted above, the use of in-kind baskets can result in several advantages to an ETF and its investors, including tax efficiencies and transaction cost savings. We believe that this approach would provide ETFs with flexibility to cover operational circumstances that make the inclusion of certain portfolio securities and other positions in a basket operationally difficult (or impossible), while also facilitating portfolio management changes in a cost- and tax-efficient manner. We believe that an ETF's policies and procedures should include details regarding the

[255] In addition, in a highly competitive market, such as the market for ETFs, low performance or high tracking error would make ETFs undesirable for participants in both the primary and secondary markets. ETFs that do not guard closely against dumping and cherry-picking could have diminished performance or higher tracking error over time, which would likely cause flows out of the fund.

[256] Proposed rule 6c–11(c)(3)(i). We also are proposing to require ETFs to maintain records detailing the composition of each custom basket. *See infra* section II.D.

[257] *See* proposed rule 6c–11(d)(2)(ii).

[258] An investment adviser has a fiduciary duty to act in the best interests of a fund it advises. *See* section 36(a) under the Act. *See also, e.g., Rosenfeld* v. *Black,* 445 F.2d 1337 (2d Cir. 1971); *Brown* v. *Bullock,* 194 F. Supp. 207, 229, 234 (S.D.N.Y.), aff'd, 294 F.2d 415 (2d Cir. 1961); *In re* Provident Management Corp., Securities Act Release No. 5155 (Dec. 1, 1970), at text accompanying n.12; Rule 38a-1 Adopting Release, *supra* footnote 223, at n.68.

[259] *See* Rule 38a–1 Adopting Release, *supra* footnote 223.

[260] For example, rule 38a–1 requires a fund's chief compliance officer to provide a written report to the ETF's board of directors, no less frequently than annually, that addresses, among other things, the operation of the fund's compliance policies and procedures and any material changes made to those policies and procedures since the date of the last report and any material changes to the policies and procedures recommended as a result of the annual review of the policies and procedures. *See* rule 38a–1(a)(4)(iii)(A).

[261] The 2008 proposal would have defined the term ''basket assets'' as the securities or other assets specified each business day in name and number by an ETF as the securities or assets in exchange for which it will issue or in return for which it will redeem ETF shares. *See* 2008 ETF Proposing Release, *supra* footnote 3.

[262] *See id.,* at nn.120–121 (describing the circumstances in which an ETF may use cash in lieu of certain securities in the basket).

[263] *See, e.g.,* ICI 2008 Comment Letter.

circumstances in which cash, securities, or other positions would be substituted.

We seek comment on this aspect of the proposed rule.

- Is our proposed definition of ''baskets'' appropriate? Should the term exclude investments that are not securities or assets? Should the term exclude instruments that cannot be transferred in kind?
- Is our proposed requirement that all ETFs adopt written policies and procedures governing basket construction appropriate? Are there alternatives we should consider? For example, should we require only ETFs that use custom baskets to adopt policies and procedures? Or, instead of requiring ETFs to adopt policies and procedures governing basket construction generally and custom basket policies and procedures, should we adopt a single requirement that all ETFs adopt policies and procedures governing the construction of baskets? If so, what parameters should be placed on those policies and procedures? What parameters, if any, should we place on board oversight of the policies and procedures governing the construction of baskets?
- Instead of permitting basket flexibility as proposed, should we require baskets to reflect a *pro rata* representation of the ETF's portfolio holdings? Should we enumerate specific exemptions to the *pro rata* representation requirement? If so, what should those exemptions include? For example, should we include an exemption for an authorized participant prohibited from transacting in a certain basket security? Should we require baskets to be representative of the ETF's portfolio holdings according to some other criteria?
- Should we allow ETFs to utilize baskets that deviate from a *pro rata* representation of the ETF's portfolio holdings, but require ETFs to utilize the same basket for all transactions on a particular business day? If so, why?
- Do the proposed basket conditions appropriately address concerns of overreaching by authorized participants or other market participants, including those that are first- or second-tier affiliates identified in the rule? Should the proposed rule include any other conditions to minimize the potential risks of overreaching or other conflicts of interest by such affiliates? For example, should we limit the ability of an ETF to utilize a custom basket when an authorized participant or other market participant is an affiliate covered by the proposed exemption from section 17(a)?
- Is our proposed definition of ''custom basket'' appropriate? Alternatively, should the term encompass any basket that deviates from a *pro rata* representation of the identities and quantities of the portfolio holdings held by the ETF? Should we provide additional guidance regarding instances where the basket is composed of a non-representative selection of the ETF's portfolio? Should we include examples in the definition of ''custom baskets''?
- Are there any reasons to prohibit an ETF from using a custom basket? If so, what are they?
- Should we provide additional guidance or include additional requirements in the rule regarding the elements of effective custom basket policies and procedures? For example, should custom basket policies and procedures set forth the minimum number of positions that would be included in a custom basket? Should the custom basket policies and procedures set forth parameters regarding the effect of the custom basket on the value of the ETF's portfolio holdings, its tracking error (if applicable), and the portfolio's risks? Should these policies and procedures set forth the circumstances under which the ETF would substitute cash in lieu of portfolio holdings after considering the effect cash would have on performance, trading costs, and if accepting cash would have tax consequences? Should they set forth the parameters in which the ETF will accept odd-lot securities in a custom basket? Are there any other considerations that should be included? Alternatively, should we eliminate any or all of the considerations discussed above?
- Should we require an ETF to adopt policies and procedures that set forth detailed parameters for the construction or acceptance of custom baskets that are in the best interests of the ETF and its shareholders as proposed? Should we require the policies and procedures to include a process for any revisions to or deviation from the parameters as proposed? Are there other parameters we should consider? Should we require the custom basket policies and procedures to list the titles or roles of the employees who review each custom basket for compliance with the parameters as proposed? Should we provide guidance regarding how this review should be done in cases where the ETF is sub-advised? Should we require that this review be done only by employees outside of portfolio management? If so, which employees and why?
- As proposed, rule 6c–11 would require an ETF to create a record stating that each custom basket complies with the ETF's custom basket policies and procedures.[264] Should we establish any other recordkeeping requirements relating to basket flexibility?
- Should the proposed rule require the ETF's investment adviser to review the basket policies and procedures (including the custom basket policies and procedures) on an annual basis or with such frequency as the ETF's adviser deems reasonable and appropriate? Should the proposed rule include board reporting requirements? For example, should the proposed rule require the adviser to deliver an annual report to the ETF's board regarding the implementation of the basket policies and procedures?

b. Posting of a Published Basket

We also are proposing to require an ETF to post on its website information regarding a published basket at the beginning of each business day, as well as the estimated cash balancing amount if any.[265] We believe this disclosure would contribute to the efficiency of the arbitrage mechanism by providing authorized participants and other market participants with timely information regarding the contents of a basket that the ETF will accept for creations and redemptions each business day. This, in turn, would allow market participants to value the contents of the basket on an intraday basis to determine whether arbitrage opportunities exist. This information also permits market makers to compare the ETF's portfolio holdings with the basket.

In particular, we are proposing to require that an ETF publish on its website one basket that it would exchange for orders to purchase or redeem creation units to be priced based on the ETF's next calculation of NAV per share each business day.[266] This ''published'' basket must be disclosed before the opening of trading of the ETF's shares and before the ETF begins accepting orders for the purchase or redemption of creation units to be priced based on the ETF's next calculation of NAV.[267] This requirement is designed to mitigate possible inefficiencies in the arbitrage

[264] *See* proposed rule 6c–11(d)(2)(ii).

[265] *See* proposed rule 6c–11(c)(1)(i)(B) and (C). Under proposed rule 6c–11(a), the ''cash balancing amount'' would be defined as an amount of cash to account for any differences between the value of a basket and the NAV of a creation unit. Our ETF exemptive orders have recognized a cash balancing amount to reconcile any difference between the asset value of a creation unit and the value of the ETF's basket.

[266] *See* proposed rule 6c–11(c)(1)(i)(B).

[267] *See id.*

mechanism that could result from delaying the publication of an ETF's basket.[268]

Under this requirement, an ETF would publish a basket that it would accept if presented by any authorized participant in exchange for creation units (or present to an authorized participant redeeming creation units).[269] Accordingly, an ETF that planned to use only custom baskets on a particular business day (*e.g.,* a basket reflecting a non-representative selection of the ETF's portfolio holdings), would be required to post a custom basket as its ''published'' basket.

Because an ETF would be required to post only one published basket to comply with this condition, there may be occasions where an ETF would not post the contents of every custom basket. We considered proposing that ETFs be required to publish, after the close of trading on each business day, information regarding every basket used by the ETF to serve as an additional check against overreaching by authorized participants. However, we preliminarily believe that this requirement is an unnecessary additional burden, resulting in compliance and other operational costs for ETFs to review the information before it is posted. Instead, as discussed below in section II.D, we are proposing to require ETFs to maintain records detailing the composition of baskets, which would allow our staff to review an ETF's baskets as part of an examination.

The 2008 proposed rule did not require ETFs to disclose their baskets. We did note in that proposal, however, that basket disclosure was a widely adopted industry practice and facilitated effective arbitrage activity.[270] On this issue, commenters on the 2008 proposal stated that it was not necessary for the Commission to require ETFs to disclose their baskets because that information was available in the portfolio composition files provided each business day by ETFs to the National Securities Clearing Corporation (''NSCC'').[271] While this still may be true, the composition of an ETF's basket for a given day may be important information to not only authorized participants and large institutional investors (who, as NSCC members, have access to the daily portfolio composition files), but to other market participants as well. For example, the information allows investors to compare the ETF's baskets for a given day with its portfolio holdings, assists market participants who are building their intraday hedge (we understand that some market participants primarily look to the baskets rather than the whole portfolio), and is important for purposes of estimating any cash balancing amounts as it allows market participants to compare the basket to the whole portfolio. We also believe that this proposed basket disclosure requirement is sufficiently narrow to not impose a significant burden on ETFs because it requires only one basket-related disclosure each trading day, at the beginning of the day.

We request comment on this proposed requirement.[272]

- Are we correct that disclosure of an ETF's basket facilitates the arbitrage mechanism? Is an ETF's basket composition useful information to ETF investors in the secondary market?
- Should we require the posting of a basket as proposed? Should we provide additional guidance regarding what types of basket would constitute a published basket?
- Would the disclosure of one basket at the beginning of each business day provide enough information to all market participants about an ETF's basket composition, particularly for ETFs using custom baskets? Should we instead require ETFs to disclose each basket used on a given business day after the close of trading on the ETF's website? Would these approaches cause competitive concerns or cause significant operational challenges? What costs and benefits would be associated with a requirement to publish all baskets used each business day? Would such an approach allow better policing of potential overreaching by authorized participants?
- If an ETF is no longer willing to accept the basket posted on its website on a particular business day because of market events, should the rule require the ETF to post a replacement basket on the website that the ETF would accept?
- Our proposal is designed to strike a balance between process and oversight requirements (*i.e.,* policies and procedures governing basket construction) and disclosure requirements. Do commenters agree with this approach? Would additional basket transparency lessen the need for policies and procedures relating to basket composition? Is there a more appropriate balance between the two types of requirements that we should consider?
- Is our proposed definition of ''cash balancing amount'' appropriate?
- Should we require the disclosure of baskets on an ETF's website as proposed? Alternatively, should we allow ETFs to comply with the basket transparency condition by sending the portfolio composition file to a central clearing facility in accordance with current practices? What would be the costs or operational burdens of each approach? Would the website disclosure of this information benefit any market participants (including retail investors) that may not have access to the portfolio composition file? If so, how would market participants use this information?

6. Website Disclosure

There has been a significant increase in the use of the internet as a tool for disseminating information,[273] and we believe that many investors obtain information regarding ETFs on the ETFs' websites. Proposed rule 6c–11 therefore would require ETFs to disclose certain information on their websites as a condition to the rule.[274] As noted above, we believe that the arbitrage mechanism works more efficiently when certain data is publicly available to investors each trading day, and are therefore proposing ETF website disclosures in order to provide transparency of portfolio holdings and baskets.[275] In addition, we are proposing several website disclosure requirements that are designed to provide investors with key metrics to evaluate their investment and trading decisions in a format that is easily accessible and frequently updated. Specifically, the proposed rule would require disclosure regarding: (i) The ETF's NAV per share, market price, and premium or discount, each as of the end of the prior business day; (ii) bid-ask spreads; and (iii) historical information regarding premiums and discounts.

Some of these conditions are based on our exemptive relief, which has required ETFs to disclose on their

[268] As proposed, an ETF relying on the rule also would be required to disclose its portfolio holdings that will form the basis of the next calculation of NAV per share in this manner. *See* proposed rule 6c–11(c)(1)(i)(A).

[269] Our proposal does not prevent an ETF from changing the assets in a published basket to respond to market conditions after the basket is published.

[270] *See* 2008 ETF Proposing Release, *supra* footnote 3, at n.27 and accompanying text. Many exemptive orders also require ETFs to make basket information available on a daily basis. *See, e.g.,* Salt Financial, LLC, *et al.,* Investment Company Act Release Nos. 32974 (Jan. 23, 2018) [83 FR 4097 (Jan. 29, 2018)] (notice) and 33007 (Feb. 21, 2018) (order) (''Salt Financial'').

[271] *See, e.g.,* NYSE Arca 2008 Comment Letter.

[272] We request comment regarding additional proposed website disclosures at *infra* section II.C.6.

[273] *See, e.g.,* Reporting Modernization Adopting Release, *supra* footnote 147.

[274] Proposed rule 6c–11(c)(1).

[275] *See supra* sections II.C.4 and II.C.5.

websites certain information regarding their investments and operations, including quantitative information regarding discounts or premiums at which the ETF's shares trade on the secondary market.[276] Our orders have required ETFs to publicly disclose on their websites: (i) The prior business day's NAV per share; (ii) the market closing price or the midpoint of the bid-ask spread at the time of the calculation of NAV; and (iii) a calculation of the premium or discount of the market closing price or midpoint of the bid-ask spread against NAV per share.[277] Similarly, Form N–1A currently provides an ETF with the option to omit certain historical information regarding premiums and discounts from its prospectus and annual report if the disclosure is provided on its website.[278] Based on our experience overseeing ETFs, we are proposing additional website disclosure requirements that have not been part of our exemptive relief or Form N–1A requirements. We also are requesting comment regarding ways to better inform investors about intraday deviations between an ETF's market price and: (i) NAV per share; (ii) the contemporaneous value of its portfolio; or (iii) both. Each of the proposed website disclosures is discussed below.

a. Daily NAV, Market Price, and Premiums and Discounts

Proposed rule 6c–11(c)(1)(ii) would require ETFs to post on their websites, on each business day, the ETF's current NAV per share, market price, and premium or discount, each as of the end of the prior business day. This disclosure provides investors with a ''snapshot'' view of the difference between an ETF's NAV per share and market price on a daily basis. It is designed to alert investors to the relationship between NAV per share and the market price of the ETF's shares and that they may sell or purchase ETF shares at prices that do not correspond to NAV of the ETF. It also is designed to allow investors to compare this information across ETFs. For example, an investor using this information likely would notice that ETFs tracking emerging markets tend to have greater premiums or discounts than ETFs tracking broad-based domestic indexes. We believe that daily website disclosure of this information would promote transparency and help investors better understand the risk that an ETF's market price may be higher or lower than the ETF's NAV per share. We further believe that ETF investors use this information today, as ETFs currently provide this website disclosure pursuant to the terms of their exemptive orders.

This proposed requirement is consistent with our exemptive orders and generally consistent with our 2008 proposal, except we have changed the definition of ''market price''.[279] Proposed rule 6c–11 would define the term ''market price'' to mean: (i) The official closing price of an ETF share; or (ii) if it more accurately reflects the market value of an ETF share at the time as of which the ETF calculates current NAV per share, the price that is the midpoint of the national best bid and national best offer (''NBBO''), calculated as of the time NAV per share is calculated.[280]

The 2008 proposed rule would have defined ''market price'' only as the last price at which ETF shares trade on their principal U.S. trading market during a regular trading session. However, we believe that using the ''official closing price,'' as opposed to the ''closing market price,'' is a better measure of an ETF's market price, particularly in situations where the last trade of the day was not reflective of the actual market price (*e.g.,* due to an erroneous order). Exchanges have detailed rules regarding the determination of the official closing price of a security.[281] For example, if a listing exchange experiences a systems disruption and cannot conduct closing auctions, exchanges use their back-up procedures to determine the ''official closing price'' for the affected securities (such as relying on a backup exchange's closing auction). As a result, we preliminarily believe that using the ''official closing price'' provides a more precise measurement of an ETF's market price, including during disruptive market events.

Commenters on the 2008 ETF Proposing Release who addressed this aspect of the proposal opposed the proposed definition of market price because of concerns that the last price at which an ETF trades could be stale at the time as of which NAV per share is calculated.[282] These commenters suggested that ETFs instead be permitted to use the midpoint between the highest bid and the lowest offer at the time as of which the ETF's NAV is calculated.[283] We generally agree and, as a result, we are proposing to permit ETFs to use a price that is the midpoint of the NBBO as of that time, if it is more accurate.[284] Because security information processors calculate NBBO continuously during the trading day, NBBO has the benefit of being a verifiable third-party quote. We believe that this approach provides an appropriate degree of flexibility to an ETF when its last reported sales price may be stale, while at the same time providing a consistent and verifiable methodology for how ETFs determine market price.

As discussed in more detail below, the proposed definition of market price also differs from the definition currently used in Form N–1A.[285] Form N–1A defines ''market price'' as the last reported sale price or, if it more accurately reflects the current market value of the ETF's shares, ''a price within the range of the highest bid and lowest offer.'' [286] We believe specifying that an ETF must use the midpoint of the NBBO, rather than ''a price within the range of the highest bid and lowest offer'' still provides the ETF with flexibility in determining a market price for its shares that accurately reflects the shares' market value. At the same time, requiring ETFs to use the midpoint in these circumstances would mitigate the potential for gaming practices that could inaccurately minimize a deviation between market price and NAV per share when showing premiums and discounts.[287] We are proposing to amend Form N–1A to remove the definition of market price in that form

[276] *See, e.g.,* Barclays Global 2008, *supra* footnote 58.

[277] *See supra* footnote 134 and accompanying text.

[278] *See infra* section II.H.

[279] *See* 2008 ETF Proposing Release, *supra* footnote 3.

[280] *See* proposed rule 6c–11(a).

[281] *See, e.g.* Self-Regulatory Organizations; New York Stock Exchange LLC; NYSE MKT LLC; Notice of Filings of Amendment No. 1, and Order Granting Accelerated Approval of Proposed Rule Changes, as Modified by Amendment No. 1, to Provide for How the Exchanges Would Determine an Official Closing Price if the Exchanges are Unable to Conduct a Closing Transaction, Exchange Act Release No. 78015 (June 8, 2016) [81 FR 38747 (June 14, 2016)] (NYSE backup procedures).

[282] *See, e.g.,* Chapman 2008 Comment Letter (noting that shares of some smaller ETFs may not trade often or at all on a particular day); ICI 2008 Comment Letter (noting that closing price may be less accurate because the last trade occurred at a much earlier time than the time as of which NAV is calculated).

[283] *See, e.g.,* Chapman 2008 Comment Letter.

[284] *See* proposed rule 6c–11(a) (defining ''market price''); *see also* rule 600(b)(42) of Regulation NMS (defining NBBO). [17 CFR 242.600]. The NBBO represents the highest bid and lowest offer for an ETF share consolidated across all exchanges.

[285] *See infra* section II.H.1.

[286] *See* General Instruction A to Form N–1A.

[287] An ETF would use the market price of an ETF share in calculating premiums and discounts. *See* proposed rule 6c–11(a) (defining ''premium or discount'' to mean the positive or negative difference between the market price of an ETF share and the ETF's current NAV per share, expressed as a percentage of the ETF's current NAV per share).

as it would no longer be used in the same manner.[288]

We believe that the daily premium/discount disclosures (and calculation methodology) we are proposing would provide investors with useful information regarding ETFs that frequently trade at a premium or discount to NAV per share. For example, some ETFs have frequent deviations between closing market price and NAV per share. These ETFs typically hold non-U.S. securities and trade during hours when the markets for their non-U.S. holdings are closed, allowing the trading price of ETF shares to reflect expected changes in the next opening price of the non-U.S. holdings (*i.e.,* to help ''discover'' the price of the holdings). ETFs also may have greater premiums and discounts to the extent that there are greater transaction costs associated with assembling baskets. In addition, an ETF with less liquid portfolio holdings also may show a deviation between closing market price and NAV per share,[289] and an ETF with a less efficient arbitrage mechanism may frequently show this type of end of day deviation.[290]

We understand, however, that proposed premium/discount disclosure would not provide investors with information regarding intraday deviations between market prices and the next-calculated NAV or the contemporaneous value of the ETF's underlying securities, even if the deviation is significant. Some commentators have stated that the lack of disclosure regarding intraday deviations could, in some circumstances, be misleading.[291] For example, some ETFs had relatively large intraday deviations between market price and intraday indicative values on August 24, 2015 that were not reflected as a ''premium'' or ''discount'' because market price and NAV per share were tightly correlated by the end of the day.[292]

While we believe that additional information regarding intraday deviations could help ETF investors understand both the potential for intraday deviations and the circumstances under which deviations have occurred in the past, developing an accurate and cost-effective methodology to calculate intraday deviations for all types of ETFs is challenging. For example, there are many ways to calculate a market price metric, such as the average of execution prices on a business day or the midpoint of the NBBO measured at specific intervals during the course of the trading day. These measures, however, often do not provide a meaningful picture of intraday deviations because they can give outliers either outsized importance (in the case of averages), particularly for ETFs with low trading volume, or insufficient importance (in the case of medians). In addition, the systems necessary to calculate and track these measures can be complex and costly.

Similarly, developing an accurate measure of the contemporaneous value of the ETF's portfolio is complex. As we noted in our discussion of the IIV,[293] calculations of contemporaneous value can be stale or inaccurate for ETFs with foreign securities or less liquid debt instruments for which market quotations are not readily available. For such an ETF, a contemporaneous value calculated using last available market quotations or stale prices may show a premium/discount to any ETF share price that factors in fair valuations of the ETF's portfolio holdings. Moreover, without prescribed uniform methodology requirements, contemporaneous values can be calculated in different, and potentially inconsistent, ways and lead to non-comparable premium/discount disclosure. We request comment below on potential alternative calculations and disclosure requirements that could inform investors about intraday deviations.[294]

b. Bid-Ask Spread Disclosure

As discussed in more detail below, our proposed amendments to Form N–1A would include new requirements for an ETF to disclose information regarding bid-ask spreads on its website and in its prospectus.[295] Specifically, an ETF would be required to disclose the median bid-ask spread for the ETF's most recent fiscal year. A bid-ask spread is the difference between the highest price a buyer is willing to pay to purchase shares of the ETF (bid) and the lowest price a seller is willing to accept for share of the ETF (ask).[296] The proposed website disclosures are designed to inform investors that they may bear bid-ask spread costs when trading ETFs on the secondary market, which ultimately could impact the overall cost of the investment. We are concerned that investors may not be aware of the impact trading costs may have on their investments in ETFs,[297] and therefore, propose to require ETFs to disclose median bid-ask spread information pursuant to a prescribed methodology that would be set forth in Form N–1A. We believe that this information would provide ETF investors with greater understanding of these costs and would allow investors to compare this information across ETFs. Spread costs for ETFs can vary significantly, and disclosure regarding these costs could aid comparisons of ETFs pursuing similar investment strategies. We believe this information also would allow investors to better understand the costs of investing in an ETF.[298]

We are proposing to require the disclosure of the bid-ask spread information on an ETF's website to provide trading information that can help investors make better informed investment decisions in a format that is easily accessible and relied upon by a growing segment of investors. Given the importance of this information to understanding the total expenses an investor may bear when investing in an ETF, we preliminarily believe that bid-ask spread information also should be included in an ETF's prospectus. Without this bid-ask spread information, we preliminarily believe

[288] *See infra* section II.H.1.

[289] *See* LRM Adopting Release, *supra* footnote 101, at n.33 and accompanying text.

[290] *See id* at text following n.524 (''[S]hares of an ETF whose underlying securities are relatively less liquid may not be able to be counted on to provide liquidity to a fund investing in these shares during times of stress. In the case of a significant decline in market liquidity, if authorized participants were unwilling or unable to trade ETF shares in the primary market, and the majority of trading took place among investors in the secondary market, the ETF's shares could trade continuously at a premium or a discount to the value of the ETF's underlying portfolio securities.'').

[291] *See, e.g.,* Henry T.C. Hu and John D. Morley, *A Regulatory Framework for Exchange-Traded Funds,* 91 S. Cal. Law Review (forthcoming 2018) (''Hu and Morley'') at 53 (''While simplicity and other reasons help explain the SEC's decision to look only at the close and not intra-day performance, the result was an emphatically reassuring picture being presented to investors. As a result, an investor may have a misleading sense as to the true risks and returns of the ETF.'').

[292] *See supra* footnote 128 and accompanying text.

[293] *See supra* section II.C.3.

[294] Many ETFs provide qualitative disclosures in their prospectuses regarding the potential for periods of market volatility that could lead to deviations from NAV per share. *See, e.g., supra* footnote 126.

[295] *See* proposed amendment to Item 3 of Form N–1A. *See also infra* section II.H.2. for a discussion of the bid-ask spread disclosure requirements. We are also proposing to require ETFs to provide an interactive calculator that would provide investors with the ability to customize the hypothetical bid-ask spread disclosures in Item 3 of Form N–1A to the investor's specific investing situation. *See id.*

[296] *See* proposed amendment to Item 3 of Form N–1A.

[297] *See, e.g.,* Simon Constable, *How to Measure ETF Spreads,* The Wall Street Journal (Nov. 5, 2017), *available at https://www.wsj.com/articles/how-to-measure-etf-spreads-1509937200.*

[298] As discussed in more detail below, mutual fund investors typically do not incur bid-ask spread costs in connection with their investment in a mutual fund. *See infra* section II.H.2.

the fee and expense information provided in a prospectus may not always provide a complete picture of an investment's true costs and/or allow investors to easily compare prospectus disclosures across certain investment options.[299]

c. Historical Information Regarding Premiums and Discounts

We also are proposing to require that ETFs disclose on their websites historical information about the extent and frequency of an ETF's premiums and discounts. In particular, proposed rule 6c–11(c)(1)(iii) and (iv) would require an ETF to post on its website both a table and line graph showing the ETF's premiums and discounts for the most recently completed calendar year and the most recently completed calendar quarters of the current year. Alternatively, for new ETFs that do not yet have this information, the proposed rule would require the ETF to post this information for the life of the fund.

Currently, an ETF is required to disclose historical premium/discount information in its prospectus by providing tabular disclosure of the number of trading days during the most recently completed calendar year and quarters since that year ended on which the market price of the ETF shares was greater than the ETF's NAV per share and the number of days it was less than the ETF's NAV per share.[300] An ETF currently may omit the disclosure of specific premium/discount information in its prospectus or annual report if the ETF provides the information on its website and discloses in the prospectus or annual report a website address where investors can locate the information.[301] We believe that investors may find this tabular information helpful in understanding how often an ETF trades at a premium or discount and the size of such premiums and discounts and are proposing to require publication of a table on the ETF's website as part of proposed rule 6c–11.[302]

We additionally believe that graphic disclosure could assist some investors with understanding how the arbitrage mechanism performs for an ETF under various market conditions. Depending on a variety of factors, an ETF could have persistent premiums or discounts (or both) from the ETF's NAV. For example, certain classes of ETFs, such as those that invest in less liquid securities, like high-yield bonds, and securities that trade on international markets, have more persistent deviations in ETF share prices from the ETF's NAV.[303] Additionally, for certain types of ETFs, the disclosure may inform investors about the pricing of the ETF's portfolio holdings. ETFs holding foreign securities that are traded on markets that are closed during U.S. trading hours, for example, may have persistent premiums or discounts resulting from this timing differential. In other cases, a persistent deviation between market price and NAV per share could demonstrate inefficiencies in an ETF's arbitrage mechanism.[304]

While past performance cannot predict how an ETF will trade in the future, we believe that it is important that investors, and particularly retail investors, understand that certain classes of ETFs could have a larger and more persistent deviation from NAV, which could result in a higher cost to investors and a potential drag on returns. In addition to alerting secondary market investors that an ETF's NAV per share and market price may differ, these disclosures would provide information regarding the frequency and extent of these deviations. These disclosures thus would help investors understand the value of their investment and could help shape whether they want to invest in a particular ETF.

We believe that presenting the data as both a table and a line graph would provide investors with useful information in a variety of formats that are easy to view and understand, depending on the investor's preference. For example, investors may find the proposed tabular disclosure an easy to understand demonstration of how often the ETF traded at a premium or discount. However, the tabular disclosure does not allow investors to observe the degree of those deviations, particularly during periods of market stress. For example, two ETFs may have traded at a discount for the same number of days. One ETF's daily deviations could have been small with little effect on investors trading on those days, whereas the other ETF could have had significant discounts. These distinctions would not be apparent based on the required tabular disclosure, but would be observable with the graphic disclosure we are proposing. As a result, in order to assist investors with understanding an ETF's premiums and discounts, we are proposing both tabular and graphical representations of daily premium and discounts.[305] In order to eliminate potentially duplicative disclosure requirements, we are proposing to eliminate historical premium/discount disclosure requirements in Item 11(g)(2) and Item 27(b)(7)(iv) of Form N–1A.[306]

Proposed rule 6c–11(c)(1)(v) also would require any ETF whose premium or discount was greater than 2% for more than seven consecutive trading days to post that information on its website, along with a discussion of the factors that are reasonably believed to have materially contributed to the premium or discount. We propose that ETFs posting this information be required to post it on their websites on the trading day immediately following the day on which the ETF's premium or discount triggered this provision (*i.e.,* on the trading day immediately following the eighth consecutive trading day on which the ETF had a premium or discount greater than 2%) and maintain it on their websites for at least one year following the first day it was posted.

We believe that this proposed disclosure of information about ETFs' premiums and discounts would promote transparency regarding the significance and/or persistency of deviations between market price and NAV per share, and thus may permit investors to make more informed

[299] Required prospectus disclosures for open-end funds currently include shareholder fees such as sales charges and redemption fees, as well as annual fund operating expenses. *See* Item 3 of Form N–1A.

[300] Instruction 2 to Item 11(g)(2) of Form N–1A. ETFs are also required to include a table with premium/discount information in their annual reports for the five most-recently completed fiscal years. Item 27(b)(7)(iv) of Form N–1A.

[301] Item 11(g)(2) of Form N–1A; Item 27(b)(7)(iv) of Form N–1A. Although the time period required in the disclosure is different in the prospectus and annual report, ETFs are permitted to omit both disclosures by providing on their websites only the premium/discount information required by Item 11(g)(2) (the most recently completed fiscal year and quarters since that year).

[302] *See* proposed rule 6c–11(c)(1)(iii).

[303] *See* Hu and Morley, *supra* footnote 291, at 12 (noting that certain kinds of ETFs have much higher 95% confidence intervals of almost 600 basis points) (internal citations omitted).

[304] *See, e.g.,* Crystal Kim, *This Levered Gold Mining ETF Looks Super Scary,* Barrons (Apr. 20, 2017), *available at https://www.barrons.com/articles/this-levered-gold-mining-etf-looks-super-scary-1492700892* (linking an ETF trading at a significant premium to NAV to the ETF's suspension of creation units, and in turn, linking the suspension to the limited availability of certain investments the ETF needed to make in order to seek its investment objective).

[305] Under the proposal, the historical premium/discount information would be required for the most recently completed calendar year and the most recently completed calendar quarters of the current year. This period was chosen as it was consistent with existing requirements in Item 11(g)(2) of Form N–1A. We believe the time period would allow investors to readily observe the extent and frequency of deviations from NAV per share in a graphic format.

[306] *See infra* section II.H.4.

investment decisions. This information also may provide the market (and the Commission) with information regarding the efficiency of an ETF's arbitrage mechanism. As noted above, in the Commission's experience, the deviation between the market price of ETFs and NAV per share, averaged across broad categories of ETF investment strategies and over time periods of several months, has been relatively small.[307] Therefore, we believe that limiting this disclosure to ETFs that have a premium or discount of greater than 2% for more than seven consecutive trading days would serve to highlight potentially unusual circumstances when an ETF has a persistent premium or discount.[308]

Given the proposed threshold, we do not believe that many ETFs would be required to disclose this information.[309] However, there could be certain categories of ETFs that could be particularly affected. An ETF that invests in foreign securities, for example, may be more likely to experience a persistent deviation between market price and NAV per share given that many foreign markets are closed during the U.S. trading day. Such deviations may be pronounced if the market on which the ETF's underlying securities trade is closed.[310]

The proposed rule would require the disclosure to include a discussion of the factors that are reasonably believed to have contributed to the premium or discount. We believe that this requirement would provide secondary market investors with useful context for the disclosed deviations. In addition, we believe that requiring ETFs to maintain it on their website for at least one year following the first day it was posted would identify those ETFs that historically have had such an instance of persistent deviation between market price and NAV per share.[311]

We request comment on our proposed website disclosure requirements for ETFs.[312]

- Would the proposed website disclosures be useful in informing investors of certain ETF characteristics and risks? For example, would the disclosures alert investors to the relationship between NAV per share and the market price of the ETF's shares? Would they assist investors in understanding that they may sell or purchase ETF shares at prices that do not correspond to NAV per share of the ETF or that may reflect a premium or discount to NAV per share that is not in line with the typical premium or discount for the same ETF? Would they assist investors in assessing costs associated with premiums and discounts and/or bid-ask spreads? Would the proposed requirements promote the goals of enhancing transparency and encouraging market discipline on ETFs? Understanding that ETF investors would be required to access each ETF's website, would this information allow investors to compare data across ETFs? Should we require ETFs to present their disclosures in a structured format on their websites or in a filing with the Commission in order to facilitate comparisons among ETFs?
- To what extent would the proposed website disclosure requirements increase ETFs' costs or result in operational challenges?
- Should we require that information regarding NAV per share, market price, and premiums and discounts be posted on an ETF's website each business day as proposed? Should we specify the time by which such information must be posted? For example, should we require that an ETF post the information on its website before the opening of trading each business day?
- Should we define ''market price'' as proposed? Does the proposed definition provide ETFs with too much discretion in determining market price? Should we define market price using only the ''official closing price''? Is there an alternative price that we should require instead of ''official closing price'' that would more accurately reflect the ETF's share price at market close? Should we provide an alternative calculation of market price, by using the midpoint of the NBBO, as proposed? Is the midpoint of the NBBO an appropriate alternative? If not, what method is appropriate? Do ETFs and their service providers currently receive the NBBO for their securities? If not, what are the additional costs, if any, of receiving a NBBO quote? Should we require ETFs to disclose if, for example, they use the midpoint of the NBBO rather than the official closing price? Should we define an alternative closing price? For example, should we use a definition similar to the one used by NYSE ARCA?[313] Alternatively, should we adopt the definition of ''market price'' currently used in Form N–1A, which may provide even more discretion by not referencing the midpoint? What definition of market price would provide the most accurate presentation of market value? Would there be investor confusion because of the proposed change?
- Does calculating premiums and discounts using market close information provide investors with information they would use?
- Should we instead require a calculation and disclosure of an intra-day premium or discount as compared to the next-calculated NAV? How would investors use the disclosure of intraday deviations between market prices and the next-calculated NAV? Would such disclosure be costly and/or burdensome to produce? What calculation methodology should we require for this disclosure? For example, should we require ETFs to disclose information regarding the difference between: (i) The mean or median of execution prices on a business day; and (ii) the next-calculated NAV per share, in order to capture situations where deviations between market price and NAV per share significantly widened during the trading day, but were tightly correlated at the time as of which NAV is calculated? Alternatively, should we require ETFs to disclose information regarding the difference between: (i) The midpoint of the NBBO calculated every minute; and (ii) the next-calculated NAV? If so, should the midpoint of the NBBO be calculated more or less frequently? Are there other ways to calculate intraday market prices that would provide investors with meaningful information regarding intraday deviations between market price and NAV per share? If we require this type of disclosure, should it be in addition to, or an alternative of, current premium/discount disclosures? Alternatively, would 5th and/or 95th percentile data be useful in this context? How frequently should ETFs disclose

[307] *See supra* footnotes 119–120 and accompanying text.

[308] This belief is based on data obtained from Morningstar and Bloomberg.

[309] *See infra* footnote 477 and accompanying text.

[310] *See* Tom Lyndon, *China A-Shares ETFs Trading at Steep Discount to NAV,* ETF Trends (Jul. 9, 2015), *available at http://www.etftrends.com/2015/07/china-a-shares-etfs-trading-at-steep-discount-to-nav/* (reporting that U.S.-listed China A-shares ETFs were trading at a steep discount to the underlying market because of the fact that a significant number of companies stopped trading on China's mainland stock exchanges).

[311] We recognize that historical information relating to these deviations may not be predictive of future deviations, and request comment below regarding whether the rule should require ETFs to include a legend in proximity to the historical information warning of its limitations.

[312] For our specific requests for comment regarding an ETF's daily portfolio and basket website disclosure, see our discussions of those subjects, at *supra* sections II.C.4 and II.C.5, respectively.

[313] *See* NYSE Arca Rule 1.1(ll) (defining how official closing price is determined if the exchange does not conduct a closing auction or if a closing auction trade is less than a round lot); *see also* Securities Exchange Act Release No. 82907 (March 20, 2018) [83 FR 12980 (March 26, 2018)] (order).

information regarding intraday deviations between market prices and the next-calculated NAV? How long should ETFs be required to maintain this information on their website?

• Should we instead require calculation and disclosure of an intra-day premium or discount as compared to the contemporaneous value of the ETF's portfolio? How would investors use the disclosure of intraday deviations between market price and the contemporaneous value of the ETF's portfolio? Would such disclosure be costly and/or burdensome to produce? What calculation methodology should we require for this disclosure? For example, despite the limitations of the IIV in the context of arbitrage activity, could the IIV be useful for the measurement and long-term tracking of an ETF's intraday market prices? If so, should we prescribe a uniform methodology for the calculation of the IIV? Should we require ETFs to value their portfolio holdings more frequently for purposes of assessing any deviations between market prices and the ETF's portfolio holdings, such as hourly or three times a day? Are there other ways to value an ETF's portfolio on an intraday basis that we should consider? How frequently should ETFs disclose information regarding intraday deviations with the contemporaneous value of the ETF's portfolio? How long should ETFs be required to maintain this information on their website?

• Alternatively, should we require ETFs to assess the efficiency of their arbitrage mechanism pursuant to internal methodologies and require ETFs to provide narrative disclosure regarding intraday deviations between market price and (i) NAV; (ii) the contemporaneous value of the ETF's portfolio; or (iii) both?

• We are proposing to require ETFs to disclose the ETF's median bid-ask spread for the most recent fiscal year. How would investors use this information? Is the median bid-ask spread an appropriate metric? For example, the median bid-ask spread would not capture extreme events and stress periods. Should we require additional bid-ask spread metrics, such as average spread, high-end spread (*e.g.,* 95th percentile) or effective spread? [314] If so, why is it preferable and how should it be calculated? Should we require ETFs to provide the median or mean spreads for the year?

• Should we require that the bid-ask spread information be included on both an ETF's website and in its prospectus? Would investors benefit from having this information in both places? Should we instead require it only on an ETF's website? Should the information be required to be updated more or less frequently than proposed? If so, how frequently? For example, should we require an ETF to disclose on its website a trailing average spread over the course of a year, updated daily? Are there particular categories of investors that may not use or have access to the internet? If so, are there alternative ways of communicating this information to them in a cost-effective manner?

• Proposed rule 6c–11(c)(1)(iii) would require an ETF to post on its website a table showing the ETF's premiums and discounts for the most recently completed calendar year and the most recently completed calendar quarters of the current year. As we discussed above, this disclosure is a condition in many of our exemptive orders and required by Form N–1A. Do investors or their advisers use this information? Are there other forms of presenting this data that would be easier for investors to understand?

• Proposed rule 6c–11(c)(1)(iv) would require an ETF to post on its website a line graph showing the ETF's premiums and discounts for the most recently completed calendar year and the most recently completed calendar quarters of the current year. How would investors and their advisers use a line graph? Are there other forms of presenting this data that would be easier for investors to understand?

• Should ETFs be required to include intra-day premiums and discounts (calculated using one of the methodologies for which we request comment above) as part of the line graph? How would this disclosure be used by investors?

• Should we require ETFs to provide both forms of disclosure (*i.e.,* table and line graph)? Would investors use this information? Should we require more layered disclosure, such as an interactive tool where investors can enter different variables to better understand historical premiums and discounts?

• Should the table and line graph cover the most recently completed calendar year and the most recently completed calendar quarters of the current year as proposed or are there other periods we should consider? Should the period be longer or shorter? Should we consider fiscal year periods instead of calendar year periods? If so, what period and why? How would this change impact the comparability of the information across ETFs? In order to give investors more information on market dislocations that particularly affect ETFs, should we also require tabular and graphic disclosure for major market events over past five or ten years?

• Proposed rule 6c–11(c)(1)(v) would require any ETF whose premium or discount was greater than 2% for more than seven consecutive trading days to post that information on its website, along with a discussion of the factors that are reasonably believed to have materially contributed to the premium or discount threshold. Should we require this proposed disclosure? Is 2% an appropriate premium or discount? If not, should we consider a higher or lower threshold for this disclosure (*e.g.,* 1% or 5%)? If so, why? Should we vary the premium or discount based on other factors, such as fund strategy, asset class, geographic region, or historic premium/discount for the class? Should we instead base the reporting threshold on a different statistic, such as standard deviation? Should it be based on the average absolute value of the premium or discount over a seven-day period? [315]

• Is the seven consecutive trading day requirement appropriate? Should we require a shorter or longer period of time? If so, what period and why? Is there a more appropriate balance between the magnitude (2%) and length (seven consecutive trading days) of an ETF's premium or discount than we have proposed (*e.g.,* 10% for one day or 5% for two days)?

• Should we permit ETFs to determine what percentage premium or discount threshold is appropriate and what time period to disclose, based on the ETF's particularized circumstances?

• Should we require any additional measures to trigger the proposed rule 6c–11(c)(1)(v) disclosure requirement? Should we require a second measure of non-consecutive days in addition to the seven trading day requirement? For example, should we also require a disclosure of factors if the ETF's premium or discount was greater than 2% for seven of the past 30 days?

• We propose that ETFs posting this information be required to post it by the end of the trading day immediately following the day on which the requirement was triggered. Is this a reasonable period of time to post this information? Why or why not? We also propose that ETFs posting this

[314] For the purposes of this comment request, we consider the effective spread the ''actual'' spread (*i.e.,* the difference between bid and the ask). We consider the average spread to be the figure that takes the average bids and asks over a period of time and finds the difference between them. As noted in the comment request, we also are soliciting input on calculation methodology.

[315] *See supra* footnote 120 (describing calculation of absolute value).

information be required to maintain it on their websites for at least one year following the first day it was posted. Should these time periods be shorter or longer?

• As an alternative (or in addition) to requiring disclosure of this information on an ETF's website, should we require disclosure in an ETF's prospectus or shareholder reports? Or should we require that it be publicly filed on EDGAR in a different regulatory filing?

• Would this disclosure requirement disproportionately affect particular types of ETFs? Would investors use this information in assessing ETFs, or could it lead to confusion?

• Should we require a discussion of the factors that are reasonably believed to have materially contributed to the premium or discount? Would this requirement provide investors with useful context for deviations between market price and NAV per share or would ETFs rely on boilerplate disclosure?

• Should we provide additional guidance or impose additional requirements for cases where a deviation persists for an extended period (*i.e.,* much longer than seven days)?

• In addition to the disclosures regarding instances where the premium or discount was greater than 2% for more than seven consecutive trading days, should we require that ETFs disclose other information relating to premiums and discounts? For example, should we require ETFs to disclose rolling average premium and discount for a prior period? If so, what period? Should we require ETFs to provide the greatest premium and/or discount for the previous month, quarter, or year? If so, what period would be most useful to investors and other market participants?

• Should we require ETFs to disclose index tracking error, if applicable? If so, how should we define tracking error? For what period should we require tracking error? Where should such disclosure be made and how frequently?

• Should we require ETFs to include a disclaimer indicating the potential limitations of historical disclosures on its website? If so, should the rule prescribe the legend that should be used and where the legend should be placed? Should we require a legend similar to the current performance-related disclosure legend in Form N–1A, which states that ''past performance . . . is not necessarily an indication of how the Fund will perform in the future''? [316]

• We are proposing that ETFs provide certain disclosures on their websites on a daily basis. Should we require funds to provide these disclosures less frequently? Are there other places that funds should be required to report this information?

• Should we require this information to be posted ''prominently'' on the ETF's website? Should we provide any other instruction as to the presentation of this information, in order to highlight the information and/or lead investors efficiently to the information? For example, should we require that the information be posted on the main page of a particular ETF series? Should the information be accessible in no more than two clicks from the ETF complex's home page? Should we adopt presentation requirements that would aid in the comparability of this information for different ETFs? In particular, should we adopt presentation requirements for the premium/discount line graph?

• In our discussion of the proposed amendments to Item 3 of Form N–1A, we are proposing an exception from the disclosure requirements of trading information and related costs for newly created ETFs with limited trading history. Should there be a similar exception for newly created ETFs from the website disclosure requirements of the ETF's NAV per share, market price, premium or discount, and bid-ask spreads as of the end of the prior business day? Should the exception apply to the requirement to disclose historical information regarding the ETF's premiums and discounts? Why or why not?

• Should we require ETFs to post the proposed additional website disclosures in a structured format and/or to file them on EDGAR or make them available in another centralized repository?

7. Marketing

Our exemptive orders and our 2008 proposal included a condition requiring each ETF to identify itself in any sales literature as an ETF that does not sell or redeem individual shares and to explain that investors may purchase or sell individual ETF shares through a broker via a national securities exchange.[317] This condition was designed to help prevent investors, particularly retail investors, from confusing ETFs with mutual funds. Given that ETFs have been available for over 26 years, and the market has developed a familiarity with the product, we no longer believe this condition is necessary. We believe that retail investors generally understand that, unlike mutual funds, individual ETF shares may be purchased and sold only on secondary markets. We further believe that the website and registration statement disclosures we are proposing provide retail investors more useful information regarding the exchange-traded nature and costs of ETFs.[318] Therefore, we are not proposing to include such a marketing disclosure requirement in rule 6c–11.

We request comment on this aspect of our proposal.

• Are we correct that a condition requiring an ETF to identify itself in any sales literature as an ETF that does not sell or redeem individual shares and to explain that investors may purchase or sell individual ETF shares through a broker via secondary markets is no longer necessary? Do retail investors understand that individual ETF shares can be bought and sold only on secondary markets? If not, should proposed rule 6c–11 condition relief on the inclusion of statements in an ETF's sales literature regarding the purchase and sale of ETF shares on secondary markets? Alternatively, should we consider adding a disclosure requirement only to Form N–1A?

• Should we consider other limitations regarding ETF sales literature?

• If the rule includes such a condition, how should we define sales literature? Should we define sales literature as we proposed in 2008? [319] Are there other definitions that we should consider, including by reference to the definition in 17 CFR 230.156 (''rule 156'')? [320]

[316] *See* Item 4(b)(2)(i) of Form N–1A.

[317] *See* 2008 ETF Proposing Release, *supra* footnote 3. Commenters who addressed this aspect of the 2008 proposal generally supported this condition. *See* ICI 2008 Comment Letter; Katten 2008 Comment Letter; Xshares 2008 Comment Letter.

[318] The proposed website disclosure requirements are described in section II.C.6 and the proposed amendments to Form N–1A are described in section II.H.

[319] The 2008 proposed rule, consistent with the use of the term in section 24(b) of the Act and the existing definition in rule 34b–1 under the Act, would have defined the term ''sales literature'' as ''any advertisement, pamphlet, circular, form letter, or other sales material addressed to or intended for distribution to prospective investors other than a registration statement filed with the Commission under section 8 of the Act.'' *See* 2008 ETF Proposing Release, *supra* footnote 3.

[320] Rule 156 under the Securities Act defines the term ''sales literature'' to include ''any communication (whether in writing, by radio, or by television) used by any person to offer to sell or induce the sale of securities of any investment company.'' It also states that communications between issuers, underwriters and dealers are included in the definition of sales literature if such communications, or the information contained therein, can be reasonably expected to be communicated to prospective investors in the offer or sale of securities or are designed to be employed in either written or oral form in the offer or sale of securities. *See* 17 CFR 230.156(c).

• If the rule included a condition regarding sales literature, should it also include an exception to permit an ETF to disclose to investors that it will issue or redeem individual shares in order to consummate a reorganization, merger, conversion or liquidation?

• To further prevent investors from confusing ETFs with mutual funds, should the rule require an ETF to include the identifier ''ETF'' in its name?

• To further prevent investors from confusing ETFs with mutual funds, should the rule require an ETF to explicitly disclose in its sales literature that shareholders may pay more than NAV when buying shares and may receive less than NAV when selling ETF shares?

• Should the rule impose any additional conditions or require any additional disclosures to help investors distinguish ETFs from other ETPs, such as exchange-traded notes or commodity pools that are not subject to the Investment Company Act? Should the Commission consider proposing naming conventions based on these or other distinctions in a future rulemaking? Are naming conventions useful to investors? Should ETFs be required to use a different identifier (*e.g.,* ''IC'' for ETFs that are registered under the Investment Company Act) before or after ''ETF'' to distinguish them from other ETPs? Should all ETPs be required to have identifiers (*e.g.,* ETF–N (for exchange-traded notes), ETF–IC (for ETFs that are not leveraged ETFs), ETF–C (for exchange-traded commodity pools), ETF–L (for leveraged ETFs))?

• Alternatively, are there ways we could address investor confusion by restricting certain sales practices? For example, should we consider proposing restrictions in a future rulemaking on how intermediaries communicate with retail investors about ETPs unless they disclose certain information designed to clearly differentiate ETPs that are not registered under the Act from ETFs that are registered investment companies?

D. Recordkeeping

For the reasons discussed above, authorized participants play a central role in the proper functioning of the ETF marketplace.[321] One of the defining characteristics of authorized participants under the proposed rule is that they have a written agreement with an ETF or one of the ETF's service providers whereby the authorized participant is allowed to purchase or redeem creation units directly from the ETF (''authorized participant agreement'').[322] Thus, these agreements are critical to understanding the relationship between the authorized participant and the ETF. While we believe that most ETFs are currently preserving copies of their written authorized participant agreements pursuant to our current recordkeeping rules, for avoidance of doubt, we are proposing to expressly require that ETFs relying on rule 6c–11 preserve and maintain copies of all such agreements.[323]

This requirement is designed to provide our examination staff with a basis to determine whether the relationship between the ETF and the authorized participant is in compliance with the requirements of proposed rule 6c–11 and other provisions of the Act and rules thereunder, based on the specific terms of their written agreement, including, but not limited to, terms related to postponement of redemptions and transaction fees. We did not include a specific preservation requirement for authorized participant agreements in the 2008 proposal.[324] However, Commission staff's experience with the ETF industry since 2008, including our examination staff's experience, has reinforced our belief that authorized participant agreements must be preserved.

We are also proposing to require ETFs to maintain information regarding the baskets exchanged with authorized participants. In particular, the proposed rule would require an ETF to maintain records setting forth the following information for each basket exchanged with an authorized participant: (i) The names and quantities of the positions composing the basket; (ii) identification of the basket as a ''custom basket'' and a record stating that the custom basket complies with the ETF's custom basket policies and procedures (if applicable); (iii) cash balancing amounts (if any); and (iv) the identity of the authorized participant conducting the transaction.[325] These records would provide our examination staff with a basis to understand how baskets are being used by ETFs, as well as to evaluate compliance with the rule and other provisions of the Act and rules thereunder. In particular, we believe these records would allow our examination staff to evaluate whether the use of custom baskets is appropriate.

ETFs would be required to maintain these records for at least five years, the first two years in an easily accessible place. The retention period is consistent with the period provided in rules 22e–4 and 38a–1(d) under the Act. Funds currently have compliance program-related recordkeeping procedures in place that incorporates this type of retention period, and we preliminarily believe consistency with that period would minimize any compliance burden to funds.

We request comment on these proposed recordkeeping requirements.

• Are these requirements necessary in light of the benefits that would result from Commission examination? Are there other records that we should require ETFs to preserve or other feasible alternatives that would minimize recordkeeping burdens? What are the costs associated with maintaining the proposed recordkeeping requirements under the rule and what effects would the proposed recordkeeping requirements have on an ETF's compliance policies and procedures?

• Do ETFs already preserve their agreements with authorized participants under our current recordkeeping requirements?

• Should we require an ETF to maintain a record stating that the custom basket complies with the ETF's custom basket policies and procedures? Is there any additional information that we should require ETFs to maintain in connection with their baskets? Should we require ETFs to record information regarding any transaction fees assessed in connection with each basket? Are there alternatives to this proposed recordkeeping requirement that would enable the Commission to examine the composition of ETFs' baskets, while minimizing the recordkeeping burdens imposed on ETFs?

• Are there other records we should consider requiring ETFs to maintain regarding transaction fees?[326] Should we consider requiring ETFs to disclose information regarding transaction fees

[321] *See supra* section I.

[322] Proposed rule 6c–11(a) (defining ''authorized participant'').

[323] *See* proposed rule 6c–11(d)(1).

[324] *See* 2008 ETF Proposing Release, *supra* footnote 3. Our orders also do not include a specific preservation requirement. *See, e.g.,* Salt Financial, *supra* footnote 270.

[325] *See* proposed rule 6c–11(d)(2).

[326] We understand transaction fees are imposed by ETFs to defray the transaction expenses associated with the creation or redemption, as applicable, and prevent possible dilution resulting from the purchase or redemption of creation units. For cash baskets, the ETF may assess transaction fees to offset certain operational, brokerage and spread costs relating to the ETF's purchasing or selling of securities. Transaction fees can impact secondary market investors in ETF shares because an authorized participant or other market maker can cause the spread to widen on ETF shares to recoup or offset some of the costs from paying the transaction fees.

in their registration statement or on Form N–CEN? For example, should ETFs be required to describe transaction fees and the amount of such fees that are charged in connection with effecting purchases and redemptions of creation units? Should there be disclosure about the aggregate dollar amount or percentage of transaction fees paid over particular periods? Should we require ETFs to disclose the dollar amount (or percentage) of transaction fees waived over a particular periods? If so, how should this information be presented? Should we require ETFs to include narrative disclosure regarding waivers, noting for example, that the waiver of transaction fees may result in additional costs borne by the ETF?

- Should we require ETFs to maintain these records for five years, the first two years in an easily accessible place, as proposed? Should we use a different retention period, such as the six-year retention period under 17 CFR 270.31a–2 (rule 31a–2 under the Act)?
- Would compliance with these proposed requirements have any effect on ETFs' internal compliance policies and procedures?
- Should we instead, or additionally, require that ETFs file their authorized participant agreements as exhibits to their registration statements? Why or why not?
- Are there any additional alternative recordkeeping requirements we should consider?

E. Share Class ETFs

The proposed rule does not provide any relief from sections 18(f)(1) or 18(i) of the Act or expand the scope of 17 CFR 270.18f–3 (''rule 18f–3'' under the Act) (the multiple class rule).[327] Sections 18(f) and (i) of the Act were intended, in large part, to protect investors from certain abuses associated with complex investment company capital structures, including conflicts of interest among a fund's share classes.[328] These provisions also were designed to address certain inequitable and discriminatory shareholder voting provisions that were associated with many investment company securities before the enactment of the Act.[329]

In 1995, the Commission adopted rule 18f–3 under the Act to create a limited exemption from sections 18(f)(1) and 18(i) for funds that issue multiple classes of shares with varying arrangements for the distribution of securities and provision of services to shareholders.[330] That rule generally provides that, notwithstanding sections 18(f)(1) and 18(i) of the Act, a registered open-end management investment company or series or class thereof may issue more than one class of voting stock, provided that each class, among other requirements, has in all other respects the same rights and obligations as each other class.[331]

An ETF cannot rely on rule 18f–3 to operate as a share class within a fund because the rights and obligations of the ETF shareholders would differ from those of investors in the fund's mutual fund share classes. For example, ETF shares would be redeemable only in creation units, while the investors in the fund's mutual fund share classes would be individually redeemable. Similarly, ETF shares are tradeable on the secondary market, whereas mutual fund shares classes would not be traded.

An ETF structured as a share class of a fund that issues multiple classes of shares representing interests in the same portfolio would not be permitted to rely on proposed rule 6c–11. We recognize that the Commission has granted ETFs exemptive relief from the aforementioned provisions of section 18 of the Act in the past, subject to various conditions.[332] However, relief from section 18 raises policy considerations that are different from those we seek to address in this rule, which is intended to address broadly the common type of relief that most ETFs have sought.

For example, an ETF share class that transacts with authorized participants on an in-kind basis and a mutual fund share class that transacts with shareholders on a cash basis may give rise to differing costs to the portfolio. As a result, while certain of these costs may result from the features of one share class or another, all shareholders would generally bear these portfolio costs.[333] At the same time, the share class structure also can provide benefits to each share class, including economies of scale. Given these additional policy considerations, we believe it is appropriate for ETFs to continue to request relief from sections 18(f)(1) and 18(i) of the Act through our exemptive application process, and for the Commission to continue to weigh these policy considerations in the context of the facts and circumstances of each particular applicant.

We request comment on this aspect of the proposal.

- Should proposed rule 6c–11 include exemptions from sections 18(f)(1) or 18(i) of the Act, or should we expand the scope of rule 18f–3 under the Act? Why or why not?
- If commenters believe that such exemptions should be included in the proposed rule, should the rule include conditions designed to take into account the potential costs and benefits of a fund with both mutual fund and ETF share classes? If so, what conditions? Are we correct in our preliminary belief that combining an ETF share class with traditional share classes of a mutual fund may, in certain circumstances, result in the costs and benefits described above?

F. Master-Feeder ETFs

Many of our recent ETF orders contain relief allowing ETFs to operate as feeder funds in a master-feeder structure.[334] In general, an ETF that operates as a feeder fund in a master-feeder structure functions like any other ETF. An authorized participant deposits a basket with the ETF and receives a

[327] *See* 15 U.S.C. 80a–18(f)(1) and (i); 17 CFR 270.18f–3. Section 18(f)(1) of the Act generally prohibits a fund from issuing a class of ''senior security,'' which is defined in section 18(g) to include any stock of a class having priority over any other class as to distribution of assets or payment of dividends. *See* 15 U.S.C. 80a–18(g). Section 18(i) of the Act provides that all shares of stock issued by a fund must have equal voting rights.

[328] *See* Exemption for Open-End Management Investment Companies Issuing Multiple Classes of Shares, Investment Company Act Release No.19955 (Dec. 15, 1993) [58 FR 68074 (Dec. 23, 1993)] (proposing release), at nn.20 and 21 and accompanying text.

[329] *See id.*

[330] *See* Exemption for Open-End Management Investment Companies Issuing Multiple Classes of Shares, Investment Company Act Release No. 20915 (Feb. 23, 1995) [60 FR 11876 (Mar. 2, 1995)] (adopting release) (''Multiple Class Adopting Release''), at n.8 and accompanying text.

[331] *See* 17 CFR 270.18f–3(a)(4).

[332] *See* Vanguard Index Funds, *et al.,* Investment Company Act Release Nos. 24680 (Oct. 6, 2000) [65 FR 61005 (Oct. 13, 2000)] (notice) and 24789 (Dec. 12, 2000) (order) and related application; Vanguard Index Funds, *et al.,* Investment Company Act Release Nos. 26282 (Dec. 2, 2003) [68 FR 68430 (Dec. 8, 2003)] (notice) and 26317 (Dec. 29, 2003) (order) and related application; Vanguard International Equity Index Funds, *et al.,* Investment Company Act Release Nos. 26246 (Nov. 3, 2003) [68 FR 63135 (Nov. 7, 2003)] (notice) and 26281 (Dec. 1, 2003) (order) and related application; Vanguard Bond Index Funds, *et. al.,* Investment Company Act Release Nos. 27750 (Mar. 9, 2007) [72 FR 12227 (Mar. 15, 2007)] (notice) and 27773 (Apr. 25, 2007) (order) and related application (collectively, the ''Vanguard orders'').

[333] These costs can include brokerage and other costs associated with buying and selling portfolio securities in response to mutual fund share class cash inflows and outflows, cash drag associated with holding the cash necessary to satisfy mutual fund share class redemptions, and distributable capital gains associated with portfolio transactions.

[334] *See, e.g.,* T. Rowe Price Associates, Inc., *et al.,* Investment Company Act Release Nos. 30299 (Dec. 7, 2012) [77 FR 74237 (Dec. 13, 2012)] (notice) and 30336 (Jan. 2, 2013) (order) and related application; SSgA Funds Management, Inc., *et al.,* Investment Company Act Release Nos. 29499 (Nov. 17, 2010) [75 FR 71753 (Nov. 24, 2010)] (notice) and 29524 (Dec. 13, 2010) (order) and related application (''SSgA'').

creation unit of ETF shares in return for those assets. Conversely, an authorized participant that redeems a creation unit of ETF shares receives a basket from the ETF. In a master-feeder arrangement, however, the feeder ETF then also enters into a corresponding transaction with its master fund. The ETF may use the basket assets it receives from an authorized participant to purchase additional shares of the master fund, or it may redeem shares of the master fund in order to obtain basket assets and satisfy a redemption request.

Because the feeder ETF may, in the course of these transactions, temporarily hold the basket assets, it would not be able to rely on section 12(d)(1)(E) of the Act, which requires that a feeder fund hold no investment securities other than securities of the master fund.[335] To accommodate these unique operational characteristics of ETFs, our recent exemptive orders have allowed a feeder ETF to rely on section 12(d)(1)(E) without complying with section 12(d)(1)(E)(ii) of the Act to the extent that the ETF temporarily holds investment securities other than the master fund's shares for use as basket assets. These orders also provided the feeder ETF and its master fund with relief from sections 17(a)(1) and 17(a)(2) of the Act, with regard to the deposit by the feeder ETF with the master fund and the receipt by the feeder ETF from the master fund of basket assets in connection with the issuance or redemption of creation units,[336] and section 22(e) of the Act if the feeder ETF includes a foreign security in its basket assets and a foreign holiday (or a series of consecutive holidays) prevents timely delivery of the foreign security.[337]

The exemptive orders we have granted to master-feeder ETFs, however, do not include relief from section 18 under the Act inasmuch as investment by several feeder funds or by mutual fund and ETF feeder funds in the same class of securities issued by a master fund generally do not involve a senior security subject to section 18. We are concerned, as discussed above, that if an ETF feeder fund transacts with a master fund on an in-kind basis, but non-ETF feeder funds transact with the master fund on a cash basis, all feeder fund shareholders would bear costs associated with the cash transactions.[338]

We understand that while many orders contain this relief, only one fund complex has established master-feeder arrangements involving ETF feeder funds, and each arrangement involves an ETF as the sole feeder fund.[339] Given the lack of interest in this structure and our concerns noted above, we are proposing to rescind the master-feeder relief granted to ETFs that do not rely on the relief as of the date of this proposal (June 28, 2018).[340] However, we also propose to grandfather existing master-feeder arrangements involving ETF feeder funds, but prevent the formation of new ones, by amending relevant exemptive orders.[341] Because these existing master-feeder ETFs involve only one feeder fund for each master fund, we do not believe they would raise the policy concerns discussed above so long as they do not add feeders, and therefore do not believe it is necessary to require these structures to change their existing investment practices.[342]

We request comment on the lack of master-feeder relief in proposed rule 6c–11.

- Are we correct that the market interest for ETFs using master-feeder structures, as discussed above, is limited?
- Should the proposed rule include master-feeder relief for ETFs, as provided in certain of our exemptive orders and discussed above? Why or why not?
- Should we amend the exemptive relief relied upon by existing master-feeder arrangements? Alternatively, should we also rescind the master-feeder relief relied upon by existing arrangements? If so, how would these ETFs be impacted if we also rescinded their relief?
- If the proposed rule provided master-feeder relief for master-feeder structures that include ETF and mutual fund feeder funds, should the rule include conditions designed to take into account the potential costs and benefits of such structures? If so, what conditions? For example, should the proposed rule require a determination that the investment in a master fund is in the best interest of the ETF and its shareholders? If so, who should be required to make such a determination? How frequently should such a determination be made? Alternatively, should the proposed rule provide master-feeder relief for master-feeder structures but allow only ETF feeder funds? If so, what conditions should apply?

G. Effect of Proposed Rule 6c–11 on Prior Orders

The Commission has authority under the Act to amend or rescind our orders when necessary or appropriate to the exercise of the powers conferred elsewhere in the Act. Pursuant to this authority, we are proposing to amend and rescind the exemptive relief we have issued to ETFs that would be permitted to rely on the proposed rule.[343] Our proposed rescission of orders would specifically be limited to the portions of an ETF's exemptive order that grant relief related to the formation and operation of an ETF and, with the exception of certain master-feeder relief discussed above in section II.F, would not rescind the relief from section 12(d)(1)[344] and sections 17(a)(1) and (a)(2)[345] under the Act related to

[335] Section 12(d)(1) of the Act limits the ability of a fund to invest substantially in shares of another fund. *See* sections 12(d)(1)(A)–(C) of the Act; *see also infra* footnote 344. Section 12(d)(1)(E) of the Act allows an investment company to invest all of its assets in one other fund so that the acquiring fund is, in effect, a conduit through which investors may access the acquired fund. *See* section 12(d)(1)(E)(ii) of the Act.

[336] Relief from the affiliated transaction prohibitions in sections 17(a)(1) and 17(a)(2) of the Act is necessary because these sections would otherwise prohibit the feeder ETF and its master fund from selling to or buying from each other the basket assets in exchange for securities of the master fund. *See* 15 U.S.C. 80a–17(a)(1)–(2).

[337] *See* 15 U.S.C. 80a–22(e) (generally requiring the satisfaction of redemptions within seven days). *See also supra* section III.B.4.

[338] *See supra* footnote 333 and accompanying text.

[339] *See, e.g.,* SSGA Active Trust Prospectus (Oct. 31, 2017), *available at https://us.spdrs.com/public/SPDR_ACTIVE%20ETF%20TRUST_PROSPECTUS.pdf.*

[340] *See infra* section II.G.

[341] Based on staff analysis, we preliminarily believe that the fund complex currently utilizing this relief operates nine master-fund arrangements, each involving only one ETF as the sole feeder fund. *See* SSgA, *supra* footnote 334.

[342] Rescinding the relief for existing master-feeder ETFs would require them to change the manner in which they invest. For example, transactions between each of the affected master funds and its corresponding feeder fund could be transacted in cash, rather than in-kind, obviating any need for exemptive relief for the feeder fund to hold securities other than those issued by the master fund. Alternatively, the feeder funds could opt to pursue their investment objectives through direct investments in securities and/or other financial instruments, rather than through investments in master funds.

[343] *See* section 38(a) of the Act, 15 U.S.C. 80a–37(a).

[344] Section 12(d)(1) generally limits the ability of registered investment companies (including ETFs) to acquire securities issued by other investment companies in excess of certain thresholds, and the ability of registered open-end investment companies (including ETFs) from knowingly selling securities to other investment companies in excess of certain thresholds. The conditions set forth in ETF exemptive applications for relief necessary to create a fund of funds structure is generally designed to prevent the abuses that led Congress to enact section 12(d)(1), including abuses associated with undue influence and control by acquiring fund shareholders, the payment of duplicative or excessive fees, and the creation of complex structures. *See* Salt Financial, *supra* footnote 270. We also note that certain standalone exemptive orders, unrelated to ETF operations, are often granted to applicants to permit investments in ETFs beyond the limits in section 12(d)(1) of the Act; we are not proposing to rescind such exemptive orders.

[345] *See supra* section II.B.3.

fund of funds arrangements involving ETFs.[346]

The terms of the exemptive relief granted to ETFs have evolved over time and have resulted in an uneven playing field among ETF complexes, subjecting ETFs that pursue the same or similar investment strategies to different operational requirements. Moreover, many ETF complexes have multiple exemptive orders permitting them to operate ETFs. Some of those orders contain different conditions for relief and different representations by the applicants regarding how the ETFs formed pursuant to the order would operate. Many of those orders also provide relief for future ETFs created pursuant to the terms of a particular exemptive order.[347] As a result, ETF complexes with multiple orders can effectively choose the exemptive relief that would be applicable to a new ETF by selecting what legal entity should form the new ETF series. Moreover, differences in the terms of our various orders have had varying impact on the structure and costs of an ETF. For example, shares of an ETF with a less flexible basket condition in its order could have wider spreads than a similarly situated ETF with more flexible basket compositions. However, investors may not be able to discern the difference between these two ETFs' orders. As we have stated elsewhere in this release, among our goals in proposing rule 6c–11 is to create a consistent, transparent and efficient regulatory framework for many ETFs. We do not believe this goal would be furthered if ETFs that could rely on the rule continue to rely on those orders.

In addition, we began including a condition in our ETF exemptive orders in 2008 stating that the relief permitting the operation of ETFs would expire on the effective date of any Commission rule that provides relief permitting the operation of ETFs.[348] The purpose of this automatic expiration condition was to better establish equal footing between ETFs that have received exemptive relief and ETFs that may rely solely on a Commission rule, and to reduce competitive advantages that could potentially arise out of the conditions for relief set forth in our earlier exemptive orders.[349] Of the approximately 300 orders we have issued that provide ETF exemptive relief, approximately 200 include this automatic expiration condition, and thus the ETF relief would terminate if and when proposed rule 6c–11 is adopted and goes into effect. To provide time for ETFs to transition to rule 6c–11, however, we propose to amend these existing orders to provide that the ETF relief contained in those orders will terminate one year following the effective date of any final rule. Absent this modification or our determining to delay the effectiveness of any final rule 6c–11, the ETF relief included in orders with the automatic expiration provision could expire before ETFs were able to make any adjustments necessary to rely on rule 6c–11.

We believe that rescinding ETF exemptive relief in connection with the proposed rule (and amending those orders that require ETF exemptive relief to automatically expire in order to allow a transitional period to any final rule) would result in a more transparent framework for covered ETFs, as those ETFs would no longer be subject to differing and sometimes inconsistent provisions of their exemptive relief. The relief and related conditions proposed under rule 6c–11, moreover, are largely consistent with our recent orders, and in some cases, provide ETFs with additional flexibility. For example, proposed rule 6c–11 would provide many ETFs with additional basket flexibility beyond what is currently permitted by their exemptive orders.[350] We preliminarily believe, therefore, that the operations of most existing ETFs would not be significantly negatively affected by the need to comply with the requirements of rule 6c–11 as opposed to their exemptive relief. However, in order to limit any hardship that revocation of existing exemptive relief would have on current ETFs with orders that do not automatically expire, we are proposing a one-year period after the effective date before we rescind that exemptive relief to give those ETFs time to bring their operations into conformity with the requirements of proposed rule 6c–11.

We do not propose to rescind the exemptive relief of ETFs that would not be permitted to rely on the proposed rule. Specifically, we do not propose to rescind the exemptive relief for ETFs organized as UITs,[351] ETFs that are organized as a share class of a fund,[352] or leveraged ETFs.[353] We believe it is appropriate for ETFs seeking to utilize these structures to continue to request relief from the Commission through our exemptive application process, and for the Commission to continue to make facts-and-circumstances-based determinations regarding whether such relief is appropriate for any particular applicant.

The Commission does not believe that it is necessary to give individual hearings to the holders of the prior exemptive relief or to any other person. Proposed rule 6c–11 would be prospective in effect and is intended to set forth for covered ETFs the Commission's exemptive standards for ETFs organized as open-end funds. Recipients of existing exemptive relief may make their views known in the context of the comment process that accompanies this rulemaking, and those views will be given due consideration. Finally, investment companies would be able to request Commission approval to operate as an ETF under conditions that differ from those in proposed rule 6c–11.

We request comment on our proposal to revoke existing ETF and certain existing master-feeder exemptive relief.

- Should we revoke some or all of the existing ETF exemptive relief? If not, why not? Would allowing existing exemptive relief to continue create an unequal playing field for ETF market participants? If not, why not?
- As discussed above, we are proposing a one year period before rescinding existing ETF exemptive relief. Is the one year period appropriate for ETFs with existing ETF exemptive

[346] ETF exemptive relief typically segregates exemptive relief from section 17(a) under the Act necessary to create a fund of funds structure from section 17(a) exemptive relief necessary for the operation of the ETFs. This segregation of ''Fund of Funds Relief'' and ''ETF Relief'' appears in numerous representations and enumerated conditions set forth in applications for exemptive relief. *See, e.g.,* Salt Financial, *supra* footnote 270.

[347] *See supra* footnote 12.

[348] *See e.g.,* PowerShares, *supra* footnote 188; Javelin Exchange-Traded Trust, Investment Company Act Release Nos. 28350 (July 31, 2008) [73 FR 46066 Aug. 7, 2008)] (notice) and 28637 (Aug. 26, 2008) (order) and related application. In some cases, the automatic expiration condition applies to the ETF-related relief only, and expressly does not apply to certain other exemptive relief requested, such as master-feeder and ''fund of funds'' relief under section 12 of the Act. *See, e.g.,* Fidelity Merrimack Street Trust, *et al.,* Investment Company Act Release Nos. 30464 (Apr. 16, 2013) [78 FR 23793 (Apr. 22, 2013)] (notice) and 30513 (May 10, 2013) (order) and related application (''The requested relief, other than the Fund of Funds Relief and the Section 17 relief related to a master-feeder structure, will expire on the effective date of any Commission rule under the Act that provides relief permitting the operation of actively managed exchange traded funds.'').

[349] *See* 2008 ETF Proposing Release, *supra* footnote 3.

[350] *See* proposed rule 6c–11(c)(3); *see also supra* section II.C.5. We note that a subset of the ETFs operating under exemptive relief has basket flexibility that would not be broadened by the proposed rule. Under the proposed rule, however, such ETFs would be required to adopt and implement written policies and procedures related to the construction of baskets and the process for the acceptance of baskets by the ETF.

[351] *See* discussion of ETFs organized as UITs, *supra* section II.A.1.

[352] *See* Vanguard orders, *supra* footnote 332.

[353] *See* discussion of leveraged ETFs, *supra* section II.A.3.

relief to bring their funds into compliance with rule 6c–11? If not, how long should this period last? Why? We are proposing to implement this one year period, in part, by amending existing orders with an automatic expiration condition to provide that the ETF exemptive relief contained in these orders would terminate one year following the effective date of any final rule. Should we, instead, delay the effectiveness of rule 6c–11 for one year? Are there different approaches we should consider?

- Should we consider rescinding the exemptive relief for ETFs organized as UITs or ETFs organized as a share class of a fund and instead allow such ETFs to be covered by rule 6c–11? If so, how would such ETFs comply with the requirements of the rule? For example, would they have to restructure or liquidate?
- Should we, as proposed, rescind the exemptive relief that we have previously granted that allows ETFs to operate as feeder funds in a master-feeder structure if they do not rely on the relief as of the date of this proposal? Do funds plan to use this relief in the future? If so, what kind of ETF master-feeder structures do funds envision creating? For what purpose?
- We understand that the existing structures are organized with an ETF as the sole feeder fund. Is this understanding correct? Should we amend the exemptive relief applicable to these funds as proposed?
- Would our proposal to rescind certain of our previously issued ETF exemptive relief, and allow the ETF exemptive relief contained in the orders with automatic expiration provisions to expire one year following the effective date of rule 6c–11, eliminate any competitive advantages arising from the relief we have granted via exemptive order?
- Would existing ETFs face significant challenges in complying with the conditions of rule 6c–11 rather than exemptive relief?
- Should we consider other approaches? For example, should we consider rescinding only ETF exemptive relief previously granted to ETF complexes that have multiple exemptive orders permitting them to operate ETFs?
- Should we consider not rescinding any of the approximately 100 pre-2008 orders that do not include the automatic expiration provision? Should we consider amending the orders that contain the automatic expiration provision of the ETF exemptive relief to remove that provision? Under these approaches, in which certain ETF exemptive orders would be left in place, ETFs would continue operating under different sets of conditions. Would permitting ETFs to operate under different sets of conditions have an adverse effect on competition and capital formation?
- Are there other approaches to the existing ETF exemptive relief that we should consider in view of proposed rule 6c–11?
- Exemptive relief granted prior to 2009 generally includes relief from section 24(d) of the Act to exempt broker-dealers selling ETF shares from the obligation to deliver prospectuses in most secondary market transactions, and the rescission of the ETF exemptive relief from those orders would eliminate this relief. We understand, however, that broker-dealers have not relied upon this relief and, subsequent to the adoption of amendments to rule 498 under the Securities Act permitting the delivery of an ETF's summary prospectus, most market participants use the summary prospectus to satisfy prospectus delivery obligations.[354] Are we correct in our understanding? Should we provide relief from section 24(d) for ETFs that have this relief in their exemptive orders if we were to rescind those orders? If so, why?

H. Amendments to Form N–1A

As discussed above in section II.C.6, because of the exchange-traded nature of ETFs, ETF investors may be subject to different costs than mutual fund investors. For example, while an ETF may, in some cases, have a lower expense ratio than a comparable mutual fund, an ETF investor will be subject to certain unique costs associated specifically with ETFs, such as the bid-ask spread and premiums and discounts from the ETF's NAV. As a result of these differences, ETF investors may not be fully aware of the full costs associated with their investment in an ETF.

We therefore are proposing several amendments to Form N–1A, the registration form used by open-end funds to register under the Act and to offer their securities under the Securities Act. The proposed amendments are designed to provide investors who purchase ETF shares in secondary market transactions with additional information regarding ETFs, including information regarding costs associated with an investment in ETFs. The proposal also would eliminate certain disclosures that would be duplicative of the proposed amendments to Item 3 of Form N–1A regarding the exchange-traded nature of ETFs. Finally, we are requesting comment on whether we should create a new ETF-specific registration form.

1. Definitions

We are proposing several amendments to Form N–1A to reflect the adoption of proposed rule 6c–11.[355] First, we are proposing to amend the definition of ''Exchange-Traded Fund'' in Form N–1A to add a specific reference to proposed rule 6c–11.[356] Currently, Form N–1A defines ''Exchange-Traded Fund'' to include a fund or class that has formed and operates in reliance on an exemptive rule adopted by the Commission.[357] We believe that Form N–1A should make specific reference to proposed rule 6c–11, rather than a generic exemptive rule, and that this change would be consistent with Form N–1A's general approach of referring specifically to exemptive rules in other defined terms.

Second, we propose to remove the defined term ''Market Price'' from the Definitions section of Form N–1A in light of our other proposed changes to Form N–1A. Market Price, as presently defined in Form N–1A, is used in several items that we are proposing to eliminate from the Form.[358] The remaining instances in which ''Market Price'' is used do not require the use of a defined term, as they contemplate a more general use of the term, such as the requirement in Item 11 of Form N–1A that an ETF explain in its prospectus that the price of its shares is based on Market Price.[359] Accordingly, given our proposed changes to Form N–1A, we do not believe it is necessary to include ''Market Price'' as a defined term, and propose to remove this definition from the Form.

We request comment on the proposal to amend the definition section of Form N–1A.

- Should we, as proposed, revise the definition of the term ''Exchange-Traded

[354] *See* rule 498 under the Securities Act [17 CFR 230.498].

[355] All of the definitions discussed in this section would appear in Proposed General Instruction A of Form N–1A.

[356] Specifically, the proposed definition of ''exchange-traded fund'' would be a fund or class, the shares of which are listed and traded on a national securities exchange, and that has formed and operates under an exemptive order granted by the Commission or in reliance on rule 6c–11 under the Act.

[357] General Instruction A to Form N–1A.

[358] *See, e.g.,* proposed changes to Item 3 of Form N–1A.

[359] Item 11(a)(1) of Form N–1A. Also, in addition to the defined term ''Market Price,'' Form N–1A currently uses the undefined term ''market price'' in several instances where a more general use of the term is appropriate. *See, e.g.,* Instruction 3 to Item 11(g) of Form N–1A. Our proposed amendments to the Form also include the use of the undefined term ''market price.'' *See, e.g.,* proposed changes to Item 3 of Form N–1A.

Fund'' in Form N–1A to make specific reference to proposed rule 6c–11?

• Should we, as proposed, remove the defined term ''Market Price'' from the Definitions section of the General Instruction to Form N–1A? Alternatively, should we replace the current definition with a reference to the defined term ''Market price,'' as defined in proposed rule 6c–11?

2. Item 3 of Form N–1A

Item 3 of Form N–1A requires funds to include a table describing the fees and expenses investors may pay if they buy and hold shares of the fund. Item 3 does not currently distinguish between ETFs and mutual funds, and only requires disclosure of sales loads, exchange fees, maximum account fees and redemption fees that funds charge directly to shareholders.[360] We therefore are proposing several amendments to this Item to clarify that there are certain fees that are not reflected in the fee table for both mutual funds and ETFs and to require new disclosure requirements that capture ETF-specific trading information and costs. Like all information disclosed in Items 2, 3, or 4 of Form N–1A, the information disclosed in amended Item 3 would have to be tagged and submitted in a structured data format.[361]

a. Changes That Affect Mutual Funds and ETFs

First, we are proposing a narrative disclosure that would clarify that, in addition to the current disclosures relating to investors who buy or hold shares, the fees and expenses reflected in the Item 3 expense table may be higher for investors if they *sell* shares of the fund.[362] This amendment would be applicable to both mutual funds and ETFs given that an investor may incur expenses other than redemption fees when selling shares of either a mutual fund or ETF. For example, although less common than they were in the past, an investor may incur a back-end sales load when selling a mutual fund share. Likewise, an investor may bear costs associated with bid-ask spreads when selling ETF shares.

We are also proposing to require a statement that investors may be subject to other fees not reflected in the table, such as brokerage commissions and fees to financial intermediaries.[363] We believe this is appropriate disclosure for both ETFs and mutual funds because brokerage commissions and fees to financial intermediaries could be applicable to ETFs and mutual funds alike.

b. Changes That Affect ETFs

Because ETF shares are exchange-traded, secondary market investors in ETF shares are subject to trading costs, such as bid-ask spreads, that are not currently required to be disclosed under Item 3. Trading costs, like all costs and expenses, affect investors' returns on their investment.[364] In addition, some investors use ETFs more heavily as trading vehicles compared to mutual funds, and the extent of the trading costs borne by an investor depends on how frequently the investor trades ETF shares. We believe that investors could overlook these costs and that additional disclosure would help them better understand the total costs of investing in an ETF. Disclosure would also facilitate comparisons between different investment options.[365]

As a result, we are proposing a new section in Item 3 that would require disclosure of certain ETF trading information and trading costs.[366] This proposed section is formatted as a series of question and answers (''Q&As''). We believe this format would help facilitate an investor's understanding of certain terminology and cost calculations. The proposed Q&A disclosures would require information related to the trading of ETFs on the secondary market and the costs associated with such trading. The specific question and answer disclosures are shown in Figure 1 below.

[360] Item 3 of Form N–1A.

[361] *See* General Instruction C.3.g.(i) to Form N–1A.

[362] Proposed amendments to Item 3 of Form N–1A. In order to eliminate duplicative disclosures, we are proposing to amend Instruction 1(e) of Item 3 to eliminate the requirement that ETFs modify the narrative explanation for the fee table to state that investors may pay brokerage commissions on their purchase and sale of ETF shares, which are not reflected in the example. We are also proposing to eliminate the instruction that funds may only exclude fees charged for the purchase and redemption of the Fund's creation units if the fund issues or redeems shares in creation units of net less than 25,000 shares. Thus, as proposed, an ETF may exclude from the fee table any fees charged for the purchase and redemption of the Fund's creation units regardless of the number of shares. *See* proposed Instruction 1(e)(ii) to Item 3; *see also* proposed Instruction 1(e)(ii) to Item 27(d)(1) (proposing the same modification for the expense example in an ETF's annual and semi-annual reports); *see also infra* footnote 397 and accompanying and following text.

[363] Proposed amendments to Item 3 of Form N–1A.

[364] *See* SEC Office of Investor Education and Advocacy, Investor Bulletin: How Fees and Expenses Affect Your Investment Portfolio (Feb. 2014), *available at https://www.sec.gov/investor/alerts/ib_fees_expenses.pdf,* at 2 (''As with any fee, transaction fees will reduce the overall amount of your investment portfolio.''); *see also* Andrea Coombes, *Calculating the Costs of an ETF,* The Wall Street Journal (Oct. 23, 2012), *available at https://www.wsj.com/articles/SB10000872396390444042420457804429300857620 4.*

[365] Alex Bryan & Michael Rawson, *The Cost of Owning ETFs and Index Mutual Funds,* Morningstar Manager Research (Dec. 1, 2014), *available at http://global.morningstar.com/us/documents/pr/Cost-Of-Owning-Index-ETF-MFS.pdf,* at 15 (''While trading commissions are the most conspicuous component of trading costs, indirect trading costs, such as the bid-ask spread and market impact of trading can often be more important.'').

[366] Proposed amendments to Item 3 of Form N–1A.

Exchange-Traded Fund Trading Information and Related Costs

What information do I need to know about how the Exchange-Traded Fund ("ETF") trades?

Individual shares of an ETF may only be bought and sold in the secondary market through a broker or dealer at a market price. The market price can change throughout the day due to the supply of and demand for ETF shares, and changes in the value of the Fund's underlying investments, among other reasons. Because ETF shares trade at market prices rather than net asset value, shares may trade at a price greater than net asset value (premium) or less than net asset value (discount).

What costs are associated with trading shares of an ETF?

An investor may incur costs when buying or selling shares on an exchange that are ***in addition to*** the costs described above. Examples include brokerage commissions, costs attributable to the bid-ask spread, and costs attributable to premiums and discounts.

What is the bid-ask spread?

The bid-ask spread is the difference between the highest price a buyer is willing to pay to purchase shares of the Fund (bid) and the lowest price a seller is willing to accept for shares of the Fund (ask). The bid-ask spread can change throughout the day due to the supply of or demand for ETF shares, the quantity of shares traded, and the time of day the trade is executed, among other factors. For the ETF's most recent fiscal year ended [____], the median bid-ask spread was

XX.XX%.

How does the bid-ask spread impact my return on investment?

The impact of the bid-ask spread depends on your trading practices. For example, based on the ETF's fiscal year-end data, purchasing $10,000 worth of ETF shares and then immediately thereafter selling $10,000 worth of ETF shares (*i.e.*, a "round-trip"), your cost, in dollars, would be as follows:

For a SINGLE round-trip (each trade being $10,000)

Assuming mid-range spread cost:	$ _____
Assuming high-end spread cost:	$ _____

But what if I plan to trade ETF shares frequently?

Based on the ETF's most recent fiscal year-end data, completing 25 round-trips of $10,000 each, your cost, in dollars, would be as follows:

For 25 round-trips (each trade being $10,000)

Mid-range spread cost:	$ _____
High-end spread cost:	$ _____

***Where* can I get more trading information for the ETF?**

The ETF's website at [www.[Series-SpecificLandingPage.com]] includes recent information on the Fund's net asset value, market price, premiums and discounts, as well as an interactive calculator you can use to determine how the bid-ask spread would impact your specific investment.

Figure 1

Q&A 1. Currently, Item 6(c) of Form N–1A requires that ETFs disclose that: (i) Shares may only be purchased and sold on a national securities exchange through a broker-dealer; and (ii) the price of ETF shares is based on market

price, and since ETFs trade at market prices rather than at net asset value, shares may trade at a price greater than net asset value (premium) or less than net asset value (discount).[367] We are proposing to move this description from Item 6 to Q&A 1 in Item 3. We believe that moving this information to Item 3 would consolidate relevant disclosures regarding ETF trading costs and provide the investor with helpful background information relating to ETF trading.[368] We also propose to replace the reference to ''national securities exchange'' with a reference to ''secondary markets'' to reflect that ETFs can be bought and sold over the counter or on an alternative trading system in addition to their primary listing exchanges.

Q&A 2. The second Q&A we are proposing identifies the specific costs associated with trading shares of an ETF, such as brokerage commissions, bid-ask spread costs, and potential costs attributable to premiums and discounts. This question clarifies that the costs being discussed in the questions that follow should be considered *in addition* to the costs previously discussed in the fee table.

Q&A 3. Proposed Q&A 3 would include ETF-specific disclosures relating to the median bid-ask spread for the ETF's most recent fiscal year.[369] Costs attributable to the bid-ask spread may increase or decrease when certain market conditions exist or certain factors are present. We believe that this disclosure would inform investors regarding the potential impact of spread costs, including for investors who frequently trade ETF shares. We also believe that disclosure regarding median bid-ask spreads would provide a helpful metric for ETF investors to determine an ETF's historic liquidity, since a narrower bid-ask spread typically signals higher liquidity and a wider bid-ask spread generally signals lower liquidity.[370] Investors can use the bid-ask spread to assess the ETF's tradability in comparison to other similar ETFs.[371]

The proposed Q&A would describe the bid-ask spread as the difference between the highest price a buyer is willing to pay to purchase shares of the ETF (bid) and the lowest price a seller is willing to accept for share of the ETF (ask). We are proposing to require this description because some investors may not be familiar with the term ''bid-ask spread,'' making it difficult for them to meaningfully analyze the specific bid-ask spread number that we propose to include in this Q&A. The proposed Q&A also would explain that the bid-ask spread can change throughout the day due to the supply of or demand for ETF shares, the quantity of shares traded, and the time of day the trade is executed, among other factors.

In addition, we are proposing that an ETF calculate and disclose its median bid-ask spread over the most recently completed fiscal year.[372] We propose that the median bid-ask spread be calculated by using trading data from each trading day of the ETF's prior fiscal year.[373] Each daily bid-ask spread would be calculated by taking the average of the intraday bid-ask spreads, which are measured by using the best bid and best ask, respectively, at ten-second intervals throughout the trading day. We understand that this is a widely accepted method for calculating the bid-ask spread and believe that using the best bid and ask would be administratively easier and less burdensome than other methods of calculating the bid and ask price, such as weighting or averaging bid and ask prices throughout the trading day. We propose that the bid-ask spread be calculated by taking the difference between the bid and the ask and dividing that difference by the midpoint between the bid and the ask. The median would be expressed as a percentage, rounded to the nearest hundredth percent.

As proposed, an ETF would be required to use data from the full trading day without excluding certain time periods, because we believe the spread metric should represent the costs that an actual investor could face at any time during the day. We note, however, that costs related to the bid-ask spread can fluctuate throughout the day. For example, the bid-ask spread tends to be higher at the beginning of the trading day and towards the end of the trading day.[374] At market open, wide spreads may persist until all underlying stocks open and start trading. At market close, market makers may be less willing to purchase ETF shares because they do not want to hold the ETF shares overnight.

We propose to require ETFs to use one full fiscal year of data because we believe a full year would capture spreads during varying market events throughout the year. Although we considered requiring ETFs to use a full calendar year of data for this disclosure requirement in order to promote greater comparability among ETFs, we are concerned that using calendar year data would necessarily mean that information in certain ETF prospectuses would be over a full year old.[375] We preliminarily believe that, to the extent there are any concerns that using fiscal year data instead of calendar year data may undermine comparability of the spreads of different ETFs when there are significant market events in a particular calendar year, such concerns are mitigated by the relatively low impact of a single market event to a full year's

[367] Item 6(c) of Form N–1A.

[368] *See* proposed amendments to Item 3 of Form N–1A.

[369] As discussed above, given the importance of this information to understanding the total expenses an investor may bear when investing in an ETF, we propose that bid-ask spread information be included in both the ETF's prospectus and on the ETF's website. Proposed Instruction 5(a) to Item 3 of Form N–1A. *See also infra* section II.C.6.

[370] CFA Institute Research Foundation, *Comprehensive Guide to Exchange-Traded Funds (ETFS)* (2015), *available at https://www.cfapubs.org/doi/pdf/10.2470/rf.v2015.n3.1,* at 67–8 (''CFA Guide''). *See also* Allen B. Atkins & Edward A. Dyl, *Transactions Costs and Holding Periods for Common Stocks,* 52 Journal of Finance 1, 309–325 (1997) (''Additional evidence of an association between transactions costs and trading volume can be found in the literature on bid-ask spreads.''). Literature also suggests that the bid-ask spread could be affected by increased transaction costs. *See* Gerald W. Buetow & Brian J. Henderson, *Are Flows Costly to ETF Investors?,* 40 Journal of Portfolio Management 3, 101 (Spring 2014), *available at http://www.bfjlaward.com/pdf/25949/100-112_Henderson_JPM_0417.pdf* (noting that authorized participants are likely to pass transaction fees onto shareholders through the spread).

[371] *See* CFA Guide, *supra* footnote 370, at 69 (noting that ''for some ETFs, even though the underlying securities are liquid, bid–ask spreads may be wide simply because the ETF trades so little that the chances of an [authorized participant] rolling up enough volume to use the creation/redemption process are low'').

[372] Proposed Instruction 5(a) to Item 3 of Form N–1A.

[373] Proposed Instruction 5(b) to Item 3 of Form N–1A.

[374] Ogden H. Hammond & Michael Lieder, J.P. Morgan Asset Management, *Debunking myths about ETF liquidity* (May 2015), *available at https://am.jpmorgan.com/blob-gim/1383272223898/83456/1323416812894_Debunking-myths-about-ETF-liquidity.pdf,* at 6 (noting that certain ETF liquidity patterns tend to repeat and are well known to veteran traders, such as limited trading of ETFs immediately prior to the close). *See also* Sunil Wahal, *Entry, Exit, Market Makers, and the Bid-Ask Spread,* 10 Rev. Financial Stud 871 (1997), *available at http://www.acsu.buffalo.edu/~keechung/MGF743/Readings/H1.pdf* (''Large-scale entry (exit) is associated with substantial declines (increases) in quoted end-of-day inside spreads, even after controlling for the effects of changes in volume and volatility. The spread changes are larger in magnitude for issues with few market makers; however, even for issues with a large number of market makers, substantial changes in quoted spreads take place.'').

[375] For example, if the ETF's fiscal year end was August 31, the annual update would be required to be filed no later than December 29, which would include spread cost information from the prior calendar year for up to one year thereafter, meaning that the spread cost information could be almost two years old. By using fiscal year end data, the information would never be more than 16 months old.

median bid-ask spread. Using one full fiscal year of data also is consistent with all other requirements for Item 3 of Form N–1A.[376]

Under our proposal, an ETF would be required to disclose median bid-ask spread instead of average bid-ask spread because we believe the median spread better represents the spread that the average investor would experience, whereas the average spread better represents the spread of an average ETF share in a given transaction. We believe sorting the spreads across the entire fiscal year to determine the median—rather than taking the median spread of each trading day throughout the fiscal year first, sorting each day's median, and taking the median spread across all trading days—provides a better representation of the true median across the entire fiscal year. Requiring disclosure of the median bid-ask spread also avoids the problem of an outlier skewing the bid-ask spread figure. For example, if the spread is .05 in nine instances but 1.00 in one instance, then the average spread will be 0.145 which we believe is a less accurate reflection of the bid-ask spread for that fund.

Q&A 4 and 5. We also propose to require ETFs to include questions on how the bid-ask spread impacts the return on a hypothetical $10,000 investment for both buy-and-hold and frequent traders.[377] These examples are designed to allow secondary market investors to see the impact that bid-ask spreads can have on the investor's trading expenses and ultimately the return on investment. For example, a hypothetical example of spread costs can highlight that these costs can be a drag on returns for someone who trades frequently in certain types of ETFs. On a percentage basis, spread costs for a single trade can equal, if not exceed, the ETF's annual operating expenses in some cases. If an investor trades in and out of an ETF several times within a relatively short period of time, the costs attributable to the bid-ask spread can increase rapidly. Transparency into trading costs also may promote greater comparability among ETFs and other investment products, such as mutual funds. For example, two ETFs may have very similar expense ratios, but one ETF consistently has higher bid-ask spreads, which could make the cost of that ETF significantly higher than the one with a low bid-ask spread.

The proposed example in Q&A 4 would require disclosure of hypothetical trading costs attributable solely to the median bid-ask spread based on data from the ETF's prior fiscal year.[378] Specifically, the spread costs example would demonstrate the hypothetical impact of the ETF's bid-ask spread for one $10,000 ''round-trip'' trade (*i.e.,* one buy *and* sell transaction). The proposed example reflects costs that are in addition to the annual fund operating expenses, which are currently disclosed in Item 3 of N–1A.[379] Thus, to assist investors with comparing the costs of investing in various ETFs, we believe that it is appropriate to use the same hypothetical investment amount, $10,000, which is used for the current expense example in Item 3 of Form N–1A.

To illustrate that more frequent trading can significantly increase costs, the proposed example in Q&A 5 demonstrates the costs associated with 25 $10,000 round-trip trades (50 total trades). This figure represents approximately two round-trip trades each month. While the number of trades that an investor makes during the course of a year can vary depending on the type of investor and the type of investment strategy the ETF pursues, we believe that an example showing the spread costs of 50 total trades could provide useful information for those that trade frequently.[380] As discussed in more detail below, our proposal also would allow investors to obtain more tailored information regarding their costs on the ETF's website.[381]

Pursuant to this requirement, an ETF would be required to disclose ''mid-range spread costs'' and ''high-end spread costs.'' The mid-range spread costs would be calculated by using the median spread, divided by two, and then multiplying the resulting number by a $10,000 trade size and the number of transactions. The high-end spread costs would be calculated by using the same calculated spread data from the ETF's prior fiscal year, except instead of choosing the median spread, the disclosure would represent the 95th percentile spread, after sorting that year's data.[382] We preliminarily believe that utilizing the 95th percentile spread (*i.e.,* the spread representing the threshold for the highest 5% of spreads) is appropriate for the purposes of representing high-end spread costs.

We considered whether to also include ''low-end spread costs'' but determined that the combination of presenting ''mid-range spread costs'' and ''high-end spread costs'' would provide the most meaningful disclosure to investors. Many ''low-end spread costs'' for ETFs with significant volume have a penny spread and would therefore not provide as useful of a comparison across funds. Furthermore, some ''mid-range spread costs'' and ''high-end spread costs'' could account for more than 50% of the cost of an initial investment in an ETF, whereas a ''low-end spread cost'' might only account for a small fraction of an investor's overall costs. We request comment on this point below.

An investor could use both the median bid-ask spread figure from proposed Q&A 4 and the costs information in Q&A 5 to better assess the overall cost impact of the bid-ask spread. Proposed Q&As 1–5 also would provide investors with a better understanding of the basic terminology needed to understand some frequently overlooked costs associated with investing in ETFs, and then provide the data needed to understand how those costs materialize for the particular fund and how those costs compare to other ETFs.

Q&A 6. *Cross-reference to ETF's website and Interactive Calculator Requirement.* As discussed above, proposed rule 6c–11 would require daily website disclosure of several items, including the NAV per share, market price, and premium or discount. As the disclosures on an ETF's website would be updated daily, we believe a cross-reference in Form N–1A to the website disclosures would enable investors to receive timely and granular information that could assist with making an investment decision.

[376] *See* Item 3 of Form N–1A.

[377] The proposal uses $10,000 in order to maintain consistency with the cost example in Item 3 of Form N–1A.

[378] Proposed Instruction 5(b) to Item 3 of Form N–1A.

[379] Item 3 of Form N–1A. Item 3 only requires 1- and 3-year expense examples for annual fund operating expenses for ''New Funds.''

[380] We acknowledge the inherent difficulty of setting a number of trades that reflects an ''average investor.'' Based on staff experience, however, we preliminarily believe that 50 total trades, which represents approximately 2 round-trip transactions per month, is a reasonable figure to utilize for the purposes of demonstrating the costs of trading for a frequent trader in Q&A 5.

[381] *See* proposed Instruction 5(e) to Item 3 of Form N–1A.

[382] We are proposing to divide the bid-ask spread by two on the assumption that the value of an ETF share is the midpoint between the bid price and the ask price. Therefore, the ''cost'' attributable to the bid-ask spread of executing one trade would be, in the case of purchasing a share of an ETF, the difference between the ask price and the midpoint between the bid and the ask prices—in other words, this difference would represent the cost above which the share was valued for this purpose and not the full ''round-trip'' cost. Likewise, in the case of selling an ETF share, the ''cost'' attributable to the bid-ask spread of executing one trade would be the difference between the bid and the midpoint between the bid and the ask prices. To calculate the cost of multiple trades, the single trade cost would be multiplied by the number of transactions.

Accordingly, we propose to require a statement in Q&A 6 that would refer investors to the ETF's website for more information.[383] Item 11(g) currently requires an ETF to provide a website address in its prospectus if the ETF omits the historical premium/discount information from the prospectus and includes this information on its website instead. As a result, many ETFs already include a website address in their prospectus.[384]

In addition, proposed Instruction 5(e) to Item 3 would require an ETF to provide an interactive calculator in a clear and prominent format on the ETF's website. The purpose of the interactive calculator is to provide investors with the ability to customize the hypothetical calculations in Item 3 to their specific investing situation. For example an investor with an investment of $2,500 opposed to $10,000 or wishing to trade 10 times opposed to the 25 times presented in Item 3 could use the calculator to find more tailored cost-related information. We are sensitive to the fact that creating a web-based interactive calculator is not without cost, especially for smaller fund complexes. We have tried to mitigate these costs by limiting the proposed investor-input to two data points: Investment amount and number of trades. We also tried to limit the complexity of the tool by proposing to require the interactive calculator to use the calculations detailed in Instructions 5(a)—(d) to Item 3 to provide the information required by Q&As 3–5, which relates to the bid-ask spread.

c. Exception for ETFs With Limited Trading History

Trading information and related costs may not be useful to secondary market investors in an ETF that has only a limited amount of trading history since inception. Therefore, we are proposing that an ETF that had its initial listing on a national securities exchange after the beginning of its most recently completed fiscal year would not be required to include the ETF's median bid-ask spread or the spread cost example in its Item 3 disclosure, nor would the ETF be required to provide an interactive calculator on its website.[385] We preliminarily believe this information is most useful when there is at least one full fiscal year of data underlying the metrics. Without a minimum amount of trading data to calculate this information, the resulting calculations could be skewed for any number of reasons. For example, it is possible that the time of year during which the ETF was trading or the fact that an ETF was relatively new to the market and had not had significant marketing to gain interest for shares of the ETF resulted in low trading volume and higher bid-ask spreads. We propose to require a newly launched ETF to provide a brief statement to the effect that the ETF does not have sufficient trading history to report trading information and related costs.[386] The proposed amendment would prohibit a new ETF from disclosing data based on very short trading histories, which we preliminarily believe could be misleading. This approach would also be consistent with our treatment of other disclosure items such as portfolio turnover data and annual returns.[387]

We seek comment on our proposed amendments to Item 3:

- Should we require ETFs and mutual funds to include a statement that investors may be subject to other costs not reflected in the fee table, such as brokerage commissions and other fees to financial intermediaries? Would this disclosure be confusing to individual investors, particularly those investing in mutual funds?
- In addition to the statement regarding brokerage commissions, should we require quantitative disclosure of the range of brokerage commissions for transactions? Should this disclosure be required of both mutual funds and ETFs? Where in the registration statement should such disclosure be included? Or, would disclosure of brokerage commissions raise challenges too great to require disclosure? For example, would variations in methods used to collect and set commissions make such disclosure too complex? How costly or difficult would it be to obtain information about brokerage commissions?
- Should other costs be disclosed in Item 3? If so, which costs and why? How and where should those other costs be disclosed? Should Item 3 include market price range or NAV range? What other trading information, if any, should be included in Item 3 and why? For example, should we require ETFs to disclose information regarding the number of days the ETF's shares traded on a national securities exchange, the ETF's average daily volume, and/or the ETF's total number of shares outstanding? If so, how should we require these metrics to be calculated and disclosed?
- Should we include the specific ETF disclosures in Item 3? Should we require that those disclosures be made in a Q&A format? Would investors understand and find the proposed Q&A format useful? Are there other formats we should consider? Should we permit ETFs to use any format that is designed to effectively convey the information to investors?
- Should we replace the reference to ''national securities exchange'' with ''secondary markets'' in Q&A 1 as proposed?
- Should we require ETFs to explain bid-ask spreads and the factors that could affect bid-ask spreads in Item 3? Are there other explanations (or means to calculate bid-ask spreads) that we should consider? Are there other factors that could impact bid-ask spreads that we should include in this explanation?
- Should the median bid-ask spread information be included in the prospectus? Should this information be included in Item 3 or in a different section of the registration statement? If so, where? Alternatively, should we require disclosure of this information on an ETF's website?
- To what extent is historical spread data predictive of future spread data? Should we require language indicating that historical spread data may not be predictive of future spread data?
- Should the spread calculation exclude data from the beginning and end of the trading day? If so, what time periods should it exclude and why? For example, should we exclude the first and last 15 minutes of each trading day?
- Should the spread calculation be based on data from an ETF's fiscal-year end or calendar-year end and why? Would the use of fiscal-year make comparability among funds more difficult since funds have different fiscal-year ends? Should the spread calculation be based on data from more than one year? If so, how many years and why? Should the spread calculation be based on data that, in addition to the fiscal or calendar year, also includes

[383] Proposed amendments to Item 3 of Form N–1A would require an ETF to include the following statement in its prospectus: ''The ETF's website at [*www.*[*Series-SpecificLandingPage.com*]] includes recent information on the Fund's net asset value, market price, premiums and discounts, as well as an interactive calculator you can use to determine how the bid-ask spread would impact your specific investment.'' The Commission explained in a 2000 release that filers submitting HTML documents on EDGAR should take reasonable steps when they create the document in order to prevent URLs from being converted into hyperlinks. *See* Rulemaking for Edgar System, Securities Act Release No. 33–7855 (Apr. 24, 2000).

[384] As discussed above, we propose to replace the historical premium/discount information in Item 11(g) with line graph disclosure regarding premiums and discounts that would be required by proposed rule 6c–11(c)(1)(iv). *See supra* section II.C.6.

[385] Proposed Instruction 5(a) to Item 3 of Form N–1A.

[386] *Id.*

[387] *See* Items 3 and 4 of Form N–1A.

data from the most recently completed fiscal or calendar quarter, respectively? Should the calculation be done on a daily basis first and then again across the entire fiscal year?

• Should the calculation for the bid-ask spread throughout the trading day be done more or less frequently than every ten seconds? If so, how frequently and why?

• Should the bid and ask be calculated using a different method, such as weighting the prices throughout the book? If so, explain the method and why it should be used.

• Should a metric other than median be used for the spread calculation? For example, should we use average spread or effective spread? [388] If so, why is it preferable and how should it be calculated? Would the use of a different spread calculation provide more comprehensive information about extreme market events? For example, should we also require disclosure of additional percentiles towards the extreme of the distribution, such as the 95th percentile?

• Instead of using the bid-ask spread as an indicator of trading costs, is there another method that would better reflect an ETF's overall trading costs? If so, what is that metric, why is it better than disclosing the bid-ask spread, and how should it be calculated and disclosed?

• How difficult or costly would it be for ETFs to obtain the data necessary to calculate median bid-ask spread as proposed? Are there any negative consequences of disclosing the bid-ask spread? If so, what are they?

• When calculating the spread costs example, should the bid-ask spread be divided by two for each transaction listed or should each transaction reflect the full round-trip spread cost?

• Should we require disclosure of costs associated with ''mid-range spread costs'' and ''high-end spread costs'', as proposed? Should we additionally include a requirement to disclose ''low-end spread costs''? Why or why not? Would the disclosure of this data result in retail investor confusion?

• Is the $10,000 trade amount used in the spread costs example reasonable? Should we consider a lower trade amount? Alternatively, should the spread costs example show varying trade sizes calculated using varying book depths? If so, what trade sizes and why should they be used?

• Should the spread example include a different number of transactions? If so, how many transactions should be used for each column and why? Should the number of transactions vary based on the type of investment strategy the ETF pursues? If so, how should we determine the number of transactions and corresponding ETF types?

• Are there any negative consequences of disclosing the spread costs example? If so, what are they?

• Should each ETF be required to disclose a website address in Item 3 as proposed? Should we permit an ETF to comply with this requirement by including a general web address to an investment company complex's website or should we require a series-specific landing page for the ETF? Would a cross-reference to the ETF's series-specific page be useful?

• Should we require ETFs to disclose information regarding premiums and discounts in Item 3 of Form N–1A, either in addition to, or in lieu of, the disclosures proposed in rule 6c–11? If so, should the information be based on data over the entire fiscal year or calendar year? Do commenters believe that the reference to the ETF's website, where such information may be found, provides investors with useful information regarding these potential costs?

• Would investors find the information in our proposed amendments to Item 3 helpful in comparing between different investment options?

• Should we require funds, as proposed, to provide investors with an interactive calculator on their website? Would investors find an interactive calculator helpful to better understand the costs of investing in ETFs? Are there data points that we have not discussed that the interactive calculator should include? Should the interactive calculator be required for both mutual funds and ETFs? For example, should the interactive calculator be expanded to include fee table information for both ETFs and mutual funds? Are there any challenges to posting an interactive calculator that we are not considering? What costs would be associated with developing this type of calculator?

• Should we require funds to provide an interactive calculator on their website for other costs, such as any costs attributable to premiums or discounts? If so, what would be the user inputs and outputs for the calculator? How would the calculator calculate such a cost?

• Should there be an exception to the requirement to disclose trading information and related costs for newly launched ETFs as proposed? If not, why not? Should a newly launched ETF nevertheless be required to provide an interactive calculator on its website? Should the threshold for the exemption to include trading information and related costs disclosure instead be based on Form N–1A's definition of ''New Fund'' [389] or a different period of time? If so, why? Should there be an exception to disclosing trading information and related costs for any other reason (*e.g.,* limited trading book depth, low volume, or trading only on a percentage of the days throughout the year)? If so, what should the threshold be and why?

• In lieu of providing an exception from the requirement to disclose trading information and related costs for newly launched ETFs, should we instead adopt a requirement for ETFs to disclose this information once the ETF reaches or exceeds a specified threshold of trading volume for a specified period of time, regardless of how long it has been in operation? Put differently, should we base this exception on level of trading volume rather than the length of an ETF's operation? If so, what should such thresholds be? If not, why not?

3. Item 6 of Form N–1A

Currently, Item 6(c)(i) of Form N–1A requires an ETF to: (i) Specify the number of shares it will issue or redeem in exchange for the deposit or delivery of baskets; (ii) explain that the individual shares of the ETF may only be purchased and sold on a national securities exchange through a broker or dealer; and (iii) disclose that the price of ETF shares is based on the market price and as a result, shares may trade at a price greater than NAV (premium) or less than NAV (discount).[390] The number of shares the ETF issues or redeems in exchange for the deposit or delivery of baskets is largely duplicative of reports required in Form N–CEN.[391] We therefore propose to remove this requirement from Item 6.[392] The remainder of the information required by Item 6(c)(i) is proposed to be moved to the Item 3 disclosure.[393] In order to eliminate duplicative disclosure, we propose to remove these requirements

[388] *See supra* footnote 314.

[389] Instruction 6 to Item 3 of Form N–1A defines a ''New Fund'' as ''a Fund that does not include in Form N–1A financial statements reporting operating results or that includes financial statements for the Fund's initial fiscal year reporting operating results for a period of 6 months or less.'' The instruction permits New Funds to estimate ''Other Expenses'' and to complete only 1- and 3-year portions of the expense example. *Id.*

[390] Item 6(c)(i) of Form N–1A.

[391] *See* Item E.3.a of Form N–CEN; s*ee also* Reporting Modernization Adopting Release, *supra* footnote 147, at n.1100 and accompanying text (requiring ETFs ''to report the number of ETF shares required to form a creation unit as of the last business day of the reporting period.'').

[392] *See* proposed amendments to Item 6 of Form N–1A.

[393] *See* proposed amendments to Item 3 of Form N–1A.

from Item 6.[394] As noted above, moving this information to Item 3 would consolidate relevant disclosures regarding the fees and trading costs that may be borne by an ETF investor in one place.

Additionally, Item 6(c)(ii) currently requires ETFs issuing shares in creation units of less than 25,000 to disclose the information required by Items 6(a) and (b).[395] Current Items 6(a) and (b) require funds to: (i) Disclose their minimum initial or subsequent investment requirements; (ii) disclose that the shares are redeemable; and (iii) describe the procedures for redeeming shares. We are proposing to eliminate these disclosures.[396] When we adopted these requirements, we reasoned that individual investors may be more likely to indirectly transact in creation units through authorized participants if the creation unit size was less than 25,000 shares.[397] Based on staff experience, we understand that retail investors do not engage in primary transactions through authorized participants. Furthermore, to the extent that authorized participants act as agents for market makers in primary transactions with the ETF, we believe that the flow of information on how to purchase and redeem shares is robust given the market maker's relationship with an authorized participant. Therefore, we do not believe that this disclosure would be beneficial.

We request comment on the proposed amendments to Item 6.

- Should we remove the disclosure regarding creation unit sizes from Form N–1A, as proposed? Are we correct in our understanding that this disclosure is largely duplicative of disclosure required in Form N–CEN? Are we correct in our belief that investors do not find this information useful in the context of a prospectus? Instead of removing this disclosure from Form N–1A entirely, should we move it to the Statement of Additional Information? Do retail investors typically use the information on creation unit size and if so, for what purpose? Is our belief correct that this information is more useful for authorized participants and market makers and less useful to investors purchasing individual shares on an exchange?
- Alternatively, should we require ETFs to disclose information regarding their creation unit sizes or transaction fees, or both, on their websites?
- Should ETFs continue to disclose in Item 6 (or any other Item included within the summary prospectus disclosure) information currently required by Items 6(a) and (b)? If so, why? Should this disclosure be based on a numerical threshold, and if so, what would the appropriate threshold be and why?
- Should we require ETFs to provide disclosure regarding transaction fees associated with the purchase and redemption of creation units? If so, where should such disclosure be provided?
- Are we correct in our understanding that that the flow of information on how to purchase and redeem ETF shares is robust due to the relationship between market makers and authorized participants?

4. Item 11 of Form N–1A

Item 11(g)(1) currently specifies that an ETF may omit information required by Items 11(a)(2), (b), and (c) if the ETF issues or redeems shares in creation units of not less than 25,000 shares each.[398] Similar to the reasoning discussed above regarding amendments to Item 6,[399] we propose to amend Item 11(g)(1) to permit all ETFs, not just ones with creation unit sizes of not less than 25,000 shares, to omit the information required by Items 11(a)(2), (b), and (c).[400]

Item 11(a)(2) requires a fund to disclose when calculations of NAV are made and that the price at which a purchase or redemption is effected is based on the next calculation of NAV after the order is placed.[401] Item 11(b) and (c) require a fund to describe the procedures used for purchasing and redeeming the fund's shares.[402] In our view, eliminating these disclosure requirements for all ETFs would not detract from an understanding of how authorized participants transact directly with the ETF in the primary market. As discussed above, the proposed rule would define an authorized participant as a member or participant of a clearing agency registered with the Commission, which has a contractual arrangement with the ETF or one of the ETF's service providers.[403] Thus, we believe the parties who purchase or redeem shares from the ETF directly would either have the knowledge necessary to do so without additional procedural disclosure or the ability to request such information.

Item 11(g)(2) currently includes a requirement for an ETF to provide a table showing the number of days the market price of the ETF's shares was greater than the ETF's NAV per share for certain time periods.[404] As discussed above, we propose to require information about the premium and discount of the ETF's shares to their NAV per share to be included on the ETF's website. Thus, we are proposing to remove the information currently required by Item 11(g)(2), as more timely information would be available on the ETF's website. For the same reasons, we are also proposing to eliminate Item 27(b)(7)(iv) of Form N–1A, which requires ETFs to include a table with premium/discount information in their annual reports for the five most-recently completed fiscal years.[405]

We request comment on the proposal to remove the requirement to disclose information required by Items 11(a)(2), (b), and (c) as well as the proposal to remove the requirement to disclose the premium/discount information in the prospectus and annual report.

- Should we keep this disclosure in the prospectus? If we were to keep this disclosure requirement, should we require ETFs to disclose different information about the procedures to purchase and redeem shares directly with the ETF?
- Do most ETFs provide the premium/discount information required by this information on their websites? If we were to keep the requirement to disclose the premium/discount information in the prospectus, should it mirror the information proposed to be required on the ETF's website?

5. Potential Alternatives to Current ETF Registration Forms

As discussed above, open-end funds, including ETFs organized as open-end funds, are required to file Form N–1A to

[394] *See* proposed amendments to Item 6 of Form N–1A.

[395] Item 6(c)(ii) of Form N–1A.

[396] *See* proposed amendments to Item 6 of Form N–1A.

[397] *See* Enhanced Disclosure and New Prospectus Delivery Option for Registered Open-End Management Investment Companies, Investment Company Act Release No. 28584 (Jan. 13, 2009) [74 FR 4546 (Jan. 26, 2009)] (''Summary Prospectus Adopting Release''), at nn.170–72.

[398] Item 11(g)(1) of Form N–1A.

[399] *See supra* section I.H.3.

[400] Proposed Item 11(g)(1) of Form N–1A.

[401] Item 11(a)(2) of Form N–1A. Item 11(a)(1) already requires that ETFs include an explanation that the price of fund shares is based on market price. Item 11(a)(1) of Form N–1A.

[402] Item 11(b) and (c) of Form N–1A.

[403] *See* proposed rule 6c–11(a).

[404] Item 11(g)(2) of Form N–1A. The item provides that an ETF may omit the table if it provides a website address that investors can use to obtain the premium/discount information required by the item.

[405] Although the time period required by this disclosure is different than the requirement in Item 11(g)(2), ETFs are permitted to omit both disclosures by providing on their websites only the premium/discount information required by Item 11(g)(2) (the most recently completed fiscal year and quarters since that year).

register under the Act and to offer their securities under the Securities Act. UITs, including ETFs organized as UITs, initially register under the Investment Company Act on Form N–8B–2 and register their offerings of securities under the Securities Act on Form S–6.[406] However, ETFs, regardless of structure, operate differently than the other investment companies that register on Forms N–1A and N–8B–2. For example, unlike traditional open-end funds and UITs, ETFs are exchange-traded and investors rely on the arbitrage mechanism to ensure that the ETF's shares trade at or close to its NAV.[407] As a result of these differences, in addition to our proposed amendments to Form N–1A and Form N–8B–2, we are seeking comment on whether we should create a new registration form that is specifically designed for ETFs or consider other disclosure formats as part of a future rulemaking.

- Should we create a new registration form for ETFs? What types of ETFs should be required to file reports on such a form? For example, should we limit the form to ETFs that would be subject to proposed rule 6c-11? Or should all ETFs, including UIT ETFs, file reports on such a form?
- What type of ETF-specific information should such a form include? Should the form require more disclosure on the effectiveness of the arbitrage mechanism?[408] Should the disclosures require qualitative disclosures that relate specifically to ETFs, including the performance of the ETF's arbitrage mechanism? Should this disclosure be required as part of an annual report?[409] Should we require a discussion of the ETF's bid-ask spread or premiums and discounts throughout the year? Should the form include a discussion of ETF-specific risk factors? If so, what risk factors should be included?
- Should we require ETFs to provide investors with a short summary document that provides key information about the ETF? What type of information should the document include? For example, should it include information related to the ETF's strategy, portfolio investments, costs, risks, or performance? Should we require it to be in a standardized format?[410]
- As an alternative to a new ETF form, or in addition to such a form, should we consider a summary prospectus targeted specifically at ETFs and their unique features?
- Should we require ETFs to file periodic reports, such as on Form 8–K? Under what circumstances should we require periodic reports? For example, should we require ETFs to file periodic reports after a market event that adversely affects the arbitrage mechanism during the trading day?

I. Amendments to Form N–8B–2

Form N–8B–2 is the registration form under the Investment Company Act for UITs which are currently issuing securities and is used for registration of ETFs organized as UITs.[411] For the reasons discussed above in section II.A.1, we believe that UIT ETFs should be regulated pursuant to their exemptive orders, rather than a rule of general applicability and are not proposing to include them within the scope of proposed rule 6c–11. However, we believe that it is important for investors to receive consistent disclosures for ETF investments, regardless of the ETF's form of organization.[412] We are therefore proposing to amend Form N–8B–2[413] to require UIT ETFs to provide disclosures that mirror certain of our proposed disclosure changes in Form N–1A.[414] Below are the proposed Form N–8B–2 amendments and the corresponding sections in Form N–1A.

Disclosure topic	Proposed Form N–1A ETF disclosure	Corresponding Form N–8B–2 proposed disclosure
Definitions for Exchange-Traded Fund	General Instructions Part A	General Instructions *Definitions.*[415]
Information Concerning Fees and Costs	Item 3. Risk/Return Summary: Fee Table	Item I.13(h).
Information Concerning Fees and Costs	Item 3. Exchange-Traded Fund Trading Information and Related Costs.	Item I.13(i).

UIT ETFs, like other ETFs, are exchange-traded. As a result, secondary market investors in UIT ETFs, like other ETFs, are subject to costs, such as: bid-ask spreads; brokerage commissions for buying and selling shares of a UIT ETF through a broker-dealer; and potential costs related to purchasing UIT ETF shares at a premium or discount to NAV per share. As with investors in ETFs organized as open-end funds, we believe that unit holders could overlook these costs for UIT ETFs. We believe that additional disclosure would help investors better understand the total costs of investing in a UIT ETF. Accordingly, we are proposing disclosure requirements in Form N–8B–

[406] *See infra* section II.0.

[407] *See generally* Hu and Morley, *supra* footnote 291 (proposing a new ETP disclosure regime that ''responds to the significance of the arbitrage mechanism, model-related complexities and evolving understandings and conditions'').

[408] *See generally id.*

[409] *Id.; see also* Item 27(b)(7) of Form N–1A.

[410] For example, in 2017, the Canadian Securities Administrators began requiring ETFs traded on Canadian exchanges to provide investors with a document, not to exceed four pages in length, called ''ETF Facts.'' The ETF Facts document is required to include certain information about the ETF, including, among other things, information related to the ETF's investments, risks, and performance, as well as background information about ETFs generally. *See* Canadian Securities Administrators, Mandating a Summary Disclosure Document for Exchange-Traded Mutual Funds and Its Delivery—CSA Notice of Amendments to National Instrument 41–101 (Dec. 8, 2016), available at *http://www.osc.gov.on.ca/documents/en/Securities-Category4/ni_20161208_41-101_traded-mutual-funds.pdf.*

[411] While open-end funds register with the Commission with Form N–1A, UITs must register with two forms: Form S–6 which is used for registering the offering of the UITs' units under the Securities Act, and Form N–8B–2, which is used for registration under the Investment Company Act. Form S–6, which must be filed with the Commission every 16 months, provides certain content requirements, mainly by referencing to the disclosure requirements in Form N–8B–2.

[412] *See* 2008 ETF Proposing Release, *supra* footnote 3, at section III.D.1. for a general discussion of ETF prospectus delivery requirements. Since UITs issue securities, and not subject to any of the applicable exemptions, both sponsors and dealers are required to deliver a current prospectus to unit holders. *See* section 5(b) of the Securities Act (requiring prospectus delivery with the sale of securities, including units of UITs); *see also* section 24(d) of the Act (eliminating the ''dealer exception'' in section 4(3) of the Securities Act for transactions in redeemable securities by UITs); *see also supra* footnote 27.

[413] Because Form S–6 requires UIT prospectuses to include disclosure required by specified provisions of Form N–8B–2, the proposed disclosure amendments to Form N–8B–2 would also apply to prospectuses on Form S–6.

[414] *See* section II.H.

[415] The proposed definition of the term ''exchange-traded fund'' in Form N–1A covers ETFs organized as open-end funds and includes ETFs relying on either exemptive orders or rule 6c–11 to operate. Form N–8B–2, on the other hand, is for UITs, which would not be able to rely on rule 6c–11 to operate. Accordingly, the proposed definition of ''exchange-traded fund'' in Form N–8B–2 omits the reference to rule 6c–11.

2 that mirror those of Item 3 of Form N–1A, thus requiring prospectuses on Form S–6 for UIT ETFs to disclose that an ETF investor may pay additional fees, such as brokerage commissions and other fees to financial intermediaries, and to provide certain ETF trading information and related costs.[416]

As discussed above, the proposed instructions to Item 3 would require median bid-ask spread to be disclosed on an ETF's website. UIT ETFs would be subject to this requirement as well. We note in this regard that UIT ETFs currently are not subject to website disclosure requirements regarding trading costs or other information. However, as a matter of practice, UIT ETFs generally disclose information regarding market price, NAV per share, premium and discounts, and spreads on their websites today.[417]

We request comment on the proposed amendments to Form N–8B–2.

- Should we require ETFs organized as UITs to provide disclosures that are consistent with Form N–1A in the manner proposed?
- Do the proposed amendments to Form N–8B–2 ensure consistency between ETFs organized as open-end funds and UIT ETFs? Why or why not?
- Are there additional amendments to Form N–8B–2 the Commission should consider? Are there any amendments to Form S–6 that the Commission should consider? For example, should we consider requiring UIT ETFs to provide disclosure regarding market price, NAV per share, and premiums and discounts? Should we consider requiring UIT ETFs to provide graphic disclosure regarding the ETF's historical premiums and discounts? Should we permit UIT ETFs to omit such premium/discount in their registration statement if they include those disclosures on the ETF's website?
- Would the proposed trading cost requirements in Form N–8B–2 Items I.13(h)–(i) result in UIT ETFs having to disclose information not currently disclosed on their websites? If so, what information would be disclosed that is not currently disclosed?

J. Amendments to Form N–CEN

Form N–CEN is a structured form that requires registered funds to provide census-type information to the Commission on an annual basis.[418] Item C.7. of Form N–CEN requires management companies to report whether they relied on certain rules under the Investment Company Act during the reporting period.[419]

We are proposing to add to Form N–CEN a requirement that ETFs report if they are relying on rule 6c–11.[420] While Form N–CEN already requires funds to report if they are an ETF,[421] we are proposing to collect specific information on which funds are relying on rule 6c–11 in order to better monitor reliance on rule 6c–11 and to assist us with our accounting, auditing and oversight functions, including compliance with the Paperwork Reduction Act.

As discussed above in section II.C.1, we are also changing the definition of ''authorized participant'' in Form N–CEN to exclude the specific reference to an authorized participant's participation in DTC in order to obviate the need for future amendments if additional clearing agencies become registered with the Commission. Revised Form N–CEN would define the term as ''a member or participant of a clearing agency registered with the Commission, which has a written agreement with the Exchange-Traded Fund or Exchange-Traded Managed Fund or one of its service providers that allows the authorized participant to place orders for the purchase and redemption of creation units.'' [422]

We request comment on our proposed amendments to Form N–CEN.

- Should we require any additional information concerning proposed rule 6c-11? If so, what information and where? For example, should we require ETFs to provide information to the Commission on a monthly basis on Form N–PORT? If so, what information?
- Should we amend the definition of ''authorized participant'' in Form N–CEN as proposed or should we retain its existing definition?

III. Economic Analysis

A. Introduction

ETF sponsors seeking to operate an ETF currently need to obtain an order from the Commission that exempts them from certain provisions of the Act that otherwise would prohibit several features essential to the ETF structure. Obtaining such exemptive relief typically has resulted in expenses and delays in forming new ETFs. In addition, the conditions in the exemptive orders issued by the Commission have evolved over time. As a result, some ETF sponsors may have a competitive advantage over other sponsors because some existing exemptive orders allow the sponsors to launch new funds under the terms and conditions of those orders, and because the terms in some of the existing exemptive orders may be more flexible than others.

Proposed rule 6c–11 would allow ETFs that satisfy certain conditions to operate without obtaining an exemptive order from the Commission. As discussed above, the Commission also proposes to rescind the exemptive relief we have issued to ETFs that could rely on the proposed rule. However, we anticipate that ETFs whose exemptive relief would be rescinded under the proposed rule generally would be able to rely on the proposed rule without substantially changing their current operations, as the conditions for relying on the proposed rule would be similar to those contained in existing exemptive relief, consistent with existing market practice, or generally more flexible than those contained within existing exemptive relief.[423] ETFs that wish to operate in a manner not covered by the proposed exemptive rule could seek individual exemptive relief from the Commission.

We believe that proposed rule 6c–11 would establish a regulatory framework that: (1) Reduces the expense and delay currently associated with forming and operating certain ETFs unable to rely on existing orders; and (2) creates a level playing field for ETFs that could rely on the proposed rule. As such, the proposed rule would enable increased product competition among certain ETF providers, which could lead to lower fees for investors, encourage financial innovation, and increase investor choice in the ETF market.

Furthermore, the amendments to Forms N–1A and N–8B–2 as well as the additional website disclosures required by the proposed rule are intended to improve the information about ETFs available to the market and to allow

[416] *See* proposed Items 13(h) and (i) of Form N–8B–2. *See also supra* section II.H.2 describing the ETF trading information and related costs disclosure requirements.

[417] UIT ETFs also would be required to provide certain ETF specific information in reports on Form N–CEN. *See* Part E of Form N–CEN. Additionally, a UIT ETF would be required to provide certain information relating to the index that it tracks, including the return difference and whether the index is constructed by an affiliated person or is exclusive to the UIT. *See* Item E.4 of Form N–CEN.

[418] *See* Reporting Modernization Adopting Release, *supra* footnote 147.

[419] Item C.7. of Form N–CEN.

[420] Proposed Item C.7.k. of Form N–CEN.

[421] *See* Item C.3.a.i. of Form N–CEN.

[422] *See* proposed amendment to Instruction to Item E.2 of Form N–CEN.

[423] As discussed in more detail below, some conditions in the proposed rule and the scope of the relief provided are less flexible than those included in certain exemptive orders (*e.g.,* the absence in the proposed rule of master-feeder relief) and others represent requirements that were not included in exemptive orders (*e.g.,* basket policies and procedures and the recordkeeping requirements).

investors to more readily obtain information about fund products, resulting in reduced investor search costs. To the extent that the proposed amendments would improve investors' ability to evaluate the performance and other characteristics of fund products, the proposed amendments might result in better informed investor decisions and more efficient allocation of investor capital among fund products, and might further promote competition among ETFs and between ETFs and mutual funds.

The proposed rule and amendments to Forms N–1A and N–8B–2 also may impact non-ETF products and market participants. To the extent that the proposed rule would lead to lower investor search costs, lower fees, and increased product innovation and investor choice in the ETF market, investors may shift their investments towards ETFs and away from funds similar to ETFs, such as mutual funds. Such a shift in investor demand also may affect broker-dealers and investment advisers, whose customers and clients may show increased interest in and demand for ETFs. Moreover, because ETF shares are traded on the secondary market, the proposed rule also could affect exchanges, alternative trading systems, facilities for OTC trading, broker-dealers, and clearing agencies to the extent that the rule causes changes in the ETF trading activity they support.

B. Economic Baseline

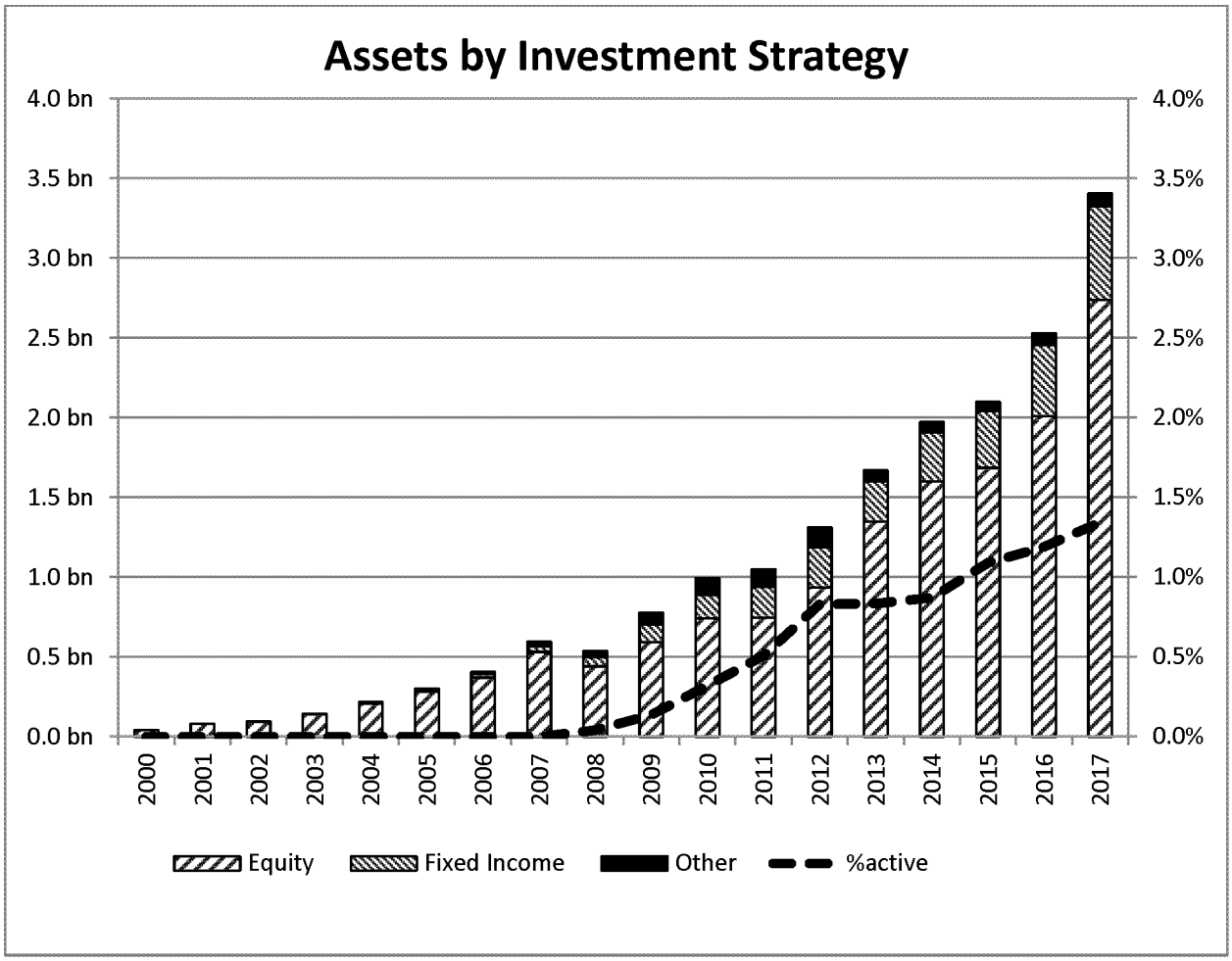
1. ETF Industry Growth and Trends

The ETF industry has experienced extensive growth since the first US ETF began trading in 1993.[424] From 1993 to 2002, an average of 10 new ETFs registered each year and ETF net assets increased by an average of $10.7 billion annually. Industry growth accelerated from 2003 to 2006, when, on average, 62 new ETFs and $77 billion in net assets were added to the industry annually. Since 2007, the industry has seen an average of 141 new ETF entrants and an average growth of $272.8 billion annually. Since 2007, ETF net assets have grown at an average rate of 18.4% per year, which compares to 4.2% for closed-end funds and 9.7% for open-end funds over the same period.[425]

At the end of December 2017, there were 1,900 registered ETFs that had a total of $3.4 trillion in net assets, spanning six broad investment style categories. ETFs are predominantly structured as open-end funds; however, eight funds that together represented 10.9% of ETF total net assets ($372.8 billion) were structured as UITs, and 70 ETFs that together represented 25.1% of total net assets ($854.9 billion) were structured as a share class of an open-end fund. The chart illustrates growth in ETF net assets by investment strategy beginning in 2000 (left-hand side axis). It also tracks the percentage of net assets invested in actively managed ETFs (right-hand side axis).

[424] For the purpose of this release, we focus exclusively on ETFs that trade on US exchanges.

[425] The number and net assets of ETFs are based on a staff analysis of Bloomberg data. Growth rates for open- and closed-end funds are based on a staff analysis of Morningstar data.



The bars show ETF net assets (in $ billions on the left vertical axis) at the end of each year by investment strategy beginning in 2000. "Other" includes commodity, specialty, mixed allocation, and alternative investment strategies. The dashed line shows the percentage of total ETF net assets in active strategies (on the right vertical axis). The data is from Bloomberg.

Although indexing is still the most common ETF strategy, over time ETFs have evolved to offer, among other things, active management, leveraged and inverse investment strategies, and exposure to various types of foreign securities. At the end of December 2017, 187 ETFs, structured as open-end funds, employed leveraged or inverse investment strategies.[426] In total, leveraged ETFs had total net assets of $35.26 billion or approximately 1% of all ETF net assets. None of the eight registered ETFs structured as UITs employed leveraged or inverse investment strategies. Of the remaining unleveraged ETFs, both index-based and active, 1,705 funds had combined net assets of $3 trillion operated as open-end funds, while eight funds had $372.8 billion in net assets operated as UITs.[427]

There were 206 actively managed ETFs with total net assets of $45.8 billion. The remaining 1,694 funds with combined $3.36 trillion in net assets were index-based funds. Of these, 1,686 with total net assets of $2.987 trillion were structured as open-end funds and eight with total net assets of $372.8 billion were structured as UITs.

The majority of ETFs, in total 1,456, held some foreign exposure in their portfolio according to Morningstar data. These ETFs had total net assets of $2.976 trillion. Of these funds, seven were structured as UITs and had $350.4 billion in net assets. The remaining 1,449 funds and $2.63 trillion in net assets were organized as open-end funds. On average, these ETFs reported foreign exposure of 37.75%. This number was 57.13% for ETFs structured as UITs and 37.66% for ETFs structured as open-end funds.[428]

2. Exemptive Order Process

As discussed above, ETFs seeking to operate as investment companies historically have needed exemptive relief from the Commission. Since the first exemptive relief was granted in 1992, the Commission has issued approximately 300 exemptive orders to

[426] As of the end of December 2017, 1,635 ETFs were neither organized as a UIT, nor as a share class of an open-end fund, and do not pursue leveraged or inverse investment strategies. During 2017, the number of such funds grew by 124. (In the last five years, the increase in such funds ranged from 90 in 2013 to 181 in 2015.)

[427] Bloomberg defines actively managed or index-based managed funds according to disclosure in the fund prospectus.

[428] We estimate funds' foreign holdings on April 11, 2018 from Morningstar data. For each ETF, foreign holdings of equity and debt securities are combined to obtain the approximate percentage of assets invested in foreign securities. Morningstar provided foreign holding data for 1,724 ETFs. In this data, 268 funds, one of which is structured as a UIT, reported holding no foreign securities and 176 funds from the original 1,900 are missing foreign holdings data.

ETFs. The average number of approved exemptive orders between 1992 and 2006 was approximately 2.5 per year, which has increased to approximately 25 per year since 2007.

Based on our review of exemptive orders that granted relief for unleveraged ETFs between January 2007 and mid-March 2018, the median processing time from the filing of an initial application to the issuance of an order was 221 days, although there was considerable variation.[429] Depending on the complexity of a fund's application, some ETF sponsors received exemptive relief in a relatively short period of time (the 10th percentile of the processing time was 83 days) while others waited over one year for approval (the 90th percentile of the processing time was 686 days).

In addition to the processing time associated with applying for an exemptive order, Commission staff estimates that the direct cost of a typical fund's application for ETF relief (associated with, for example, legal fees) is approximately $100,000, which may vary considerably depending on the complexity of the prospective fund.

3. Market Participants

As discussed above, several non-ETF market participants may be affected by the proposed rule, including fund sponsors, authorized participants, trading venues, and institutional and retail investors.

Using data from Bloomberg, we find that there are 83 unique ETF sponsors with approximately 1,900 ETFs as of December 31, 2017. The median number of ETFs per sponsor is eight and the mean is 23, suggesting that a small number of sponsors have a large share of the ETF market (in terms of number of ETFs). Indeed, the top five sponsors operate a combined 898 ETFs, whereas the bottom half of sponsors operate only a combined 121 ETFs.

An ETF (or one of its service providers) has contractual arrangements with a set of authorized participants, who can place orders for the purchase or redemption of creation units with the ETF.[430] While we currently lack data on authorized participants, a 2015 survey-based study of fifteen fund sponsors, which together offer two-thirds of all existing ETFs (covering 90% of all ETF assets), finds that the average ETF has 34 authorized participant agreements.[431] The study further reports that creation and redemption transactions occurred only on between 10% to 20% of trading days and that only 10% of the daily activity in all ETF shares (by volume) are creations or redemptions.[432]

ETF shares are mainly traded on securities exchanges.[433] Table 1 lists the 10 exchanges with the largest average daily ETF trading volume, measured over the 30 business days ending on February 12, 2018. The data is from Bloomberg and shows that NYSE Arca handles the largest portion of ETF trades ($23.8 billion), followed by Nasdaq InterMarket ($12.8 billion), and Cboe BZX Exchange ($11.0 billion).

TABLE 1—ETFS LISTED ON NATIONAL EXCHANGES AND THEIR TRADING VOLUME

Exchange	Number of ETFs	Trading volume (billion)
NYSE Arca	1,899	$23.8
NASDAQ InterMarket	1,537	12.2
Cboe BZX Exchange, Inc	1,840	11.0
Cboe EDGX Exchange, Inc	1,864	7.4
Cboe BYX Exchange, Inc	1,816	4.5
NASDAQ Global Market	339	3.2
Nasdaq BX, Inc	1,801	2.7
Chicago Stock Exchange, Inc	169	2.5
Cboe EDGA Exchange, Inc	1,781	2.4
NASDAQ OMX PSX	1,343	2.2

The table reports the number of ETFs traded at each exchange and the average daily ETF trading volume, measured over the 30 business days ending on February 12, 2018. Trading volume is calculated as trade price multiplied by the number of shares relating to each price by exchange. The figures reflect an analysis by the Commission staff using data obtained through a subscription to Bloomberg.

Both institutional and retail investors participate in the ETF secondary market. Using combined data from WRDS SEC Analytics Suite, Morningstar, and the Center for Research in Security Prices (CRSP) from the first quarter of 2014 to the fourth quarter of 2016, we estimate that institutions own, on average, 43% of ETF shares, when calculating the average using equal weights for all ETFs, and 55%, when calculating the average using total net assets (''TNA'')-based weights. The difference between the equal-weighted and TNA-weighted average institutional ownership numbers—43% vs. 55%—suggests that institutional investors tend to hold larger shares of ETFs with larger TNA. The table also shows that the median ownership by institutional investors is 40%. Additionally, the table shows that there is considerable variation in institutional investor holdings, ranging from an average for the 5th percentile of 6% to an average for the 95th percentile of 90%.[434] However, we observe that the average institutional holding did not change considerably over time during the sample period.

[429] The earliest order in our sample was approved on 1/17/2007 and the latest order was approved on 4/10/2018.

[430] Some market makers and other market participants engage in creation and redemptions indirectly through authorized participants. *See supra* section I.B. The Commission, however, lacks data on the number of such market participants.

[431] *See* Antoniewicz, *supra* footnote 30. While we currently lack data on authorized participants, we note that, starting July 30, 2018, Form N–CEN Item E.2 will require a fund to provide certain information regarding its authorized participants, including the authorized participant's name, the SEC file number, CRD number, and other information. *See* Reporting Modernization Adopting Release, *supra* footnote 147. This Item, however, will not provide data about other market participants that may transact through authorized participants.

[432] NSCC is the sole provider of clearing services for ETF primary market transactions. Whether a creation or redemption order is eligible to be processed through NSCC depends on the eligibility for NSCC processing of the securities in the ETF's basket. *See* Antoniewicz, *supra* footnote 30.

[433] In the first quarter of 2018, 68% of ETF trading by dollar volume was executed on exchanges, 23% over the counter, and 10% using alternative trading systems (ATSs), based on Trade and Quote (TAQ) data provided by the New York Stock Exchange, Trade Reporting Facility (TRF) data provided by FINRA, and ATS information made publicly available on the FINRA website.

[434] The data we use is from Form 13F filings, which does not capture all institutional positions because Form 13F does not require reporting of short positions (which would lead to an overstatement of institutional ownership) and because not all institutional investors are required to file the form, for example because they exercise investment discretion in less than $100 million in Section 13(f) securities (which would lead to an understatement of institutional ownership).

TABLE 2—INSTITUTIONAL OWNERSHIP OF ETFS

Quarter	Equal-weighted average (%)	TNA-weighted average (%)	SD (%)	P5 (%)	P25 (%)	P50 (%)	P75 (%)	P95 (%)
2014Q1	40	53	24	6	22	37	56	86
2014Q2	42	54	25	7	22	37	58	90
2014Q3	41	55	24	7	23	38	59	88
2014Q4	43	55	24	6	24	40	60	88
2015Q1	41	54	24	5	22	38	58	85
2015Q2	42	55	25	6	23	40	60	91
2015Q3	44	56	26	7	25	41	62	94
2015Q4	44	57	26	5	24	43	62	92
2016Q1	44	57	26	5	24	42	62	92
2016Q2	43	56	26	6	23	41	61	92
2016Q3	43	56	26	5	24	41	62	91
2016Q4	44	57	25	6	24	42	61	91
Average	43	55	25	6	23	40	60	90

The table reports the quarterly institutional ownership ratio of ETFs, measured as the total number of shares owned by institutional investors divided by the total shares outstanding adjusted for share splits. SD refers to standard deviation. Columns P5 to P95 refer to the 5th to 95th percentiles. All descriptive stats are equal-weighted except TNA-Weighted Average. The figures reflect an analysis by the Commission staff using data from 2014Q1 to 2016Q4 obtained through a subscription to WRDS SEC Analytics Suite and the Center for Research in Security Prices (CRSP).

Further analysis shows that the ownership structure varies considerably by the type of ETF. Using Morningstar categories, for the fourth quarter of 2016, Table 3 below shows that ETFs' equal-weighted average institutional ownership ranges from 23% for alternative ETFs to 56% for taxable bond ETFs. We also find that TNA-weighted average institutional ownership is higher than equal-weighted average institutional ownership for international equity, municipal bond, sector equity, taxable bond, and U.S. ETFs, suggesting that institutional investors tend to hold ETFs with larger TNA within these categories. The converse is true for allocation, alternative and commodity ETFs. The table also shows that there is large variation within categories.[435]

TABLE 3—INSTITUTIONAL OWNERSHIP OF ETFS BY MORNINGSTAR CATEGORY FOR 2016: Q4

Quarter	Equal weighted average (%)	TNA weighted average (%)	SD (%)	P5 (%)	P25 (%)	P50 (%)	P75 (%)	P95 (%)
Allocation	43	38	26	8	23	36	58	95
Alternative	23	16	22	2	6	17	33	68
Commodities	41	38	20	10	29	39	59	71
International Equity	48	63	23	12	31	46	64	91
Municipal Bond	48	55	16	15	39	50	59	74
Sector Equity	42	57	22	10	26	40	58	83
Taxable Bond	56	63	21	20	41	57	72	91
U.S. Equity	45	60	23	11	29	43	59	93

The table reports the institutional ownership ratio of ETFs, measured as the total number of shares owned by institutional investors divided by the total shares outstanding adjusted for share splits, by Morningstar Category. SD refers to standard deviation. Columns P5 to P95 refer to the 5th to 95th percentiles. All descriptive stats are equal-weighted except TNA-Weighted Average. The figures reflect an analysis by the Commission staff using data for 2016Q4 obtained a through subscription to WRDS SEC Analytics Suite and the Center for Research in Security Prices (CRSP).

4. Secondary Market Trading, Arbitrage, and ETF Liquidity

Unlike shares of open-end funds, ETF shares are traded in the secondary market at prices that may deviate from the ETF's NAV. As a result, ETF investors may trade shares at prices that do not necessarily reflect the intrinsic value of the underlying ETF assets.[436] To reduce the frequency and size of ETF premiums and discounts, our exemptive orders have contained several conditions designed to facilitate an efficient arbitrage mechanism, help ensure the proper functioning of the ETF market, and ultimately protect investors.

One set of conditions has required that ETFs be listed on a national stock exchange and that exchanges publish the fund's IIV every 15 seconds for domestic ETFs and every 60 seconds for international ETFs. Another condition, which was designed to support the effective functioning of the arbitrage mechanism, is portfolio transparency. All ETFs in operation today have a provision in their exemptive order that requires them to provide some degree of transparency regarding their portfolio

[435] Morningstar category is assigned based on the underlying securities in each portfolio. Per Morningstar, funds in *allocation* categories seek to provide both income and capital appreciation by investing in multiple asset classes, including stocks, bonds, and cash. Funds in *alternative* strategies employ investment approaches (similar to those used by hedge funds) designed to offer returns different than those of the long-only investments in the stock, bond, or commodity markets. *International equity* portfolios expand their focus to include stocks domiciled in diverse countries outside the United States though most invest primarily in developed markets. *Municipal bond* strategies are generally defined by state or national focus and duration exposure. A fund is considered state-specific if at least 70% of its assets are invested in municipal securities issued by the various government entities of a single state. *Sector-specific equity* funds are usually equity funds, in that they maintain at least 85% exposure to equity. *Fixed Income Taxable bond* portfolios invest at least 80% of assets in securities that provide bond or cash exposure. *U.S. equity* portfolios are defined as maintaining at least 85% exposure to equity and investing at least 70% of assets in U.S.-domiciled securities.

[436] It is possible for both the ETF's NAV per share and its share price to deviate from the intrinsic value of the ETF's underlying portfolio. In addition, there may be cases in which the ETF's share price is closer to the intrinsic value of the ETF's portfolio than its NAV per share. *See, e.g.,* Madhavan, Ananth, & Aleksander Sobczyk, *Price Discovery and Liquidity of Exchange-Traded Funds,* 14 Journal of Investment Management 2 (2016).

holdings. As discussed above, actively managed ETFs and some ETFs that track an index from an affiliated index provider have been required to disclose their holdings prior to the commencement of trading each business day (*i.e.,* full portfolio transparency). Other index-based ETFs are permitted to disclose their portfolio holdings indirectly, by specifying which index they seek to track, as long as the index provider lists the constituent securities on its website (*i.e.,* index transparency) or by disclosing the components of their baskets. Based on a staff review of 100 index-based ETFs, randomly selected from all index-based ETFs, and 50 actively-managed ETFs, randomly selected from all actively-managed ETFs, all 150 ETFs maintain a website and provide the ETF's complete daily portfolio holdings. Therefore, we believe that all index-based and actively-managed ETFs that could rely on the proposed rule now, including those that are not subject to a full transparency condition in their exemptive order, currently provide full portfolio transparency.[437]

The degree to which ETFs have flexibility in choosing the composition of creation and redemption baskets plays an important role for the effective functioning of the arbitrage mechanism. A more flexible basket composition may, among other considerations discussed in more detail below, allow authorized participants to exchange baskets for ETF shares at a lower cost, thus increasing arbitrage activity and efficient functioning of markets.[438] The extent to which our exemptive orders have allowed ETFs to use creation and redemption baskets that deviate from a *pro rata* representation of the ETF's portfolio holdings (*i.e.,* basket flexibility) has evolved over time. ETFs that received their exemptive orders in the early period from 1992–1995 were mostly structured as UITs and, as a result, the creation and redemption baskets were mostly a strict *pro rata* representation of the index, plus some cash balancing amount. From 1996 to 2006, exemptive orders for ETFs, which then were mostly structured as open-end funds, did not expressly limit baskets to a *pro rata* representation of the ETF's portfolio holdings. From 2006 to 2010, the Commission limited basket flexibility in exemptive orders for ETFs organized as open-end funds by requiring baskets to generally represent a *pro rata* slice of the fund's portfolio holdings and including conditions limiting the circumstances under which substitutions would be permitted. Starting around 2011, the exemptive orders required baskets to be a strict *pro rata* slice of the portfolio holdings and, in addition, to be the same for all authorized participants, with minor exceptions.[439]

For ETFs that hold foreign investments in their portfolio, the redemption process for these securities may take more than the seven days specified under section 22(e) of the Act. The Commission has granted exemptive relief to certain ETFs who hold foreign investments, in many instances up to 15 days, to satisfy redemption of a foreign investment.

Many exemptive orders have required ETFs to disclose on their website, free of charge, the previous day's NAV and the price of the ETF shares, as well as the premium or discount associated with the ETF's share price at the market close.[440] Based on a staff review of the websites of 150 randomly selected ETFs, all of which provided the previous day's NAV, price of the ETF shares (one active ETF provided a price based on the midpoint between the bid and ask prices while the remainder of the active and all index-based ETFs provided closing prices), as well as the premium or discount associated with the ETF share price at the market close, we believe that all ETFs that could rely on the proposed rule currently disclose this information on their website.[441]

ETFs have also been required to have contractual agreements with authorized participants to purchase or redeem ETF shares in creation unit aggregations in exchange for a basket of securities and other assets. Having an accurate estimate of the current ETF share value and an opportunity to efficiently create or redeem ETF shares in creation unit sizes allows authorized participants to engage in arbitrage activity that brings the market price of ETF shares and the value of the ETF's portfolio closer together. As noted earlier, market participants can also engage in arbitrage activity in the secondary market by taking a long and short position on the ETF shares and the underlying basket assets. For example, if the ETF is trading at a premium relative to the NAV per share of the ETF's portfolio, a market participant can short the ETF and buy the underlying basket assets in proportion to the ETF shares. Alternatively, if the ETF is trading at a discount relative to NAV per share, a market participant may buy the ETF and short the underlying basket assets in proportion to the ETF shares. Then the market participant could realize a profit by closing the position when the gap between the ETF's share price and NAV per share gets closer to zero. This trading activity could help close the gap even further.

However, authorized participants, other market participants, and arbitrageurs acting in secondary markets may incur costs and be exposed to risk when engaging in arbitrage. The costs include bid-ask spreads and transaction fees associated with the arbitrage trades. In addition, during the time it takes arbitrageurs to execute these trades, they are exposed to the risk that the prices of the basket assets and the ETF shares change. As a consequence, arbitrageurs may decide to wait for any mispricing between the market price of ETF shares and NAV per share to widen until the expected profit from arbitrage is large enough to compensate for any additional costs and risks associated with engaging in the transaction.

Using data from Bloomberg, we find that ETFs, on average, trade at a price slightly higher than the NAV per share (*i.e.,* at a premium), as shown in Table 4 below. The equal-weighted and TNA-weighted average premium/discount over the last 15 years for all ETFs in the dataset are, respectively, 0.074% and 0.065%, and the median is 0.024%, indicating that the prices of ETF shares are, on average, higher than the NAV per share. One study finds similar results and concludes that, on average, ETF market prices tend to reflect NAV per share closely. However, consistent with the study, we find that ETF premiums/discounts vary significantly.[442] For example, we find

[437] The samples were randomly drawn from all index-based ETFs and all actively managed ETFs currently trading according to Bloomberg. We recognize that the selection of ETFs examined by Staff overweights the sample of actively managed ETFs relative to the entire population of actively managed ETFs. Our sampling procedure was done to avoid small sample bias as equally proportioned sampling would call for a survey of approximately 2 actively managed funds.

[438] A more flexible basket composition may create potential risks such as dumping and cherry-picking, as discussed in more detail below.

[439] Our exemptive orders have generally included future funds relief to allow sponsors to form and operate new ETFs without having to obtain additional exemptive orders. *See supra* footnote 5. As a result, the Commission does not have records that would allow us to determine the specific exemptive order under which any particular fund is operating. We thus do not quantify the number of funds operating under each of the different basket flexibility conditions included in our orders.

[440] In addition, some funds disclose some historical information on premiums and discounts on their website pursuant to the flexibility provided on Form N–1A. *See supra* section II.C.6.c.

[441] *See supra* footnote 437.

[442] Commenters to our 2015 ETP Request for Comment, *supra* footnote 9, report qualitatively similar results. *See, e.g.,* Comment Letter of Eaton Vance Corp. to Request for Comment on Exchange-Traded Products (File No. S7–11–15) (Aug. 17, 2015).

that the average premiums/discounts ranges from 0.03% in 2003 to 0.14% in 2009, and the average standard deviation of premiums/discounts ranges from 0.16% in 2017 to 0.60% in 2008. Moreover, not all ETF shares trade at a premium. For example, the table shows, in a given year, *at least* 25% of ETF shares trade at a discount, at an average discount of −0.044% between all years (see the column P25).

TABLE 4—TIME-SERIES AVERAGES OF CROSS-SECTIONAL DESCRIPTIVE STATISTICS OF PREMIUM/DISCOUNT (%) USING DAILY DATA

Year	Equal weighted average	TNA weighted average	SD	P5	P25	P50	P75	P95
2003	0.134	0.030	0.235	−0.215	−0.061	0.015	0.091	0.343
2004	0.095	0.039	0.262	−0.259	−0.060	0.023	0.095	0.549
2005	0.058	0.078	0.276	−0.221	−0.038	0.036	0.111	0.617
2006	0.074	0.082	0.338	−0.344	−0.042	0.029	0.141	0.671
2007	0.140	0.079	0.386	−0.389	−0.060	0.034	0.198	0.639
2008	0.087	0.100	0.603	−0.785	−0.142	0.055	0.343	1.054
2009	0.126	0.143	0.537	−0.557	−0.079	0.020	0.342	1.027
2010	0.072	0.066	0.353	−0.436	−0.046	0.022	0.164	0.635
2011	0.035	0.068	0.412	−0.550	−0.040	0.021	0.170	0.766
2012	0.058	0.072	0.286	−0.309	−0.019	0.022	0.141	0.582
2013	0.060	0.035	0.278	−0.352	−0.025	0.017	0.091	0.432
2014	0.046	0.038	0.216	−0.245	−0.013	0.016	0.082	0.351
2015	0.036	0.042	0.235	−0.25	−0.015	0.015	0.079	0.401
2016	0.026	0.044	0.228	−0.222	−0.015	0.013	0.091	0.389
2017	0.069	0.058	0.159	−0.085	−0.008	0.015	0.094	0.332
Average	0.074	0.065	0.320	−0.348	−0.044	0.024	0.149	0.586

The table reports time-series averages of cross-sectional descriptive statistics of premiums/discounts (%). The TNA-Weighted Average is weighted based on an ETF's previous month's total net assets. SD refers to standard deviation. Columns P5 to P95 refer to the 5th to 95th percentiles. Fund premiums or discounts are from daily Bloomberg data covering 1,838 funds for a total of 2,732,620 daily observations. Per Bloomberg, premium/discount (%) is the difference between the fund's closing price on the day of the most recent Net Asset Value (NAV) and the NAV of the fund on that day. The data covers the period from 01/03/2003 to 08/31/2017.

Premiums and discounts to NAV per share also vary considerably by the type of assets that make up the ETF.[443] We use Morningstar investment categories to divide ETFs into groups of similar assets and, in Table 5, report the time-series averages of cross-sectional descriptive statistics for premiums/discounts in the different Morningstar Investment Categories. We find that the TNA-weighted average premium/discount ranges from as low as 0.003% for alternative to 0.197% for taxable bond ETFs. The results are qualitatively similar for equal-weighted average premium/discounts.

TABLE 5—TIME-SERIES AVERAGES OF CROSS-SECTIONAL DESCRIPTIVE STATISTICS OF PREMIUM/DISCOUNT (%) BY MORNINGSTAR INVESTMENT CATEGORY

Category	Equal weighted average	TNA weighted average	SD	P5	P25	P50	P75	P95
Allocation	0.072	0.083	0.233	−0.119	−0.039	0.047	0.237	0.295
Alternative	0.007	0.003	0.345	−0.404	−0.126	−0.004	0.116	0.468
Commodities	0.211	0.112	0.481	−0.545	0.011	0.084	0.158	1.007
International Equity	0.185	0.193	0.440	−0.482	−0.068	0.204	0.458	0.833
Municipal Bond	0.086	0.076	0.314	−0.358	−0.090	0.061	0.273	0.532
Sector Equity	0.031	0.013	0.189	−0.243	−0.074	0.005	0.085	0.304
Taxable Bond	0.207	0.197	0.206	−0.068	0.088	0.188	0.273	0.539
U.S. Equity	−0.001	0.005	0.079	−0.104	−0.036	0.008	0.048	0.113

The table reports time-series averages of cross-sectional descriptive statistics of premiums/discounts (%). The funds are first divided into groups based on Morningstar categories. The TNA-Weighted Average is weighted based on an ETF's previous month's total net assets. SD refers to standard deviation. Columns P5 to P95 refer to the 5th to 95th percentiles. Fund premiums or discounts are from daily Bloomberg data covering 1,838 funds for a total of 2,732,620 daily observations. Per Bloomberg, premium/discount (%) is the difference between the fund's closing price on the day of the most recent Net Asset Value (NAV) and the NAV of the fund on that day. The data covers the period from 01/03/2003 to 08/31/2017.

When the ETF arbitrage mechanism functions effectively, ETFs also should trade at smaller bid-ask spreads.[444] As shown in Table 6, the TNA-weighted average bid-ask spread, as a percentage of the mid-price, has declined from 0.062% in 2012 to 0.030% in 2017.[445] The table shows a qualitatively similar decreasing pattern when using equal-weighted average bid-ask spreads. The percentiles of the bid-ask spreads also follow a decreasing trend. For example, we observe that the median bid-ask spread drops from 0.024% in 2012 to 0.016% in 2017 (see column P50). The table also shows that the bid-ask spread varies considerably. For example, the average standard deviation of the bid-ask spread (0.081%) is almost twice as large as its average (0.043%).

[443] *See* Engle Article, *supra* footnote 95.

[444] *See, e.g.,* CFA Guide, *supra* footnote 370.

[445] This analysis starts in 2012 because the available data begins in that year.

TABLE 6—TIME-SERIES AVERAGES OF CROSS-SECTIONAL DESCRIPTIVE STATISTICS OF RELATIVE BID-ASK SPREAD (%)

Year	Equal weighted average	TNA weighted average	SD	P5	P25	P50	P75	P95
2012	0.370	0.062	0.125	0.007	0.016	0.024	0.049	0.275
2013	0.330	0.053	0.106	0.006	0.014	0.022	0.048	0.212
2014	0.273	0.038	0.061	0.005	0.012	0.020	0.045	0.114
2015	0.324	0.039	0.067	0.005	0.012	0.019	0.045	0.122
2016	0.372	0.037	0.066	0.005	0.011	0.019	0.038	0.111
2017	0.349	0.030	0.063	0.004	0.009	0.016	0.030	0.086
Average	0.336	0.043	0.081	0.005	0.012	0.020	0.043	0.153

This table reports time-series averages of cross-sectional descriptive statistic of relative bid-ask spreads (%). The TNA-Weighted Average is weighted based on an ETF's previous month's total net assets. SD refers to standard deviation. Columns P5 to P95 refer to the 5th to 95th percentiles. Bid-ask spreads are from daily Bloomberg data covering 1,838 funds for a total of 1,843,729 daily bid-ask spreads. Per Bloomberg, the bid-ask spread (%) is the average of all bid/ask spreads taken as a percentage of the mid-price. The data covers the period from 01/03/2003 to 08/31/2017.

Table 7 reports bid-ask spreads for ETF shares by Morningstar category. US Equity ETFs have the smallest average bid-ask spread of 0.027%, whereas allocation ETFs—funds that seek to provide both income and capital appreciation by investing in multiple asset classes, including stocks, bonds, and cash strategy—have the largest average bid-ask spread of 0.223%.

TABLE 7—TIME-SERIES AVERAGES OF CROSS-SECTIONAL DESCRIPTIVE STATISTICS OF RELATIVE BID-ASK SPREAD (%) BY MORNINGSTAR INVESTMENT

Category	Equal weighted average	TNA weighted average	SD	P5	P25	P50	P75	P95
Allocation	0.590	0.223	0.307	0.073	0.084	0.147	0.227	0.642
Alternative	0.391	0.094	0.162	0.017	0.03	0.047	0.089	0.315
Commodities	0.353	0.041	0.060	0.009	0.009	0.009	0.061	0.118
International Equity	0.450	0.072	0.110	0.017	0.024	0.030	0.086	0.212
Municipal Bond	0.281	0.100	0.111	0.038	0.045	0.064	0.107	0.306
Sector Equity	0.285	0.061	0.092	0.015	0.018	0.036	0.062	0.198
Taxable Bond	0.306	0.043	0.080	0.011	0.014	0.016	0.041	0.159
U.S. Equity	0.207	0.027	0.041	0.006	0.012	0.014	0.029	0.081

This table reports time-series averages of cross-sectional descriptive statistic of relative bid-ask spreads (%). The funds are first divided into groups based on Morningstar categories. The mean is weighted based on an ETF's previous month TNA and the data covers the period from 01/03/2012 to 08/31/2017. SD, Min and Max refer to standard deviation, minimum and maximum. Columns P5 to P95 refer to the 5th to 95th percentiles. Bid-ask spreads are from daily Bloomberg data covering 1,838 funds for a total of 1,843,729 daily bid-ask spreads. Per Bloomberg, the bid-ask spread (%) is the average of all bid/ask spreads taken as a percentage of the mid-price.

The summary statistics presented thus far in this section suggest that the arbitrage mechanism generally functions effectively during normal market conditions. However, as described above in section III.B, the Commission has observed periods of market stress during which the arbitrage mechanism has functioned less effectively and during which there were significant deviations for some ETFs between market price and NAV per share and when bid-ask spreads widened considerably. We note, however, that these conditions only persisted for very short periods of time for the periods of market stress we have observed, suggesting that the arbitrage mechanism recovered quickly.[446]

C. Benefits and Costs of Proposed Rule 6c–11 and Amendments to Forms N–1A and N–8B–2

The Commission is sensitive to the economic effects that could result from proposed rule 6c–11 and amendments to Forms N–1A and N–8B–2, including benefits and costs. However, as discussed in further detail below, the Commission is unable to quantify many of the economic effects, either because they are inherently difficult to quantify or because we lack the information necessary to provide a reasonable estimate.

1. Proposed Rule 6c–11

Proposed rule 6c–11 would allow new ETFs to operate in reliance on a rule rather than individual exemptive orders if they meet the requirements and conditions of the rule. In addition, we propose to rescind all existing ETF exemptive orders, with the exception of: (i) The section 12(d)(1) relief included in those orders;[447] and (ii) orders relating to ETFs structured as UITs, leveraged ETFs, and those that are organized as a share class of a mutual fund.[448] This section first evaluates the general considerations associated with the proposed rulemaking and then discusses the effects of the specific requirements and conditions of the proposed rule.

a. General Considerations

Proposed rule 6c–11 would grant exemptive relief from the provisions of the Act that would otherwise prohibit several features essential to the ETF structure. This section evaluates the overall effect of reducing the expense and delay of operating certain new ETFs by granting this exemptive relief as part of a rule rather than through the individual exemptive order process.

As the requirements and conditions of the proposed rule are either similar to those contained in existing exemptive orders, consistent with market practice, or generally provide more flexibility, we anticipate that the proposed rule and the related rescission of ETF exemptive

[446] *See, e.g.* Madhavan Article, *supra* footnote 130.

[447] The proposal would however rescind relief that has been provided to allow master-feeder arrangements for those ETFs that do not currently rely on the relief. In addition, we propose to grandfather existing master-feeder arrangements involving ETF feeder funds, but prevent the formation of new ones, by amending relevant exemptive orders.

[448] ETFs relying on exemptive orders that we propose to rescind could no longer rely on their orders to launch additional ETFs.

relief would not require any existing ETFs whose exemptive relief would be rescinded to significantly change the way they operate. Conversely, some funds whose exemptive orders contain conditions that are more restrictive than those contained in the proposed rule may decide to change the way they operate in order to make use of such increased flexibility.

Relative to the baseline, proposed rule 6c–11 would eliminate the costs associated with applying to the Commission for an exemptive order to form and operate as an ETF for funds relying on the rule. Specifically, the process of forming new ETFs in reliance on the proposed rule would be quicker, more predictable, less complex, and therefore less costly than obtaining an exemptive order as new ETFs are currently required to do. ETFs that could not rely on the rule, which includes those structured as UITs, leveraged ETFs, and those that are organized as a share class of a mutual fund, would continue to be required to apply for an exemptive order to form and operate.[449]

As described above in section IV.B.2, we estimate that the cost for a typical ETF of filing for exemptive relief is $100,000. In addition, based on our review of exemptive orders that granted relief for unleveraged ETFs between January 2007 and mid-March 2018, the median processing time from the filing of an initial application to the issuance of an order was 221 days, although there was considerable variation. Thus, any new ETF planning to operate within the parameters set forth by the proposed rule would save this expected cost and avoid this delay. In addition, such ETFs would avoid the uncertainty about the length of the delay associated with the exemptive order process, allowing sponsors to better control the timetable for launching a new ETF product in a way that maximizes benefits to its business. Conversely, funds that are not able to comply with the conditions of the rule would continue to need to apply for an exemptive order. Assuming that the number of new ETFs seeking to form and operate under the proposed rule that would otherwise have needed to apply for exemptive relief is equal to the average number of ETFs that have applied for exemptive relief since 2007, these cost and time savings would accrue to approximately 25 ETFs per year.[450] Using this assumption, the annual costs savings to this group of ETF sponsors would equal $2.5 million.[451] We are unable to quantify the benefit a new ETF would derive from avoiding the delay and the uncertainty about the length of the delay associated with the exemptive order process as the cost of a delayed registration for a new ETF is inherently difficult to measure.

By eliminating the need for ETFs that can rely on the proposed rule to seek an exemptive order from the Commission, the proposed rule would also eliminate certain indirect costs associated with the exemptive application process. Specifically, ETFs that apply for an order forgo potential market opportunities until they receive the order, while others forgo the market opportunity entirely rather than seek an exemptive order because they have concluded that the cost of seeking an exemptive order would exceed the anticipated benefit of the market opportunity.

In addition, we believe that the proposed rule would make it easier for some fund complexes to ensure that each ETF in the complex is in compliance with regulations. Specifically, we anticipate that it would be easier, and thus less costly, for ETF complexes that today operate funds under multiple exemptive orders to ensure compliance with a single set of requirements and conditions contained in the proposed rule rather than with multiple exemptive orders to the extent that the orders vary in the requirements and conditions they contain.

We acknowledge that fund complexes may initially incur costs associated with assessing the requirements of the proposed rule. However, we believe that these costs would be relatively small.[452] In addition, we anticipate that it would be easier for third-party providers, such as lawyers and compliance consultants, to offer services that help ETFs ensure compliance with the proposed rules, which will have broad applicability, than is currently the case with ETFs relying on exemptive orders with varying conditions. As a result, third party service providers may be able to reduce the price of their services, compared to the baseline, for ETFs that could rely on the proposed rule, which may partially or fully offset the initial costs of studying the requirements of the proposed rulemaking that ETFs may incur.

We expect that the proposed rule also would benefit ETF investors to the extent it would remove a possible disincentive for ETF sponsors to form and operate new ETFs that provide investors with additional investment choices for which these sponsors currently do not have relief. As noted above, the direct and indirect costs of the exemptive application process may discourage potential sponsors, particularly sponsors interested in offering smaller, more narrowly focused ETFs that may serve the particular investment needs of certain investors. By eliminating the need for individual exemptive relief we anticipate that the proposed rule would accelerate the rate at which the ETF industry would otherwise grow. In those circumstances, the proposed rule would provide ETF investors with greater investment choices.

As we discuss below in section IV.D, we believe that the proposed rule could increase competition in the ETF market as a whole, which could also lead to lower fees. Any effect of increased competition on fees would likely be larger for segments of the ETF market that currently may be less competitive (*e.g.,* active ETFs) and smaller for segments of the market that currently may be more competitive (*e.g.,* index-based ETFs tracking major stock indices).

Additionally, some types of funds could experience reductions in trading costs associated with bid-ask spreads or premiums and discounts to NAV per share. Specifically, as discussed below in section IV.C.1.c, the proposed rule's increased basket flexibility could reduce

[449] As discussed below, some ETFs would incur additional costs as a result of the rule's requirement to adopt and implement written policies and procedures that govern the construction of basket assets and the process that will be used for the acceptance of basket assets, the rule's additional website disclosure requirements, and the proposed amendments to Forms N–1A and N–8B–2. The operation of such ETFs may therefore become more costly, on balance, to the extent that these costs are not offset by the benefits from the other parts of the proposed rule, such as the increased basket flexibility and, for new funds, the reduced costs of forming the fund.

[450] Compared to the baseline, these cost and time savings would only accrue to such new ETFs whose sponsors have not received exemptive relief that would allow such ETFs to operate.

[451] This estimate is based on the following calculation: 25 × $100,000 = $2,500,000.

[452] We estimate that assessing the requirements of the proposed rule would require 5 hours of a compliance manager ($298 per hour) and 5 hours of a compliance attorney ($352 per hour), resulting in a cost of $6,500 (10 × $298 + 10 × $352) per fund. The total cost for all 1,635 ETFs that could rely on the proposed rule would thus be $10,627,500 (1,635 × $6,500). The Commission's estimates of the relevant wage rates are based on salary information for the securities industry compiled by the Securities Industry and Financial Markets Association's Office Salaries in the Securities Industry 2013. The estimated wage figures are modified by Commission staff to account for an 1,800-hour work-year and multiplied by 2.93 to account for bonuses, firm size, employee benefits, overhead, and adjusted to account for the effects of inflation. *See* Securities Industry and Financial Markets Association, Report on Management & Professional Earnings in the Securities Industry 2013 (''SIFMA Report'').

the cost of arbitrage for authorized participants of fixed-income, international and actively managed ETFs more than for authorized participants and other market participants of other types of ETFs. This could potentially lead to a reduction in costs for investors associated with bid-ask spreads and premiums and discounts to NAV per share for fixed-income and international ETFs that could be significantly smaller or immaterial for other types of ETFs.

As discussed above, by eliminating the need for individual exemptive relief, we anticipate that the proposed rule would, over time, lead to an increase in ETFs that can meet the requirements and conditions of the rule and thus reinforce the current growth trend in the ETF industry. In addition, the proposed rule would increase demand for such ETFs, to the extent that such ETFs lower their fees to investors and investors are sensitive to fees.[453] To the extent that some ETFs would experience larger reductions in trading costs (*e.g.,* fixed-income, international, and active) or larger increases in competition (*e.g.,* actively managed), demand for these types of ETFs would likely increase more than for other types of ETFs. The increased demand would likely be due in part to investors substituting away from comparable types of funds, such as mutual funds, and possibly due to investors increasing the rate at which they save.[454] Consequently, the proposed rule could increase total assets of ETFs and could decrease total assets of other funds, such as mutual funds. The size of these effects would depend on the degree to which ETFs would lower their fees or experience reduced trading costs, as well as on the sensitivity of investor demand for ETFs and other funds to changes in ETF fees and trading costs. We are unable to quantify these effects on investor demand for various types of funds, in part, because we cannot estimate the extent to which funds would lower their fees or experience reduced trading costs and how lower fees and trading costs could change investor demand.

Since ETFs are traded in the secondary market, an increase in total assets of ETFs would likely coincide with larger trade volumes for the exchanges where ETFs are traded, as well as the clearing agencies and broker-dealers involved in these trades. To the extent that these market participants are compensated by volume, the proposed rule would thus benefit them by leading to an increase in revenues.

In addition, we expect the proposed rule to remove applications for more standard forms of exemptive relief from consideration, leaving for staff review only applications for more complex or novel exemptive relief that falls outside the parameters of the proposed rule. To the extent that this speeds up the processing time for these remaining applications, the proposal may reduce the indirect costs of forming and operating for funds that seek to operate outside its parameters.

b. Conditions for Reliance on Proposed Rule

Proposed rule 6c–11 contains several conditions that are designed to facilitate an effective arbitrage mechanism, reduce costs, and inform and protect investors. Beyond the general impact of reducing the expense and delay of new ETFs discussed above, much of the codification of conditions in proposed rule 6c–11 does not offer any additional benefits or costs when measured against the baseline, as they are generally codifications of the current regulatory practice. However, some conditions are departures from current exemptive orders or current market practice and we discuss the effects of these departures in more detail below.

i. Conditions We Believe May Facilitate an Effective Arbitrage Mechanism

Arbitrage is the practice of buying and selling equivalent or similar assets (or portfolios of assets) in different markets to take advantage of a price difference.[455] As a consequence, arbitrageurs generate price pressure that works to equalize the prices of these assets across different markets. Arbitrage is thus important for investors as it helps ensure that asset prices reflect market fundamentals (*i.e.,* are efficient) irrespective of the market in which they are traded.

The ETF structure makes use of such an arbitrage mechanism with the goal of establishing a close link between the price of an ETF's shares and the NAV per share of the ETF portfolio. Specifically, as discussed above, the combination of the creation and redemption process with the secondary market trading in ETF shares provides arbitrage opportunities that, if effective, help keep the market price of ETF shares at or close to the NAV per share of the ETF and also help reduce bid-ask spreads of ETF shares. Smaller deviations of ETF prices from the NAV per share of the ETF benefit investors as they allow investors to transact in ETF shares at prices closer to the value of the ETF's underlying portfolio of securities. Similarly, small bid-ask spreads for ETF shares benefit investors as they reduce the cost to trading ETF shares.[456]

There are several factors that are important for arbitrageurs to determine the existence of arbitrage opportunities and execute an arbitrage strategy effectively. First, when the assets involved in the arbitrage are similar but not the same, as is the case for ETFs, arbitrage will be more effective the more closely the prices of the two assets track each other and the more transparency arbitrageurs have into any factors that may cause price differences between the two assets. In addition, arbitrage requires that arbitrageurs have the ability to enter into the trades necessary to execute the arbitrage strategy, and arbitrage is more effective the smaller and more predictable the associated trading costs are. The proposed rule contains several provisions (many codifying current exemptive orders) that take these considerations into account and are designed to promote the effective functioning of the arbitrage mechanism for ETFs.

First, the proposed rule would require ETFs relying on the rule to adopt and implement written policies and procedures that govern the construction of basket assets and the process that will be used for the acceptance of basket assets, including policies and

[453] There is research to support that fund investors are sensitive to fees. For instance, one paper (Erik R. Sirri & Peter Tufano, *Costly Search and Mutual Fund Flows,* 53 The Journal of Finance 5 (1998)) finds that ''lower-fee funds and funds that reduce their fees grow faster''. However, we acknowledge that there are studies that suggest that investors' sensitivity to fees may be limited. For instance, one experimental study (James J. Choi, David Laibson, & Brigitte C. Madrian, *Why does the law of one price fail? An experiment on index mutual funds,* 23 The Review of Financial Studies 4 (2010)) finds that investors may not always pick the lowest-fee fund when presented with a menu of otherwise identical funds to choose from. In addition, other studies (*e.g.,* Michael J. Cooper, Michael Halling, & Wenhao Yang, *The Mutual Fund Fee Puzzle,* Working Paper (2016)) find evidence of significant fee dispersion among mutual funds, even after controlling for other observable differences between funds. While these studies investigate the sensitivity of investors to fees of mutual funds rather than ETFs, we believe that these results are likely hold for ETFs as well. We are not aware of any studies that specifically study the sensitivity of ETF investors to fees.

[454] Investments in ETFs are one of many ways for investors to save. If investors choose to increase their investment in ETFs, there can be two sources for this additional investment: (1) An increase in overall savings and (2) a decrease in savings allocated to other investments, such as mutual funds. These two sources are not mutually exclusive, so that an increase in ETF investments can be accompanied by both an increase in overall savings and a decrease in savings invested elsewhere, for example in mutual funds.

[455] *See, e.g.,* Jonathan B. Berk & Peter DeMarzo, Corporate Finance, 3rd Ed (2013).

[456] For a detailed discussion of the ETF arbitrage mechanism, *see, e.g.,* CFA Guide, *supra* footnote 370.

procedures specific to the creation of custom baskets.

As discussed in section II.C.5.a, the proposed additional policies and procedures requirements for custom baskets are designed to reduce the potential for cherry-picking, dumping, and other potential abuses by authorized participants. We acknowledge that this principles-based approach may not be effective at preventing all such abuses by authorized participants. However, as proposed, ETFs would be required to maintain records related to the custom baskets used, which would allow the Commission to examine for potential abuses.

As outlined above, current exemptive orders contain varying provisions for basket flexibility. However, based on a staff review of existing orders, we believe that the existing ETFs that would operate under the proposed rule and have their exemptive orders rescinded would not be required to change how they construct their baskets, because the proposed rule would give ETFs the ability to implement policies and procedures for basket flexibility, subject to certain enumerated requirements for the custom basket policies and procedures. In addition, we expect that some existing ETFs that would operate under the proposed rule would be able to implement policies and procedures with respect to basket flexibility that would give them more flexibility than what is allowed by their existing exemptive orders.

We believe that fixed-income, international, and actively managed ETFs would particularly benefit from the increased basket flexibility the rule would afford compared to existing exemptive orders. Specifically, the increased basket flexibility should allow fixed-income ETFs to avoid losing hard-to-find bonds when meeting redemptions or to use sampling techniques to construct baskets that are composed of fewer individual bonds and thus reduce trading costs for authorized participants. Similarly, international ETFs would be able to tailor their creation and redemption baskets to accommodate difficulties in transacting in certain international securities. In addition, actively managed ETFs would, in certain instances, be able to use the increased basket flexibility to acquire or dispose of securities by adjusting the composition of the creation or redemption basket rather than by directly purchasing or selling the securities. In these instances, actively managed funds would be able to reduce certain transaction costs, such as those associated with bid-ask spreads.

For these reasons we believe the proposed rule would benefit ETFs that make use of the increased basket flexibility the rule affords as well as their investors to the extent that ETFs are able to implement procedures that facilitate the arbitrage mechanism or reduce costs for the ETFs. Due to a lack of data, however, we are unable to quantify the number of ETFs that would choose to implement policies and procedures to increase basket flexibility, and thus the potential benefits arising to ETFs and their investors.

To the extent that existing ETFs do not already have policies and procedures governing basket assets in place, ETFs would incur a cost associated with developing and implementing such policies and procedures.[457] However, such costs may be partially or totally offset by the basket flexibility discussed above. As discussed in section IV.B, we estimate that an average ETF would incur an initial cost of $10,268 [458] associated with setting up the process for documenting the construction and acceptance of baskets and with documenting and adopting the custom basket policies and procedures. In addition, we estimate that an average ETF would incur an ongoing cost of $3,985 [459] each year to review and update its custom basket policies and procedures as well as its process for documenting the construction and acceptance of baskets. We thus estimate that the total industry cost associated with the policies and procedures requirement in the proposed rule for ETFs that could rely on the rule in the first year would equal $23,303,655.[460]

Second, the proposed rule would require an ETF to disclose prominently on its website the portfolio holdings that will form the basis for the next calculation of NAV per share. We believe that this requirement supports the effective functioning of the arbitrage mechanism as it allows authorized participants to identify arbitrage opportunities and chose an appropriate hedging strategy.

As discussed above in section III.B.4, the requirements for portfolio transparency in existing exemptive orders have varied.[461] As also discussed in section III.B.4, based on a staff review of ETFs' websites, we understand that all ETFs that could rely on the proposed rule currently provide daily full portfolio transparency, including all actively managed ETFs, and thus already bear ongoing costs associated with maintaining such disclosures.[462] However, we believe that the ETFs that could rely on the proposed rule would incur a one-time cost associated with reviewing whether their current portfolio disclosure is compliant with the requirements of proposed rule 6c–11 and, if necessary, make changes to the information that is presented on their website.[463] We estimate this one-time cost to be $1,939.50 for the average ETF, resulting in an aggregate one-time cost of $3,171,082.50 for all ETFs that could rely on the proposed rule.[464]

Finally, the proposed rule also would require additional disclosure by the ETF of the median daily bid-ask spread over the most recent fiscal year on its website. We believe that this

[457] While exemptive orders do not require ETFs to have policies and procedures for basket assets in place, we believe that some ETFs may currently have methodologies or compliance policies for basket assets in place.

[458] *See infra* footnote 553.

[459] *See infra* footnote 554.

[460] This estimate is based on the following calculation: ($10,268 + $3,985) × 1,635 ETFs = $23,303,655. This estimate may be an over-estimate in that it assumes that all ETFs, regardless of their actual use of custom baskets, would implement policies and procedures for custom basket assets.

[461] Actively managed ETFs and some ETFs that track an index from an affiliated index provider have been required to disclose their holdings prior to the commencement of trading each business day (*i.e.,* full portfolio transparency). Other index-based ETFs are permitted to disclose their portfolio holdings indirectly, by specifying which index they seek to track, as long as the index provider lists the constituent securities on its website (*i.e.,* index transparency) or by disclosing the components of their baskets. Some index-based ETFs have been required to provide full portfolio transparency. *See* discussion of portfolio transparency, *supra* section II.C.4.a; *see also supra* footnote 207 and accompanying text.

[462] From a staff review of ETF websites, the sampled index and actively-managed ETFs already provide daily portfolio holdings. Extrapolating the sampled results to the entire universe of ETFs, ETFs in general should bear no additional costs above the baseline to collect and maintain on their websites these holdings. If some ETFs that were not sampled, however, do not currently maintain on their websites their daily portfolio holdings, Commission staff estimates that an ETF each year would spend approximately 5 hours of professional time to update the relevant web page daily with this information at a cost of $1,405.50. *See supra* note 537. We preliminarily believe that the number of ETFs that would have to bear these additional costs would be small due to our experience with the sampled ETFs.

[463] The proposed rule would require that portfolio holdings information be presented and contain information regarding description, amount, value and/or unrealized gain/loss (if applicable) in the manner prescribed within Article 12 of Regulation S–X.

[464] This estimate is based on the following calculations: 3 hours (for website development) × $296.50 per hour (blended rate for a senior systems analyst ($274) and senior programmer ($319) + 2 hours (for review of current portfolio disclosures) × $325 (blended rate for a compliance manager ($298) and a compliance attorney ($352)) + $400 for external website development = $1,939.50. The industry cost is 1,635 × $1,939.50 = $3,171,082.50.

requirement would further inform investors about the expected cost of trading an ETF and facilitate comparison of transaction costs across ETFs. As such, the disclosure of median bid-ask spreads could reduce investors' uncertainty about the trading environment and facilitate the selection of ETF investments that fit individual investors' needs. Currently, disclosure of median bid-ask spreads by ETFs are not required by exemptive orders, although some funds may voluntarily provide this information on their websites. For those funds that do not already disclose this information, they would have to implement processes and systems to compute the median bid-ask spreads and would have to accommodate a new data point on their web page to report this information. We preliminarily do not believe the incremental cost of such disclosure will be substantial. The estimated costs for computing and establishing processes and systems to update the median bid-ask spread are $296.50 per fund, while aggregate costs for computing and updating the web pages of ETFs to include the median bid-ask spread would be $484,777.50.[465] We preliminarily believe that funds will incorporate the processes of updating the median bid-ask spread with other daily processes associated with updating the web page, such as reporting the daily portfolio holdings, and therefore, there will be no additional daily costs associated with updating the median bid-ask spread on the webpage. We also believe that funds currently maintain a record of historical prices as a matter of current business practices which could be used to satisfy the requirement at a nominal cost, as discussed above. If a fund does not maintain a record of historical prices, it may incur a one-time estimated cost of $296.50 to satisfy the requirement, or an upper bound of $484,777.50 in aggregate, assuming that no ETFs currently maintain historical price records.[466]

ii. Omission of Conditions We Believe May Save Costs for Funds

First, the proposed rule would not contain a requirement that an ETF's IIV be disseminated at least every 15 seconds during regular trading hours (60 seconds for international ETFs), as is currently required under all exemptive orders. We believe that many sophisticated institutional market participants do not rely on the IIV to value an ETF's assets, as discussed above in section II.C.3.

In some cases, the IIV may not reflect the actual value of an ETF's assets (*e.g.,* for funds that invest in foreign securities whose markets are closed during the ETF's trading day or funds whose assets trade infrequently, as is the case for certain bond funds). In those cases, we believe that both institutional and retail market participants would benefit from the omission of the IIV as a requirement of the proposed rule by avoiding the possibility that investors base their investment decisions on this potentially misleading information. However, the IIV may, for certain funds, provide a reasonably accurate estimate of the value of an ETF's assets, including for those funds whose underlying assets are very frequently traded during the ETF's trading day. Less sophisticated institutional investors as well as retail investors relying on the IIV for those ETFs may thus find the IIV useful and could see their ability to evaluate ETFs reduced without this metric.[467]

Exchange listing standards currently require the IIV to be disseminated. As long as exchange listing standards continue to include this requirement, the proposed rule's omission of such a requirement would not represent a change from the baseline and would not result in any costs or benefits to market participants. Nonetheless, if the listing standards change, ETFs would not be subject to the cost of dissemination of IIV information under the proposed rule.

Second, under the terms of the exemptive orders, ETFs are required to disclose in their registration statement that redemptions may be postponed for foreign holidays. The proposed amendments to Forms N–1A and N–8B–2 do not contain such a requirement and would thus eliminate the cost of preparing and updating this disclosure for existing ETFs. As discussed above in section III.B.4, we believe that such a requirement is not necessary, since this information is already covered by the agreement between the ETF and the authorized participant.[468] As discussed in section III.C.1, we further believe that such a disclosure would not be relevant for retail investors, who purchase ETF shares on the secondary market.

Third, the proposed rule would not require an ETF to identify itself in any sales literature as an ETF that does not sell or redeem individual shares and explain that investors may purchase or sell individual ETF shares through a broker via a national securities exchange. Although this condition has been included in our exemptive orders, we no longer believe that it is necessary given that markets have become familiar with ETFs in the multiple decades they have been available. The omission of such a requirement could lead to cost savings for existing and future ETFs associated with preparing and reviewing this disclosure for sales literature.[469]

iii. Website Disclosure Provisions

Proposed rule 6c–11 would require an ETF to disclose certain information prominently on its website, which is publicly accessible and free of charge.[470] The goal of these disclosure requirements is to provide investors with key metrics to evaluate their trading and investment decisions in a location that is easily accessible and frequently updated.[471] Based on a staff

[465] Commission staff estimate a one-time cost of computing and implementing processes and systems for daily updating of the median bid-ask spread of one burden hour at a per hour cost of $296.50 (blended rate for a senior systems analyst ($274) and senior programmer ($319)). The one-time cost of updating the web page to include the median bid-ask spread would be incorporated as part of the web page development discussed in section IV.B.1 (*see also infra* footnote 535). As median bid-ask spreads are not currently required to be reported or computed by ETFs, we estimate that the aggregate costs would be $296.50 × 1,635 ETFs = $484,777.50.

[466] Commission staff estimate a one-time cost of computing and implementing processes and systems for daily updating of historical prices of one burden hour at a per hour cost of $296.50 (blended rate for a senior systems analyst ($274) and senior programmer ($319)). Although we preliminarily estimate that funds already maintain a record of historical prices, an upper bound on aggregate costs would be estimated at $296.50 × 1,635 ETFs = $484,777.50.

[467] While the IIV may be very accurate for ETFs whose underlying assets trade frequently (and thus are liquid as well), such ETFs also tend to have small premiums/discounts to NAV per share, reducing the incremental usefulness of the IIV for investors in these ETFs compared to observing only the ETF's share price.

[468] As discussed above, we believe that authorized participants would share this information with other market participants as necessary, for example when a market participant uses an authorized participant as agent for transacting with an ETF and this information is a necessary part of the creation or redemption process.

[469] We estimate that the omission of this requirement would save 0.25 hours of a compliance attorney ($352 per hour), resulting in a cost savings of $88 (0.25 × $352) per fund each year. The total cost savings for all 1,635 ETFs that could rely on the proposed rule would thus be $143,880 (1,635 × $88).

[470] *See supra* footnote 208.

[471] According to the most recent U.S. census data, approximately 77.2% of U.S. households had some form of internet access in their home in 2015 and 86.8% have a computer (*e.g.,* desktop, laptop, tablet or smartphone). *See* Camille Ryan & Jamie M. Lewis, *Computer and internet Usage in the United States: 2015,* ACS–37 (Sept. 2017), *available at https://www.census.gov/content/dam/Census/library/publications/2017/acs/acs-37.pdf*; *see also* Sarah Holden, Daniel Schrass & Michael Bogdan, *Ownership of Mutual Funds, Shareholder Sentiment, and Use of the internet, 2017* (Oct. 2017), *available at https://www.ici.org/pdf/per23-07.pdf* (''[i]n mid-2017, 95 percent of households owning mutual funds had internet access, up from about two-thirds in 2000'' and ''86 percent of

review of ETFs' websites, we believe that all ETFs that could rely on the proposed rule currently have a website.[472] As a consequence, existing ETFs would generally not incur any additional cost associated with the creation and technical maintenance of a website.

As discussed above, a requirement for daily website disclosures of NAV, closing price, and premiums and discounts—each as of the end of the prior business day has been included in substantially all exemptive relief orders starting from 2008. As discussed in section III.B.4, based on a staff review of ETFs' websites, we believe that all ETFs that could rely on the proposed rule currently provide daily website disclosures of NAV, closing price, and premiums or discounts.[473] As a consequence, existing ETFs would generally not incur any additional cost associated with these website disclosure requirements.

Our exemptive orders have not included requirements for line graph and tabular historical information regarding premiums and discounts. However, Form N–1A contains tabular website disclosures relating historical premium/discount in Items 11(g)(2) and 27(b)(7)(iv), which we are proposing to eliminate.[474] Nonetheless, we anticipate that all existing ETFs that fall within the scope of the proposed rule would incur some additional costs associated with these disclosures. We believe that substantially all ETFs already have the required data available to them as part of their regular operations (as it is required by Form N–1A and also allows ETFs to monitor the trading behavior of their shares), as well as have systems (such as computer equipment, an internet connection, and a website) in place that can be used for processing this data and uploading it to their websites. However, these ETFs would still incur the costs associated with establishing and following (potentially automated) processes for processing and uploading this data to their websites. We estimate that an average ETF would incur a one-time cost of $1,939.5[475] for implementing this website disclosure and an ongoing cost of $473.25[476] per year for updating the relevant web page with this information. We thus estimate the total industry cost, in the first year, to ETFs that could rely on the proposed rule for providing this website disclosure, of $3,944,846.35.

Our exemptive orders have not included a requirement for ETFs to provide disclosure of the factors that materially contributed to a premium or discount, if known, if an ETF's premium or discount is greater than 2% for more than seven consecutive trading days. As a result, under the proposed rule those ETFs that experience such a premium or discount would incur additional costs associated with determining what factors contributed to the premiums or discounts and drafting and uploading a discussion to their website. Based on a staff analysis of historical data on ETF premiums and discounts from 2008 to 2017 using Bloomberg data, we believe that this disclosure requirement would be triggered for, on average, 4.7% of those ETFs that could rely on the proposed rule per year.[477] We estimate that a fund required to make such a disclosure in a given year would incur an average cost of $1,438.50, yielding a total annual industry cost of $110,541.53.[478]

The proposed rule would also require an ETF to post on its website one ''published'' basket at the beginning of each business day. While we believe that authorized participants already have access to this information in the daily portfolio composition file provided to NSCC, many market participants, such as smaller institutional investors and retail investors, are not NSCC members and do not currently have access to this information.

Our exemptive orders have not included requirements for daily website disclosures of ETF baskets. As a result, we anticipate that all existing ETFs that rely on the proposed rule would incur additional costs associated with this disclosure.[479] Since specifying basket assets is part of the regular operation of an ETF, we believe that all ETFs already have the required data available to them. In addition, we believe that most ETFs already have systems (such as computer equipment, an internet connection, and a website) in place that can be used for processing this data and uploading it to their websites. However, these ETFs would still incur the costs associated with establishing and following (potentially automated) processes for processing and uploading this data to their websites. We estimate that an average ETF would incur a one-time cost of $2,909.25[480] for implementing this website disclosure and an ongoing cost of $784[481] per year for updating the relevant web page daily with this information. We thus estimate the total industry cost, in the first year, to ETFs that could rely on the proposed rule for providing this website disclosure, of 6,038,463.75.[482]

As discussed in section IV.A above, the proposed disclosures on ETFs' websites, which are publicly available and free of charge, would enable investors to more readily obtain certain key metrics for individual ETFs,

mutual fund-owning households with a household head aged 65 or older had internet access in mid-2017''); Andrew Perrin & Maeve Duggan, *Americans' Internet Access: 2000–2015,* Pew Research Center (June 2015), *available at http://assets.pewresearch.org/wp-content/uploads/sites/14/2015/06/2015-06-26_internet-usage-across-demographics-discover_FINAL.pdf* (finding in 2015, 84% of all U.S. adults use the internet). Retail investors that do not have internet access in their homes may have access outside their homes, such as at public libraries.

[472] *See supra* footnote 437.

[473] *See supra* footnote 437.

[474] *See infra* section II.H.4.

[475] This estimate is based on the following calculations: 3 hours (for website development) × $296.50 per hour (blended rate for a senior systems analyst ($274) and senior programmer ($319)) + (2 hours (for review of website disclosures) × $325 (blended rate for a compliance manager ($298) and a compliance attorney ($352)) + $400 for an external website developer to develop the web page = $1,939.50.

[476] This estimate is based on the following calculations: 0.5 hours (for website updates) × $296.50 per hour (blended rate for a senior systems analyst ($274) and senior programmer ($319)) + (1 hour (for review of website disclosures) × $325 (blended rate for a compliance manager ($298) and a compliance attorney ($352) = $473.25.

[477] This estimate represents the average of the percentage of ETFs for which the reporting requirement was triggered at least once in a given year, for those ETFs that could rely on the proposed rule. During the sample period from 2008 to 2017, the percentage of ETFs for which the reporting requirement was triggered at least once varied from 1.5% in 2010 to 10% in 2008.

[478] We believe that such disclosure would require 4 internal hours (2.5 hours for the compliance attorney to determine if this requirement has been triggered and produce a draft of the required disclosures + 1.5 hours for the webmaster to include the information on the website), at a time cost of (2.5 hours × $352 compliance attorney hourly rate) + (1.5 hours × $239 webmaster hourly rate) in addition to $200 for external website development = $1,738.50. The annual cost of this requirement for those ETFs that could rely on the proposed rule is calculated as 4.7% × 1,635 ETFs × $1,738.50 = $110,541.53.

[479] As proposed, the rule would require that basket information be presented and contain information regarding description, amount, value and/or unrealized gain/loss (if applicable) in the manner prescribed within Article 12 of Regulation S–X.

[480] This estimate is based on the following calculations: 4.5 hours (for website development) × $296.50 per hour (blended rate for a senior systems analyst ($274) and senior programmer ($319)) + (3 hours (for review of website disclosures) × $325 (blended rate for a compliance manager ($298) and a compliance attorney ($352)) + $600 for an external website developer to develop the web page = $2,909.25.

[481] This estimate is based on the following calculations: 1 hour (for website updates) × $296.50 per hour (blended rate for a senior systems analyst ($274) and senior programmer ($319)) + (1.5 hours (for review of website disclosures) × $325 (blended rate for a compliance manager ($298) and a compliance attorney ($352) = $784.

[482] This estimate is based on the following calculation: 1,635 ETFs × ($2,909.25 + $784) = $6,038,463.75.

potentially resulting in better informed investment decisions.[483] The proposed conditions standardize certain content requirements to facilitate investor analysis of information while allowing ETFs to select a format for posting information that the individual ETF finds most efficient and appropriate for their website. Because the information in the proposed disclosures would be made available on individual websites, in the format chosen by the ETF, we acknowledge that an investor's ability to efficiently extract information from website disclosures for purposes of aggregation, comparison, and analysis across multiple funds and time periods may be limited. Investors seeking to compare multiple ETFs would have to visit the website of every ETF, navigate to the relevant section of the website, and extract the information provided in the format chosen by the fund. Depending on the manner in which a typical fund investor would use the website disclosures, these considerations may decrease the information benefits of the proposed disclosures. However, we recognize that investors may rely on third-party providers that aggregate such information for all ETFs into a structured format that investors can more easily access and process for the purpose of statistical and comparative analyses. While investors may incur costs of obtaining information from third-party service providers, it would likely be lower than the cost they would incur than if they performed the collection themselves, and the cost of such services may otherwise be reduced as a result of competition among service providers. Overall, we believe that requiring ETFs to provide this information on their websites would ultimately provide an efficient means for facilitating investor access to information.

c. Recordkeeping

The proposed rule would require that ETFs preserve and maintain copies of all written authorized participant agreements for at least five years, the first two years in an easily accessible place. This requirement would provide Commission examination staff with a basis to evaluate whether the authorized participant agreement is in compliance with the rule and other provisions of the Investment Company Act and the rules thereunder, and would also promote internal supervision and compliance.[484] As the agreement forms the contractual foundation on which authorized participants engage in arbitrage activity, compliance of the agreement with the proposed rule is important for the arbitrage mechanism to function properly.

We are also proposing to require ETFs to maintain information regarding the baskets exchanged with authorized participants on each business day the ETF exchanged creation units, including a record stating that the custom basket complies with the ETF's custom basket policies and procedures. As discussed above, we believe that these records would help our examination staff understand how baskets are being used by ETFs, evaluate compliance with the rule and other provisions of the Act and rules thereunder, and examine for potential overreach by ETFs in connection with the use of custom baskets or transactions with affiliates.

Existing exemptive orders have not required ETFs to preserve and maintain copies of authorized participant agreements or information about basket composition. However, we believe that most ETFs already preserve and maintain copies of authorized participant agreements as well as data on baskets used as a matter of established business practice. Existing ETFs that do not already preserve and maintain copies of these documents and data, as well as all new ETFs that would operate under the proposed rule, would incur maintenance and storage costs associated with these requirements. As discussed in section IV.B, we estimate that an average ETF that does not currently comply with these recordkeeping requirements would incur an annual cost of $380 per year[485] to maintain these records.[486] Assuming that 20% of ETFs would incur this cost, the total industry cost for ETFs that could rely on the proposed rule would be $124,260 per year.[487] In addition, the existing orders have not required that ETFs prepare and maintain a record stating that custom baskets comply with the custom basket policies and procedures. We anticipate that all ETFs that could operate under the proposed rule will incur additional recordkeeping costs associated with the requirement that custom baskets comply with custom basket policies and procedures. Assuming that 25% of the total annual recordkeeping costs can be attributed to the new requirement for custom baskets, we estimate a total cost per ETF of $95 per year for the requisite five-year period and an annual industry cost of $155,325 for ETFs that could rely on the rule.[488]

d. Master-Feeder Relief

The proposed rule would rescind the master-feeder relief granted to ETFs that do not rely on the relief as of the date of this proposal. We are proposing to rescind such relief because there generally is a lack of interest in ETF master-feeder arrangements, and certain master-feeder arrangements raise policy concerns discussed above. While there are currently many exemptive orders that contain the master-feeder relief, it is our understanding that only one fund complex currently relies on this relief to structure several master-feeder arrangements with one master and one feeder fund each.[489] As discussed above, we would also propose to grandfather existing master-feeder arrangements involving ETF feeder funds, but prevent the formation of new ones, by amending relevant exemptive orders.[490] As a result, we do not expect that the rescission of the existing master-feeder relief would impose costs on ETFs that currently rely on the relief to structure master-feeder arrangements.

[483] *See supra* footnote 208.

[484] ETFs already will be required to provide some information about authorized participants on Form N–CEN, including the name of each authorized participant, additional identifying information, and the dollar values of the fund shares the authorized participant purchased and redeemed during the reporting period. However, this information alone would not be sufficient for Commission staff to evaluate whether a fund's authorized participant agreements are in compliance with the proposed rule.

[485] *See infra* footnote 544.

[486] An average ETF would have to maintain and store 34 authorized participant agreements. *See supra* footnote 431 and accompanying text.

[487] This estimate is based on the following calculation: 1,635 ETFs × $380 × 20% = $124,260.

[488] This estimate is based on a total record keeping cost of $380 per ETF over five years, *see infra* note 544, 25% × $380 = $95, $95 × 1,635 ETFs = $155,325.

[489] *See supra* footnote 341.

[490] As discussed above, without this relief, the affected funds could continue operating by effecting creation and redemption transactions between authorized participants and the feeder fund (as well as the transactions between the master and feeder fund) in cash rather than in kind. As cash creations and redemptions can be less efficient than in-kind transactions for certain ETFs, this could impose a cost on the ETFs that are part of the fund family. Cash redemptions and creations could also affect the current relationships that funds have with authorized participants if the authorized participants would be unwilling to perform the arbitrage function when receiving cash instead of baskets of securities, which could have unintended spillover effects on the secondary market trading of these funds' shares. Alternatively, these feeder funds may opt to pursue their investment objectives through direct investments in securities and/or other financial instruments, rather than through investments in master funds. Such a restructuring of the funds involved would also lead to costs (primarily associated with legal and accounting work) on the ETFs that are part of the fund family. As a result, if this change would require portfolio transactions to occur at the fund, there could be additional costs such as lower overall total returns to the fund or that investors may find the fund to be a less attractive investment.

At the same time, the rescission of the relief may benefit investors in prospective feeder ETFs to the extent that it protects them from any concerns associated with feeder ETFs discussed above.[491]

2. Disclosure (Amendments to Forms N–1A and N–8B–2)

The amendments to Form N–1A and N–8B–2 are designed to provide authorized participants and investors with tailored information regarding the costs associated with investing in ETFs. As discussed in section IV.A above, we expect that the new disclosures would benefit investors by helping them better understand and compare specific funds, potentially resulting in more informed investment decisions, more efficient allocation of investor capital, and greater competition for investor capital among funds.

As discussed above, we propose to add a set of Q&As related to fees and trading information and costs that we anticipate would help investors better understand costs specific to ETFs, such as bid-ask spreads, brokerage commissions, and purchasing or selling ETF shares at a premium or discount to NAV. The answers to the Q&As would include information about trading costs specific to an ETF, such as the median bid-ask spread over the previous year.

In addition, the proposed amendments to Forms N–1A and N–8B–2 would require an ETF to provide information on the ETF's median bid-ask spread as well as an interactive calculator on the ETF's website that can be used to determine how the bid-ask spread would impact the costs associated with frequent trading of ETF shares. As discussed above, the purpose of the interactive calculator is to provide investors with the ability to customize the hypothetical calculations in Item 3 of Form N–1A to their specific investing situation by choosing either the number or size of the hypothetical round-trip trades, or both.

While we believe that substantially all ETFs already have the required data for these new disclosures on Forms N–1A and N–8B–2 and for the interactive calculator as part of their regular operations, these funds would still incur costs for processing the data, entering them into the form, and programming the interactive calculator.[492] We estimate that each ETF would incur a one-time cost of $6,710 [493] and an ongoing cost of $3,355 [494] per year.[495] We thus estimate that the total industry cost for ETFs in the first year would equal $19,123,500.[496]

D. Effects on Efficiency, Competition, and Capital Formation

This section evaluates the impact of proposed rule 6c–11 and the amendments to Forms N–1A and N–8B–2 on efficiency, competition, and capital formation. However, as discussed in further detail below, the Commission is unable to quantify many of the effects on efficiency, competition and capital formation either because they are inherently difficult to quantify or because it lacks the information necessary to provide a reasonable estimate.

1. Efficiency

The proposed rule would likely increase total assets of ETFs, as a result of reducing the expense and delay of forming and operating new ETFs organized as open-end funds, reducing the cost for certain ETFs to monitor their own compliance with regulations, and as well increased competition among ETFs as discussed below. At the same time, the proposed rule could lead to a decrease in total assets of other fund types that investors may regard as substitutes, such as certain mutual funds.[497] As a result, ETF ownership (as a percentage of market capitalization) for some securities, such as stocks and bonds, would likely increase, and ownership by other funds, such as mutual funds, would likely decrease. The academic literature that we discuss in this section suggest that such a shift in ownership could affect the price efficiency (the extent to which an asset price reflects all public information at any point in time) and liquidity of these portfolio securities.[498]

The literature suggests that a shift in stock ownership towards ETFs may improve some dimensions of price efficiency while impeding price efficiency along other dimensions. Specifically, the results in one paper suggest that stock prices incorporate systematic information more quickly when they are held in ETF portfolios.[499] The evidence in this paper thus indicates that ETF activity increases stock market efficiency with regard to systematic information, *i.e.,* information relating to market-wide risks. On the other hand, some studies find that an increase in ETF ownership may introduce non-fundamental volatility into stock prices, *i.e.,* cause temporary deviations of stock prices from their fundamental values. For example, one paper finds that ownership by US equity index ETFs is associated with higher volatility among component stocks and argues that the increased volatility is non-fundamental.[500] Another paper finds that higher authorized participant arbitrage activity in US equity ETFs is

[491] *See supra* section II.F.

[492] As discussed in more detail below in section V.D, the ongoing costs of complying with the proposed amendments to Form N–8B–2 for all UIT ETFs as well as the one-time initial costs for existing UIT ETFs would accrue to Form S–6.

[493] We estimate that each ETF would incur a one-time burden of an additional 20 hours, at a time cost of an additional $6,710 (10 hours x $335.50 (blended rate for a compliance attorney ($352) and a senior programmer ($319)) = $6,710) to draft and finalize the required disclosure, amend its registration statement, implement the interactive calculator, and update its website.

[494] We estimate that each ETF would incur an ongoing burden of an additional 10 hours, at a time cost of an additional $3,355 (10 hours × $335.50 (blended rate for a compliance attorney ($352) and a senior programmer ($319)) = $3,355) each year to review and update the proposed disclosures.

[495] Like all information disclosed in Items 2, 3, or 4 of Form N–1A, the information disclosed in amended Item 3 would have to be tagged and submitted in a structured data format. *See supra* footnote 361. We note that we are adopting amendments to require the use of Inline XBRL format in a companion release, which would apply to the information disclosed in amended Item 3 according to the compliance dates of those amendments. *See* Inline XBRL Filing of Tagged Data, Investment Company Act Release No. 33139 (June 28, 2018). Given that filers already have systems in place to submit the existing information in Item 3 in a structured format and that filers will already be required to update those systems to comply with the Inline XBRL requirement, we believe that there would not be any significant additional costs associated with the information in amended Item 3 being filed in a structured format.

[496] This estimate is based on the following calculation: 1,900 ETFs × ($6,710 + $3,355) = $19,123,500.

[497] The proposed disclosure requirements would also serve to increase investors' awareness of the trading costs that they can incur when trading ETFs, which can be substantial in some cases. As a result, investors who may previously not have been fully aware of these costs may shift their demand away from ETFs and towards other types of funds, such as mutual funds. We believe, however, that the rulemaking as a whole is likely to increase demand for ETFs rather than decrease it.

[498] In documenting the impact of ETF arbitrage on price efficiency and liquidity, the academic literature does not generally distinguish ETFs that could rely on the rule from those that could not. However, these studies investigate a broad range of ETFs with varying degrees of relief including basket flexibility. Therefore, we believe that the subsample of ETFs that could rely on the rule (those organized as open-end funds that are not leveraged) is representative of those used in the academic literature. As a result, we believe that inferences from the academic research generally apply to ETFs that can rely on the rule.

[499] Lawrence Glosten, Suresh Nallareddy & Yuan Zou, *ETF Trading and Informational Efficiency of Underlying Securities,* Columbia Business School Research Paper No. 16–71 (2016).

[500] *See* Itzhak Ben-David, Francesco Franzoni & Rabih Moussawi, *Do ETFs Increase Volatility?,* Swiss Finance Institute Research Paper No. 11–66 (2017). This paper also finds that mutual fund ownership is associated with higher volatility in the underlying indexes. Thus, to the extent that part of the increase in ETF assets would be accompanied by a decrease in mutual fund assets, the net effect on price efficiency would be unclear.

associated with a higher correlation of returns among stocks in the ETF's portfolio.[501] The authors find evidence that changes in the prices of these stocks tend to partially revert over the next trading day and argue that the increased co-movement in returns is thus a sign of excessive price movement due to non-fundamental shocks that ETF trading helps propagate.

The proposed rule could decrease the liquidity of stocks held by ETFs, as one study finds that higher ownership of a stock by US equity ETFs is associated with lower liquidity as measured by market impact.[502] Conversely, the academic literature offers mixed evidence regarding the impact of ETFs on bond liquidity. While one paper finds that increased ETF ownership is associated with lower bond liquidity for investment grade bonds,[503] another study finds that bonds included in ETFs experience improvements in their liquidity.[504]

A shift in stock ownership towards ETFs could also have an effect on the co-movement of liquidity for stocks held by ETFs. Specifically, one paper observes that the liquidity of a stock with high ETF ownership co-moves with the liquidity of other stocks that also have high ETF ownership.[505] The authors argue that this co-movement in liquidity represents a risk to investors, as it exposes them to the possibility that many assets in their portfolio will be illiquid at the same time.

Since we do not know the degree to which the proposed rule would increase ETF ownership of stocks and bonds, we are unable to quantify the proposed rule's effects on price efficiency and liquidity.

As a result of the proposed rule's allowance of increased basket flexibility, some ETFs that did not already have this flexibility in their baskets may choose to increase the weight of more liquid securities and decrease the weight of less liquid securities in their baskets compared to their portfolios.[506] During normal market conditions, this may lead those ETFs' shares to trade at smaller bid-ask spreads, thus benefiting investors. We note, however, that such a reduction in bid-ask spreads by over-weighting more liquid securities may not work during stressed market conditions, if a large proportion of such an ETF's portfolio securities become less liquid.[507] As a result, the gap between bid-ask spreads of some ETFs' shares during normal and stressed market periods may grow as a result of the proposed rulemaking, which some investors may not anticipate and fail to fully take into account when making their investment decisions.[508]

Finally, the proposed amendments to Forms N–1A and N–8B–2 as well as the additional website disclosures required by proposed rule 6c–11 would allow investors and other market participants to better understand and compare ETFs using more relevant and standardized disclosure. For example, as discussed above, the proposed amendments to Item 3 of Form N–1A would add a requirement for ETFs to disclose their median bid-ask spread and include a statement that ETF investors may be subject to other expenses that are specific to ETF trading, including brokerage commissions and potential costs related to purchasing ETF shares at a premium or discount to NAV per share.[509] These costs are not currently required to be disclosed by Item 3. Since these costs are incurred by ETF investors and not mutual fund investors, we believe that adding this disclosure would help investors and other market participants better assess and compare fees and expenses between certain funds and fund types, such as ETFs and mutual funds. Thus, the proposed rule could help investors make more informed investment decisions that are more suited for their investment objectives. The degree to which investors would benefit from the ability to make more informed investment decisions is inherently difficult to quantify, so we are unable to estimate the size of this benefit.

2. Competition

The proposed rule would likely increase competition among ETFs that could rely on the proposed rule. The first channel through which the proposed rule would likely foster competition is by reducing the costs for ETF sponsors to form new ETFs that comply with the conditions set by the proposed rule. This cost reduction would lower the barriers to entering the ETF market, which would likely lead to increased competition among ETFs that could rely on the proposed rule.

In addition, new ETFs that enter the market in reliance on the proposed rule as well as those existing ETFs that would have their exemptive relief rescinded and replaced by the proposed rule, would no longer be subject to requirements that vary between exemptive orders. Instead, these ETFs would operate under uniform requirements, which would help promote competition among ETFs that could rely on the proposed rule.

An increase in competition among ETFs that could rely on the proposed rule would likely also lead to an increase in competition between those ETFs and ETFs that could not rely on the proposed rule as well as other types of funds and products that investors may perceive to be substitutes for ETFs, such as certain mutual funds.[510]

Furthermore, as discussed above, the proposed website disclosures and amendments to Forms N–1A and N–8B–2 would allow investors to compare ETFs and other open-end investment companies, which could further foster

[501] Zhi Da & Sophie Shive, *Exchange Traded Funds and Asset Return Correlations,* Working Paper, Notre Dame University (2016).

[502] *See* Sophia JW. Hamm, *The effect of ETFs on stock liquidity,* Working Paper, Ohio State University (2014). However, the study also finds the same relationship for ownership by index mutual funds. Thus, to the extent that part of the increase in ETF assets would be accompanied by a decrease in mutual fund assets, the net effect on price efficiency would be unclear.

[503] Caitlin Dillon Dannhauser, *The Impact of Innovation: Evidence from Corporate Bond ETFs,* Journal of Financial Economics, forthcoming (2016) (''Dannhauser Article'').

[504] Jayoung Nam, *Market Accessibility, Corporate Bond ETFs, and Liquidity,* Working Paper, Indiana University Bloomington (2017).

[505] Vikas Agarwal, Paul Hanouna, *et al., Do ETFs Increase the Commonality in Liquidity of Underlying Stocks,* Working Paper, Villanova University (2017).

[506] This would be the case for those ETFs that hold less liquid securities in their portfolios.

[507] Under rule 22e–4 under the Act, an ETF is required to consider: (i) The relationship between portfolio liquidity and the way in which, and the prices and spreads at which, ETF shares trade, including, the efficiency of the arbitrage mechanism and the level of active participation by market participants (including authorized participants); and (ii) the effect of the composition of baskets on the overall liquidity of the ETF's portfolio as part of its assessment, management and review of liquidity risk. *See* LRM Adopting Release, *supra* footnote 101.

[508] Conversely, some ETFs may choose to decrease, rather than increase, the weight of more liquid securities and increase the weight of less liquid securities in their basket compared to their portfolio in order to reduce transaction costs borne by an ETF's existing/remaining shareholders when the ETF must buy and sell portfolio holdings. This would lead to a reduction in transaction costs for existing/remaining shareholders and to an increase in transactions costs for authorized participants and, ultimately, investors buying and selling ETF shares. Thus, we believe that most funds would choose to limit such behavior as they would likely find it to be in their best interest to balance costs imposed on remaining and existing/remaining shareholders.

[509] James J. Angel, Todd J. Broms, & Gary L. Gastineau, *ETF Transaction Costs Are Often Higher Than Investors Realize,* 42 The Journal of Portfolio Management 3, 65–75 (2016) find that the cost of trading ETF shares depends both on bid-ask spreads as well as premiums and discounts to NAV per share.

[510] The types of funds and products that investors may consider substitutes for ETFs would depend on an individual investor's preferences and investment objectives. Other types of products that some investors may consider to be substitutes for ETFs include closed-end funds and other exchange-traded products, such as exchange-traded notes and commodity pools.

competition among open-end investment companies as well as between open-end investment companies and other types of funds that investors may perceive to be substitutes for open-end investment companies, such as closed-end funds and certain exchange-traded products.

Increased competition would likely lead to lower fees for investors, encourage financial innovation, and increase consumer choice in the markets for ETFs, open-end investment companies, and other types of funds that investors may perceive to be substitutes.[511] Due to the limited availability of data, however, we are unable to quantify these effects.

To the extent the proposed rule would increase the number and total assets of ETFs, more authorized participants or other market participants may enter the market. This could lead to increased competition among authorized participants or other market participants and result in authorized participants or other market participants exploiting arbitrage opportunities sooner (*i.e.,* when premiums/discounts to NAV per share are smaller). As a result, bid-ask spreads may tighten and premiums/discounts to NAV per share for ETF shares may decrease. As authorized participants and some of the other market participants that engage in ETF arbitrage are large broker-dealers, however, we would expect new entries of authorized participants or other arbitrageurs as a result of the rule to be limited and any effects on bid-ask spreads and premiums/discounts to NAV per share to be small.

3. Capital Formation

The proposed rule may lead to increased capital formation. Specifically, an increase in the demand for ETFs, to the extent that it would increase demand for intermediated assets as a whole, would likely spill over into primary markets for equity and debt securities. As a consequence, companies may be able to issue new debt and equity at higher prices in light of the increased demand for these assets in secondary markets created by ETFs. As a consequence, the cost of capital for firms could fall, facilitating capital formation.

The conclusion that an increase in the demand for ETFs may lower the firm's cost of capital is further supported by a paper[512] that finds that bonds with a higher share of ETF ownership have lower expected returns.[513] Due to the limited availability of data, however, we are unable to quantify these effects of the proposed rule on capital formation.

E. Reasonable Alternatives

1. Treatment of Existing Exemptive Relief

As discussed above, we propose to rescind the exemptive relief we have issued to ETFs that would be permitted to rely on the proposed rule. As an alternative, we considered allowing ETFs with existing exemptive relief in orders that do not contain a self-termination clause to continue operating under their relief rather than requiring them to operate in reliance on the rule.

The Commission believes that allowing ETFs to continue operating under their existing relief would create differences in the conditions under which funds operate. Specifically, some ETFs that determine they do not need the additional flexibility (*e.g.,* basket flexibility) the proposed rule would provide compared to their existing exemptive relief could choose to continue operating under their existing relief rather than in reliance on the rule. This could allow these ETFs to circumvent the other requirements that are part of the rule (*e.g.,* daily website disclosure of the basket assets). This self-selection would create a disparity in the conditions under which ETFs are allowed to operate.

Measured against the baseline, the alternative would thus have smaller benefits arising from improved disclosure, including that the alternative would not level the playing field among ETFs with regard to these conditions and thus not be as effective at promoting product competition as the proposed rule. In addition, it would be more difficult for the Commission to evaluate compliance with regulations under the alternative compared to the proposed rule, as some of the ETFs whose exemptive relief we propose to rescind could choose to continue to operate under their exemptive relief. The Commission also believes that the costs to funds associated with rescinding the existing exemptive relief would be minimal, as we anticipate that substantially all funds whose relief would be rescinded would be able to continue operating with only minor adjustments, other than being required to comply with the additional website disclosures and to develop basket asset policies and procedures.[514]

2. ETFs Organized as UITs

Proposed rule 6c–11 would be available only to ETFs that are organized as open-end funds.[515] As an alternative, we considered including ETFs organized as UITs in the scope of the proposed rule. However, as discussed above in section III.A.1, we believe that the terms and conditions of the existing exemptive orders for UITs are appropriately tailored to address the unique features of the UIT structure.

In addition, as also discussed above, ETFs have greater investment flexibility under the open-end fund structure than the UIT structure, which leads us to believe that most new ETFs entering into the market would prefer to operate under the open-end fund structure rather than the UIT structure. No new UIT ETFs have come to market in recent years, and we do not think that there would be significant economic benefits to including UITs in the scope of the proposed rule, and thus we propose to exclude ETFs organized as UITs from the proposed rule.[516]

3. Basket Flexibility

Proposed rule 6c–11would require ETFs relying on the rule to adopt and implement written policies and procedures that govern the construction of basket assets and the process that will be used for the acceptance of basket assets. As an alternative, we considered requiring that an ETF's basket generally correspond *pro rata* to its portfolio holdings, while identifying certain limited circumstances under which an ETF may use a non-*pro rata* basket, as

[511] As discussed above, the proposed rule would likely lead to increased competition both among ETFs that could rely on the proposed rule as well as between ETFs that could rely on the rule and those that could not. While we believe that increased competition generally is conducive to innovation, any increased competition in the ETF market resulting from the proposed rule would be more likely to involve novel ETFs that would continue to need to obtain exemptive relief from the Commission.

[512] Dannhauser Article, *supra* footnote 503.

[513] We acknowledge that there is research (*see* Yakov Amihud & Haim Mendelson, *Asset Pricing and the Bid-Ask Spread,* 17 Journal of Financial Economics 2, 223–249 (1986)) that provides evidence that expected returns of an asset are positively associated with its liquidity. As discussed above, the academic literature suggests that stocks with a higher share of ETF ownership have lower liquidity (whereas the evidence on the effect of underlying bonds is mixed). Thus, there may be an offsetting effect that could weaken the potential benefits of the rule for capital formation through new equity issuances by firms.

[514] Some ETFs may change the way they operate voluntarily by taking advantage of the increased basket flexibility of the proposed rule.

[515] As discussed in above in section IV.B.1, while the vast majority of ETFs currently in operation are organized as open-end funds, some early ETFs, which currently have a significant amount of assets, are organized as UITs. Examples include SPDR S&P 500 ETF Trust (SPY) and PowerShares QQQ Trust, Series 1 (QQQ).

[516] We note that fund sponsors that plan to launch a new ETF organized as a UIT would continue to be able to rely on the exemptive order process.

we have done in our exemptive orders since approximately 2006.[517]

The requirement included in these orders was designed to address the risk that an authorized participant or other market participant could take advantage of its relationship with the ETF (*i.e.,* engage in cherry picking or dumping). However, as discussed above, we believe that the proposed rule's additional policies and procedures requirements for custom baskets would provide a principles-based approach that is designed to limit potential abuses so that they would be unlikely to cause significant harm to investors. In addition, as also discussed above in section III.C.1.b, we believe that the increased basket flexibility under the proposed rule would benefit the effective functioning of the arbitrage mechanism, particularly benefiting fixed-income, international, and actively managed ETFs.[518]

4. Website Disclosure of Every Basket Used by an ETF

Proposed rule 6c–11 would require ETFs to post, on the ETF's website at the beginning of each business day, a published basket applicable to orders for the purchase or redemption of creation units to be priced based on the ETF's next calculation of NAV. Because an ETF would be required to post only one published basket to comply with this condition, it would not be required to post the contents of its other custom baskets in many instances. As an alternative, we considered proposing that ETFs be required to publish information regarding every basket used by the ETF after the close of trading on each business day.

The additional disclosure under this alternative could reveal whether an authorized participant has pressured an ETF into accepting illiquid securities in exchange for liquid ETF shares (*i.e.,* dumping) or into giving an authorized participant desirable securities in exchange for ETF shares tendered for redemption (*i.e.,* cherry-picking) by comparing an ETF's portfolio assets and published basket to the baskets used by various authorized participants throughout the day.

However, the proposed rule contains additional conditions for basket policies and procedures, which seek to prevent overreaching. Moreover, the proposed rule would require an ETF to maintain records regarding the baskets used, which would allow Commission staff to examine an ETF's use of basket flexibility. Consequently, we believe that the risk for these abusive practices under the proposed rule would be low while, at the same time, the rule would avoid additional operational and compliance costs for ETFs to post and review the information, under the alternative.[519]

5. The Use of a Structured Format for Additional Website Disclosures and the Filing of Additional Website Disclosures in a Structured Format on EDGAR

As discussed in section II.C.6 above, we are proposing to require ETFs to post on their websites certain disclosures to enable investors to more readily obtain certain key metrics for individual ETFs. The proposed rule would allow ETFs to select a format for posting information that the individual ETF finds most efficient and appropriate for the content management system of their website.

As an alternative, we could require ETFs to post the disclosures in a structured format on their websites. Structured disclosures are made machine-readable by having reported disclosure items labeled (tagged) using a markup language that can be processed by software for analysis.[520] Compared with each ETF selecting its own layout and format for the website disclosures, the resulting standardization under this alternative would allow for extraction, aggregation, comparison, and large-scale analysis of reported information through significantly more automated means than is possible with unstructured formats such as HTML. This alternative would facilitate the extraction and analysis through automated means of an individual fund's disclosures over time—which would offer the greatest benefit for higher-frequency ETF disclosures—and potentially the comparison of disclosures across a small number of ETFs. However, requiring a structured disclosure format would not lower the collection burden incurred by the requirement to separately visit each website to obtain each ETFs disclosure.

The structured data requirement could impose an incremental cost on ETFs of tagging the information in a structured format, particularly to the extent that ETFs don't otherwise structure this data for their own purposes. Although, if the XML format is used for the additional disclosure, the incremental cost of tagging information in a structured format would likely be small.[521]

As another alternative, we could require ETFs to make the additional website disclosures available in a centralized repository in a structured format, such as by filing them on EDGAR. Making the information available in a structured format on EDGAR would likely improve its accessibility and the ability of investors, the Commission, and other data users to efficiently extract information for purposes of aggregation, comparison and analysis of information across multiple funds and time periods.[522] As stated above, if the XML format is used for the additional disclosure, the incremental cost of tagging the information in a structured format would likely be small. However, funds would still incur a cost of filing the disclosures on EDGAR, which might be higher than the cost of posting the disclosures on individual ETF websites.

6. Treatment of Leveraged ETFs

As discussed in section II.A.3. above, leveraged ETFs would not be able to

[517] ETFs whose orders we are proposing to rescind and that are operating under exemptive orders issued before approximately 2006, which included few explicit restrictions, would have reduced basket flexibility under the alternative compared to the baseline.

[518] Section III.D discusses the possibility that some ETFs may use the increased basket flexibility of the proposed rule to over- or under-weight securities in their baskets compared to their portfolios based on the liquidity of these securities. Such a practice would not be possible under the alternative that would require an ETF's basket to generally correspond *pro rata* to its portfolio holdings.

[519] We estimate that, under the alternative, an average ETF would incur a one-time cost of $3,879 (6 hours (for website development) × $296.50 per hour (blended rate for a senior systems analyst ($274) and senior programmer ($319)) + (4 hours (for review of website disclosures) × $325 (blended rate for a compliance manager ($298) and a compliance attorney ($352)) + $800 for an external website developer to develop the web page = $3,879) for implementing this website disclosure and an ongoing cost of $1,596.50 (1 hour (for website updates) × $296.50 per hour (blended rate for a senior systems analyst ($274) and senior programmer ($319)) + (4 hours (for review of website disclosures) × $325 (blended rate for a compliance manager ($298) and a compliance attorney ($352)) = $1,596.50) per year for updating the relevant web page daily with this information.

[520] Structured information can be stored, shared and presented in different systems or platforms. Standardized markup languages, such as XML or XBRL, use sets of data element tags for each required reporting element, referred to as taxonomies.

[521] For example, based on staff experience with XML filings, the costs of tagging the information in XML are expected to be minimal given the technology that will be used to structure the data. XML is a widely used data format, and based on the Commission's understanding of current practices, most reporting persons and third party service providers have production systems already in place to report schedules of investments and other information. Therefore, we believe systems should be able to accommodate XML data without significant costs, and large-scale changes will likely not be necessary to output structured data files.

[522] The Commission has implemented requirements for the structuring of certain information disclosed by funds. *See, e.g.,* Release No. 33–10231 (Oct. 13, 2016) [81 FR 81870]; Release No. IC–29132 (Feb. 23, 2010) [75 FR 10059]; Release No. 33–9006 (Feb. 11, 2009) [74 FR 7747].

rely on proposed rule 6c–11. As an alternative, we considered permitting leveraged ETFs to rely on the proposed rule, while maintaining the status quo of existing exemptive orders with respect to the amount of leveraged market exposure that leveraged ETFs may obtain (*i.e.,* 300% of the return or inverse return).[523] This alternative would thus prohibit a leveraged ETF from seeking a performance result, directly or indirectly, that exceeds three times the performance, or inverse performance, of the specified market index or benchmark. This alternative could benefit competition among leveraged ETFs as compared to the baseline, as fund sponsors that currently do not have an exemptive order permitting them to operate this type of ETF could enter the market. As a result, fees for leveraged ETFs would likely decrease and their assets could increase. However, as discussed in detail in section II.A.3., in light of our ongoing consideration, including the potential staff recommendation of a re-proposal on funds' use of derivatives, we do not believe it is appropriate to permit sponsors to form and operate leveraged ETFs in reliance on our proposed rule.

F. Request for Comments

The Commission requests comment on all aspects of this initial economic analysis, including whether the analysis has: (1) Identified all benefits and costs, including all effects on efficiency, competition, and capital formation; (2) given due consideration to each benefit and cost, including each effect on efficiency, competition, and capital formation; and (3) identified and considered reasonable alternatives to the proposed new rule and disclosure amendments. We request and encourage any interested person to submit comments regarding the proposed rule, our analysis of the potential effects of the proposed rule and proposed amendments, and other matters that may have an effect on the proposed rule. We request that commenters identify sources of data and information as well as provide data and information to assist us in analyzing the economic consequences of the proposed rule and proposed amendments. We also are interested in comments on the qualitative benefits and costs we have identified and any benefits and costs we may have overlooked. In addition to our general request for comment on the economic analysis associated with the proposed rule and proposed amendments, we request specific comment on certain aspects of the proposal:

- Would the proposed rule require any existing ETFs whose exemptive orders would be rescinded to materially change the way they operate? If so, what types of funds would have to materially change the way they operate and it what ways? Would these funds require any additional exemptive relief to continue operating?
- Would the elimination of the direct costs of obtaining exemptive relief result in additional benefits to ETFs or their investors? Are there other costs of the proposed rule that would offset any cost savings resulting from not having to file an exemptive application?
- Would the proposed rule result in greater product innovation in the ETF market? Would the proposed rule result in increased investment options?
- Are we correct to assume that substantially all ETFs that are currently not required to make daily website disclosures of NAV, closing price, and premiums and discounts would have the data required to make these disclosures available to them as part of their regular operations as well as systems (such as computer equipment, an internet connection, and a website) in place that can be used for processing this data and uploading it to their websites? If not, what data or systems would currently be unavailable, which ETFs would it be unavailable for, and what would the cost of acquiring the unavailable data or systems be?
- Do ETFs already have policies and procedures in place governing the composition of baskets? How long would it take and how much would it cost to implement such policies and procedures for funds that do not already have them in place, particularly the custom basket policies and procedures?
- Are we correct to assume that substantially all ETFs would already have the required data available for daily website disclosures of bid-ask spreads and historical information regarding premiums and discounts as well as systems (such as computer equipment, an internet connection, and a website) in place that can be used for processing this data and uploading it to their websites? If not, what data or systems would currently be unavailable, which funds would it be unavailable for, and what would the cost of acquiring the unavailable data or systems be?
- Are we correct to assume that substantially all funds would already have the required data to complete the new disclosures required by the proposed amendments to Forms N–1A and N–8B–2 available to them as part of their regular operations? If not, what data would currently be unavailable, which funds would it be unavailable for, and what would the cost of acquiring the unavailable data be?
- Is our estimate correct that the cost to a typical fund for applying for an ETF exemptive order is approximately $100,000? If not, what would be a more accurate estimate?
- How many ETFs (representing how much in assets) currently are required to disclose on their website, free of charge, the previous day's NAV and the price of the ETF shares, as well as the premium or discount associated with the closing price and information pertaining to the composition and proportion of underlying holdings? How many ETFs (representing how much in assets) are not required to provide this disclosure but nevertheless voluntarily provide it?
- Do commenters agree that requiring ETFs to make the additional website disclosures available in a structured format, which is an alternative we considered, would be associated with only a small cost of tagging this information?
- Would the proposed rule lead to more competition and lower fees in the leveraged ETF market if leveraged ETFs were allowed to rely on the rule?

IV. Paperwork Reduction Act

A. Introduction

Proposed rule 6c–11 would result in new ''collection of information'' requirements within the meaning of the Paperwork Reduction Act of 1995 (''PRA'').[524] In addition, the proposed amendments to Form N–1A, Form N–8B–2, and Form N–CEN would impact the collection of information burden under those forms and Form S–6.[525] Proposed rule 6c–11 also would impact the current collection of information burden of rule 0–2 under the Act.[526]

The titles for the existing collection of information are: ''Form N–1A under the Securities Act of 1933 and under the Investment Company Act of 1940, Registration Statement for Open-End Management Companies'' (OMB No. 3235–0307); ''Form N–8B–2 under the Investment Company Act of 1940, Registration Statement of Unit Investment Trusts Which are Currently Issuing Securities'' (OMB No. 3235–0186); ''Form S–6 [17 CFR 239.19], for registration under the Securities Act of 1933 of Unit Investment Trusts registered on Form N–8B–2'' (OMB Control No. 3235–0184); ''Form N–

[523] *See supra* footnote 77.

[524] 44 U.S.C. 3501–3520.

[525] 17 CFR 274.11A; 17 CFR 274.12; 17 CFR part 101; 17 CFR 239.16.

[526] 17 CFR 270.0–2.

CEN'' (OMB Control No. 3235–0730); and ''Rule 0–2 under the Investment Company Act of 1940, General Requirements of Papers and Applications'' (OMB Control No. 3235–0636). The title for the new collection of information would be: ''Rule 6c–11 under the Investment Company Act of 1940, 'Exchange-traded funds.' '' The Commission is submitting these collections of information to the Office of Management and Budget (''OMB'') for review in accordance with 44 U.S.C. 3507(d) and 5 CFR 1320.11. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

We published notice soliciting comments on the collection of information requirements in the 2008 ETF Proposing Release and submitted the proposed collections of information to OMB for review and approval in accordance with 44 U.S.C. 3507(d) and 5 CFR 1320.11.[527] We received no comments on the collection of information requirements.

We discuss below the collection of information burdens associated with proposed rule 6c–11 and its impact on rule 0–2 as well as proposed amendments to Forms N–1A, N–8B–2, S–6 and N–CEN.

B. Proposed Rule 6c–11

Proposed rule 6c–11 would permit ETFs that satisfy certain conditions to operate without first obtaining an exemptive order from the Commission. The rule is designed to create a consistent, transparent, and efficient regulatory framework for such ETFs and facilitate greater competition and innovation among ETFs. The proposal attempts to eliminate historical distinctions and conditions that we no longer believe are necessary and thus appropriately level the playing field for such ETFs that pursue the same or similar investment strategies.

Proposed rule 6c–11 would require an ETF to disclose certain information on its website, to maintain certain records, and to adopt and implement written policies and procedures governing their constructions of baskets, as well as written policies and procedures that set forth detailed parameters for the construction and acceptance of custom baskets that are in the best interests of the ETF and its shareholders. These requirements are collections of information under the PRA.

The respondents to proposed rule 6c–11 would be ETFs registered as open-end management investment companies other than ETFs within multiple-class funds or leveraged ETFs.[528] This collection would not be mandatory, but would be necessary for those ETFs seeking to operate without individual exemptive orders. We estimate that 1,635 ETFs would likely rely on rule 6c–11.[529] Information provided to the Commission in connection with staff examinations or investigations would be kept confidential subject to the provisions of applicable law.

1. Website Disclosures

Under the proposal, ETFs would be required to post on their websites: (i) The ETF's NAV per share, market price, and premium or discount; and (ii) historical information regarding premiums and discounts. In addition, proposed rule 6c–11 would require an ETF to disclose on its website, each business day, the portfolio holdings that will form the basis for each calculation of NAV per share,[530] and information regarding a published basket that will apply to orders for the purchase or redemption of creation units each business day.[531] As proposed, the rule would require that portfolio holdings and basket information be presented and contain information regarding description, amount, value and/or unrealized gain/loss (if applicable) in the manner prescribed within Article 12 of Regulation S–X.[532] Additionally, the proposed rule would require an ETF to disclose on its website a tabular chart and line graph showing the ETF's premiums and discounts for the most recently completed calendar year and the most recently completed calendar quarters of the current year. For new ETFs that do not yet have this information, the proposed rule would require the ETF to post this information for the life of the fund. As discussed above, we believe the disclosures provide useful information to investors who purchase and sell ETF shares on national securities exchanges.

Proposed rule 6c–11(c)(1)(v) also would require any ETF whose premium or discount was greater than 2% for more than seven consecutive trading days to post that information on its website, along with a discussion of the factors that are reasonably believed to have materially contributed to the premium or discount.[533] Given the proposed threshold, we do not believe that many ETFs would be required to disclose this information on a routine basis. For purposes of this PRA, we assume that all ETFs will be required to make this disclosure only once in their lifetime. Therefore, we believe that this requirement will impose only initial costs and that there will be no ongoing costs associated with it.[534]

For purposes of the PRA analysis, we estimate that an ETF would incur a one-time average burden of 25 hours associated with updating the relevant website disclosures, at a time cost of $7,697.50.[535] The staff estimates the initial external cost would be $2,000 for an external website developer to develop the web page.[536] Amortized over a 3-year period, the hour burden per ETF would be approximately 8.3 hours, at a time cost of $2,565.8, and an external cost of approximately $666.65. Additionally, Commission staff estimates that an ETF each year would spend approximately 5 hours of professional time to update the relevant web page daily with this information, at a time cost of $1,405.50.[537] Commission staff does not believe there will be any ongoing external costs related to the website disclosure requirements. Accordingly, we estimate that the total burden for drafting, reviewing and uploading the website disclosures would be 21,745.50 hours,[538] at a time

[527] *See* 2008 ETF Proposing Release, *supra* footnote 3.

[528] *See* proposed rule 6c–11(a) (defining ''exchange-traded fund'').

[529] *See supra* footnote 425 and accompanying text. This is estimate does not include UIT ETFs, share class ETFs, or leveraged ETFs.

[530] *See* proposed rule 6c–11(c)(1)(i)(A).

[531] *See* proposed rule 6c–11(c)(1)(i)(B).

[532] *See supra* footnote 220.

[533] This information would be posted on the trading day immediately following the eighth consecutive trading day on which the ETF had a premium or discount greater than 2% and be maintained on the ETF's website for at least one year following the first day it was posted. *See supra* at text following footnote 306.

[534] For purposes of this analysis, we estimate that 1,635 ETFs would be required to make this disclosure at least once in their lifetime.

[535] This estimate is based on the following calculations: (15 hours (for website development) × $296.50 per hour (blended rate for a senior systems analyst ($274) and senior programmer ($319)) + (10 hours (for review of website disclosures) × $325 (blended rate for a compliance manager ($298) and a compliance attorney ($352)) = $7,697.50).

[536] Based on staff experience, the staff estimates that each ETF initially would spend an additional $2,000 on external website developers.

[537] This estimate is based on the following calculations: (2 hours (for website updates) × $296.50 per hour (blended rate for a senior systems analyst ($274) and senior programmer ($319)) + (2.5 hours (for review of website disclosures) × $325 (blended rate for a compliance manager ($298) and a compliance attorney ($352)) = $1,405.50. *See* SIFMA Report, *supra* footnote 452.

[538] This estimate is based on the following calculation: 13.3 hours × 1,635 ETFs = 21,745.50 hours.

cost of approximately $6,493,075.50,[539] and an external cost of $1,089,972.75.[540]

2. Recordkeeping

The proposed rule requires that ETFs to preserve and maintain copies of all written authorized participant agreements.[541] Additionally, we are proposing to require ETFs to maintain records setting forth the following information for each basket exchanged with an authorized participant: (i) The names and quantities of the positions composing the basket; (ii) identification of the basket as a ''custom basket'' and a record stating that the custom basket complies with the ETF's custom basket policies and procedures (if applicable); (iii) cash balancing amounts (if any); and (iv) the identity of the authorized participant conducting the transaction.[542]

ETFs would have to maintain these records for at least five years, the first two years in an easily accessible place.[543] We estimate that the burden would be 5 hours per ETF to retain these records, with 2.5 hours spent by a general clerk and 2.5 hours spent by a senior computer operator. We estimate a time cost per ETF of $380.[544] We estimate the total recordkeeping burden related to rule 6c–11 would be 8,175 hours, at an aggregate cost of $621,300.[545]

3. Policies and Procedures

As proposed, rule 6c–11 would require ETFs relying on the proposed rule to adopt and implement written policies and procedures that govern the construction of baskets and the process that will be used for the acceptance of basket assets.[546] Additionally, to use custom baskets, an ETF would be required to adopt and implement written policies and procedures setting forth detailed parameters for the construction and acceptance of custom baskets that are in the best interests of the ETF and its shareholders.[547] These policies and procedures also may include a periodic review requirement in order to ensure that the ETF's custom basket procedures are being consistently followed.[548] Finally, as discussed above, such an ETF would be required to maintain records detailing the composition of each custom basket.

For purposes of this PRA analysis, we estimate that an ETF would incur a one-time average burden of 6 hours associated with setting up the process for documenting the construction and acceptance of baskets.[549] Accordingly, we estimate that a total initial burden associated with setting up the process for documenting the construction and acceptance of baskets would be 9,810 hours,[550] at a time cost of $4,094,325.[551] An ETF utilizing custom baskets would also incur a one-time average burden of 20 hours associated with documenting and adopting the custom basket policies and procedures. Amortized over a 3-year period, this would be an annual burden per ETF of about 2 hours for documenting the construction and acceptance of baskets and an annual burden per ETF of about 6.7 hours for the custom basket policies and procedures. Accordingly, we estimate that a total burden for initial documentation and review of both the process for documenting the construction and acceptance of baskets as well as an ETF's custom basket policies and procedures would be 42,510 hours,[552] at a time cost of $16,788,180.[553] Amortizing these costs over three years, the annual burden of complying with these requirements would be 14,170 hours, at a time cost of $5,596,060. We also estimate that there would be no external cost for an ETF associated with these requirements.

We estimate that each ETF would incur an ongoing burden of an additional 10 hours, at a time cost of an additional $3,985 [554] each year to review and update its custom basket policies and procedures as well as its process for documenting the construction and acceptance of baskets. In aggregate, we estimate that the total ongoing costs associated with these requirements are 16,350 hours, at a time cost of $6,515,475.[555] We do not estimate that there will be any ongoing external costs associated with these requirements. Therefore, we estimate that the total initial and ongoing costs associated with complying with the policies and procedures requirements of proposed rule 6c–11 would be 30,520 [556] hours at a time cost of $12,111,535.[557]

4. Estimated Total Burden

We estimate that the total hour burdens and time costs associated with proposed rule 6c–11, including the burden associated with: (i) Website disclosure; (ii) recordkeeping; and (iii) developing policies and procedures, would result in an average aggregate annual burden of 60,440.5 hours [558] and an average aggregate time cost of $19,225,910.50.[559] We also estimate that there are $1,089,972.75 external costs associated with this collection of information. [560] Therefore, to comply with rule 6c–11 each ETF would incur an annual burden of approximately 36.97 [561] hours, at an average time cost of approximately $11,758.97 [562], and an external cost of $666.65.[563]

[539] This estimate is based on the following calculation: $3,971.3 × 1,635 ETFs = $6,493,075.50.

[540] This estimate is based on the following calculation: $666.65 × 1,635 ETFs = $1,089,972.75.

[541] *See* proposed rule 6c–11(d).

[542] *See supra* footnote 325 and accompanying text.

[543] *Id.*

[544] This estimate is based on the following calculations: 2.5 hours × $60 (hourly rate for a general clerk) = $150; 2.5 hours × $92 (hour rate for a senior computer operator) = $230. $150 + $230 = $380.

[545] We estimate that 1,635 ETFs would be required to maintain these records.

[546] *See* proposed rule 6c–11(c)(3).

[547] *See* proposed rule 6c–11(c)(3)(i).

[548] *See supra* text accompanying footnote 256.

[549] We estimate that all ETFs relying on the rule will use custom baskets to some extent. Moreover, we estimate that the cost associated with this requirement is small because the records detailing the composition of each custom basket are readily available.

[550] This estimate is based on the following calculations: 6 hours × 1,635 ETFs = 9,810 hours.

[551] This estimate is based on the following calculations: 3 hours × 317 (hourly rate for a senior manager) = $951; 2 hours × 511 (hourly rate for chief compliance officer) = $1,022; 1 hour × $352 (hourly rate for compliance attorney) = $352; $951 + $1,022 + $352 = $2,325; $2,325 × 1,635 ETFs = $3,801,375.

[552] This estimate is based on the following calculation: (6 hours + 20 hours) × 1,635 ETFs = 42,510 hours.

[553] These estimates are based on the following calculations: 12 hours × $317 (hourly rate for a senior portfolio manager) = $3,804; 12 hours × $480 (blended hourly rate for assistant general counsel ($449) and chief compliance officer ($511) = $5,760; 2 hours (for a fund attorney's time to prepare and review materials) × $352 (hourly rate for a compliance attorney) = $704. $3,804 + $5,760 + $704 = $10,268; $10,268 × 1,635 ETFs = $16,788,180. *See* SIFMA Report, *supra* footnote 452.

[554] These estimates are based on the following calculations: 5 hours × $317 (hourly rate for a senior portfolio manager) = $1,585; 5 hours × $480 (blended hourly rate for assistant general counsel ($449) and chief compliance officer ($511) = $2,400. $1,585 + $2,400 = $3,985.

[555] This estimate is based on the following calculation: $3,985 × 1,635 ETFs = $6,515,475.

[556] This estimate is based on the following calculation: 14,170 hours + 16,350 hours = 30,520 hours.

[557] This estimate is based on the following calculation: $5,596,060 + $6,515,475 = $12,111,535.

[558] This estimate is based on the following calculation: 21,745.5 hours + 8,175 hours + 30,520 hours = 60,440.5 hours.

[559] This estimate is based on the following calculation: $6,493,075.50 + $621,300 + $12,111,535 = $19,225,910.50.

[560] *See supra* footnote 540 and accompanying text.

[561] This estimate is based on the following calculation: 60,440.5 hours ÷ 1,635 ETFs = 36.97 hours.

[562] This estimate is based on the following calculation: $19,225,910.50 ÷ 1,635 ETFs = $11,758.97.

[563] This estimate is based on the following calculation: $1,089,972.75 ÷ 1,635 ETFs = $666.65.

C. Rule 0–2

Section 6(c) of the Act provides the Commission with authority to conditionally or unconditionally exempt persons, securities or transactions from any provision 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. Rule 0–2 under the Act, entitled ''General Requirements of Papers and Applications,'' prescribes general instructions for filing an application seeking exemptive relief with the Commission.[564] We currently estimate for rule 0–2 a total hour burden of 5,340 hours at an annual time cost of $2,029,200.60 and the total annual external cost burden is $14,090,000.[565]

As discussed above, proposed rule 6c–11 would permit ETFs that satisfy the conditions of the rule to operate without the need to obtain an exemptive order from the Commission under the Act. Therefore, proposed rule 6c–11 would alleviate some of the burdens associated with rule 0–2 because it would reduce the number of entities that require exemptive relief in order to operate.[566] Based on staff experience, we estimate that approximately one-third of the annual burdens associated with rule 0–2 are attributable to ETF applications. Therefore, we estimate that proposed rule 6c–11 would result in a decrease of the annual burden of rule 0–2 to approximately 3,738 [567] hours at an annual time cost of $1,420,440.42 [568] and an annual external cost of $9,863,000.[569]

D. Form N–1A

Form N–1A is the registration form used by open-end management investment companies. The respondents to the proposed amendments to Form N–1A are open-end management investment companies registered or registering with the Commission. Compliance with the proposed disclosure requirements of Form N–1A is mandatory for open-end funds (to the extent applicable) including all ETFs organized as open-end funds. Responses to the disclosure requirements are not confidential. We currently estimate for Form N–1A a total burden hour of 1,579,974 burden hours, with an estimated internal cost of $129,338,408, and external cost of $124,820,197.[570]

We are proposing amendments to Form N–1A designed to provide investors who purchase ETF shares in secondary market transactions with tailored information regarding ETFs, including information regarding costs associated with an investment in ETFs.[571] Specifically, the proposed amendments to Form N–1A would require new disclosures regarding fees and expenses, such as brokerage commission and financial intermediary fees, and certain trading costs.[572] In addition, we are proposing to include instructions in Form N–1A requiring an ETF to provide bid-ask spread information on the ETF's website and an interactive calculator, in a clear and prominent format on the ETF's website, to allow investors to customize certain hypothetical calculations to their specific investing situation.[573]

We also are proposing amendments to Form N–1A designed to eliminate certain disclosures for ETFs that are duplicative of the new disclosures we are proposing, discussed above, or are no longer necessary.[574] These proposed amendments include eliminating certain disclosures in Item 6(c) of Form N–1A relating to creation units, secondary market transactions, premiums and discounts, as well as certain disclosures required of ETFs issuing creation units of less than 25,000 shares. Additionally, we are proposing to eliminate historical premium/discount disclosure requirements in Item 11(g)(2) and Item 27(b)(7)(iv) of Form N–1A.

Form N–1A generally imposes two types of reporting burdens on investment companies: (i) The burden of preparing and filing the initial registration statement; and (ii) the burden of preparing and filing post-effective amendments to a previously effective registration statement (including post-effective amendments filed pursuant to 17 CFR 230.485(a) or (b) (rule 485(a) or 485(b) under the Securities Act), as applicable). We estimate that each ETF would incur a one-time burden of an additional 10 hours, at a time cost of an additional $3,355,[575] to draft and finalize the required disclosure and amend its registration statement. We further estimate that an ETF would incur a one-time average burden of 10 hours associated with implementing the bid-ask spread disclosures and interactive calculator on its website, at a time cost of $3,355,[576] as required by proposed Instruction 5(e) to Item 3. In the aggregate, we estimate that ETFs would incur a one-time burden of an additional 20 hours, at a time cost of an additional $6,710 to comply with the proposed Form N–1A disclosure requirements for ETFs. Amortizing the one-time burden over a three-year period results in an average annual burden of an additional 6.67 hours at a time cost of an additional $2,236.67.

We estimate that each ETF would incur an ongoing burden of an additional 5 hours, at a time cost of an additional $1,677.50 [577] each year to review and update the proposed disclosures.[578] We also estimate that each ETF would incur an ongoing burden of an additional 5 hours, at a time cost of an additional $1,677.50,[579] relating to the bid-ask spread disclosures and to maintain the interactive calculator on its website. In aggregate, we estimate that each ETF would incur an annual ongoing burden of an additional 10 hours, at a time cost of an additional $3,355, to comply with the proposed Form N–1A disclosure requirements. We do not estimate any change to the external costs associated with the proposed amendment for Form N–1A.

In total, we estimate that ETFs, other than UIT ETFs, would incur an average

[564] *See* Supporting Statement of Rule 0–2 under the Investment Company Act of 1940, General Requirements of Paper Applications (Nov. 23, 2016), *available at https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201602-3235-008* (summarizing how applications are filed with the Commission in accordance with the requirements of rule 0–2).

[565] This estimate is based on the last time the rule's information collection was submitted for PRA renewal in 2016.

[566] As discussed above, we expect to continue to receive applications for complex or novel ETF exemptive relief that are beyond the scope of the proposed rule. *See supra* at text following footnote 454.

[567] This estimate is based on the following calculation: 5,340 hours − (5,340 hours × 0.3) = 3,738 hours.

[568] This estimate is based on the following calculation: $2,029,200.60 − ($2,029,200.60 × 0.3) = $1,420,440.42.

[569] This estimate is based on the following calculation: $14,090,000 − ($14,090,000 × 0.3) = $9,863,000.

[570] This estimate is based on the last time the form's information collection was submitted for PRA renewal in 2017.

[571] *See* proposed Instruction 5(e) to Item 3 of Form N–1A.

[572] *See* proposed amendments to Item 3 of Form N–1A.

[573] Proposed Instruction 5(e) to Item 3 of Form N–1A.

[574] *See supra* footnotes 390–397 and accompanying text.

[575] This estimate is based on the following calculation: 10 hours × $335.50 (blended rate for a compliance attorney ($352) and a senior programmer ($319)) = $3,355.

[576] *Id.*

[577] This estimate is based on the following calculation: 5 hours × $335.50 (blended rate for a compliance attorney ($352) and a senior programmer ($319)) = $1,677.50.

[578] The estimated burden associated with the amendments to Form N–1A accounts for the proposal to remove the information currently required by Item 11(g)(2) and Item 27(b)(7)(iv) of Form N–1A.

[579] *Id.*

annual increased burden of approximately 31,596.4 hours,[580] at a time cost of approximately $10,579,307.2,[581] to comply with the proposed Form N–1A disclosure requirements. We do not estimate any change to the external costs associated with the proposed amendment for Form N–1A.

E. Disclosure Amendments to Forms N–8B–2 and S–6

Form N–8B–2 is used by UITs to initially register under the Investment Company Act pursuant to section 8 thereof.[582] UITs are required to file Form S–6 in order to register offerings of securities with the Commission under the Securities Act.[583] As a result, UITs file Form N–8B–2 only once when the UIT is initially created and then use Form S–6 to file all post-effective amendments to their registration statements in order to update their prospectuses.[584] We currently estimate for Form S–6 a total burden of 106,620 hours, with an internal cost burden of approximately $34,000,000, and an external cost burden estimate of $67,359,556.[585] Additionally, we currently estimate for Form N–8B–2 a total burden of 10 hours, with an internal cost burden of approximately $3,360, and an external burden estimate of $10,000.[586]

In order to assist investors with better understanding the total costs of investing in a UIT ETF, we are proposing disclosure requirements in Form N–8B–2 that mirror those disclosures proposed for Form N–1A.[587] All UIT ETFs would be subject to these disclosure requirements. For existing UIT ETFs, the one-time and ongoing costs of complying with the amendments to Form N–8B–2 would accrue on Form S–6.[588]

For purposes of the PRA analysis, we estimate that each UIT ETF would incur a one-time burden of an additional 20 hours, at a time cost of an additional $6,710 [589] to draft and finalize the required disclosure and amend its Form S–6. For each newly created UIT ETF, these same costs would be incurred on Form N–8B–2.[590] Therefore, in the aggregate, we estimate that existing UIT ETFs would incur a one-time burden of an additional 160 hours,[591] at a time cost of an additional $53,680,[592] to comply with the proposed Form N–8B–2 disclosure requirements on Form S–6. Additionally, in the aggregate, we estimate that newly created UIT ETFs would incur a one-time burden of an additional 20 hours, at a time cost of an additional $6,710, to comply with the proposed amendments and complete Form N–8B–2. Amortizing the one-time burden for both existing and newly created UIT ETFs over a three-year period results in an average annual burden of an additional 6.67 hours, at a time cost of an additional $2,236.67.

We estimate that each UIT ETF would incur an ongoing burden of an additional 10 hours, at a time cost of an additional $3,355, each year to review and update the proposed disclosures on Form S–6. In aggregate, we estimate that UIT ETFs would incur an annual burden of an additional 80 hours,[593] at a time cost of an additional $26,840,[594] to comply with the proposed Form N–8B–2 disclosure requirements on Form S–6.

Additionally, we estimate that newly created UIT ETFs would also incur an average annual increased burden of approximately 10 hours, at a time cost of an additional $3,355, to complete Form N–8B–2. We do not estimate any change to the external costs, on either Form N–8B–2 or Form S–6, associated with the proposed amendments to Form N–8B–2.

F. Form N–CEN

As discussed above, Form N–CEN is a structured form that requires registered funds to provide census-type information to the Commission on an annual basis.[595] The Commission is proposing amendments to Form N–CEN to require ETFs to report if they are relying on rule 6c–11.[596]

In the Reporting Modernization Adopting Release, we estimated that the Commission would receive an average of 3,113 reports on Form N–CEN.[597] We estimated that the average annual hour burden per response for Form N–CEN for the first year to be 32.37 hours and 12.37 hours in subsequent years.[598] Amortizing the burden over three years, we estimated that the average annual hour burden per fund per year to be 19.04 hours and the total aggregate annual hour burden to be 59,272 hours.[599] Finally, we estimated that all applicable funds will incur, in the aggregate, external annual costs of $2,088,176 to prepare and file reports on Form N–CEN.[600]

Based on Commission staff experience, we believe that our proposal to require ETFs to report if they are relying on rule 6c–11 would increase the estimated burden hours associated with Form N–CEN by approximately 0.1 hours, both initially and on an ongoing basis.[601] Therefore, in the aggregate, we estimate that ETFs will incur an annual burden of an additional 163.5 hours to comply with the proposed amendments to Form N–CEN.[602] We estimate that there are no additional external costs associated with this collection of information.

G. Request for Comments

We request comment on whether these estimates are reasonable. Pursuant to 44 U.S.C. 3506(c)(2)(B), the Commission solicits comments in order to: (i) Evaluate whether the proposed collections of information are necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (ii) evaluate the accuracy of the Commission's estimate of the burden of the proposed

[580] This estimate is based on the following calculation: (6.7 hours + 10 hours) × 1,892 ETFs = 31,596.4 hours.

[581] This estimate is based on the following calculation: ($2,236.67 + $3,355) × 1,892 ETFs= $10,579,307.20.

[582] *See* Form N–8B–2 [17 CFR 274.12].

[583] *See* Form S–6 [17 CFR 239.16]. Form S–6 is used for registration under the Securities Act of securities of any UIT registered under the Act on Form N–8B–2.

[584] Form S–6 incorporates by reference the disclosure requirements of Form N–8B–2 and allows UITs to meet the filing and disclosure requirements of the Securities Act.

[585] This estimate is based on the last time the form's information collection was submitted for PRA renewal in 2014.

[586] This estimate is based on the last time the form's information collection was submitted for PRA renewal in 2018.

[587] *See* proposed Items 13(h) and (i) of Form N–8B–2. *See also supra* section II.H.5.

[588] *See supra* footnote 583.

[589] This estimate is based on the following calculation: 20 hours × $335.50 (blended rate for a compliance attorney ($352) and a senior programmer ($319)) = $6,710.

[590] Although we noted above that no new UIT ETFs have come to market since 2002, for purposes of calculating the time and cost burdens associated with completing Form N–8B–2, we estimate that 1 UIT ETF will be created annually. *See supra* footnote 41 and accompanying text.

[591] This estimate is based on the following calculation: 20 hours × 8 UIT ETFs= 160 hours.

[592] This estimate is based on the following calculation: $6,710 × 8 UIT ETFs = $53,680.

[593] This estimate is based on the following calculation: 10 hours × 8 UIT ETFs = 80 hours.

[594] This estimate is based on the following calculation: $3,355 × 8 UIT ETFs = $26,840.

[595] *See* Reporting Modernization Adopting Release, *supra* footnote 147. The compliance date for Form N–CEN is June 1, 2018.

[596] *See* proposed Item C.7.k. of Form N–CEN.

[597] *See* Reporting Modernization Adopting Release, *supra* footnote 147, at text accompanying n.1524.

[598] *See id.,* at text accompanying nn.1531–1532.

[599] *See id.,* at text accompanying nn.1533–1534.

[600] *See* Reporting Modernization Adopting Release, *supra* footnote 147, at text accompanying n.1538.

[601] This estimate stems from the Commission staff's understanding of the time it takes to complete initially complete and review items on Form N–CEN.

[602] This estimate is based on the following calculation: 0.1 hours × 1,635 ETFs = 163.5 hours.

collections of information; (iii) determine whether there are ways to enhance the quality, utility, and clarity of the information to be collected; and (iv) determine whether there are ways to minimize the burden of the collections of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology.

Persons wishing to submit comments on the collection of information requirements of the proposed rules and amendments should direct them to the OMB, Attention Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Washington, DC 20503, and should send a copy to, Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090, with reference to File No. S7–15–18. OMB is required to make a decision concerning the collections of information between 30 and 60 days after publication of this release; therefore a comment to OMB is best assured of having its full effect if OMB receives it within 30 days after publication of this release. Requests for materials submitted to OMB by the Commission with regard to these collections of information should be in writing, refer to File No. S7–15–18, and be submitted to the Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736.

V. Initial Regulatory Flexibility Analysis

The Commission has prepared the following Initial Regulatory Flexibility Analysis (''IRFA'') in accordance with section 3 of the Regulatory Flexibility Act[603] regarding our proposed new rule 6c–11 and proposed amendments to Form N–1A, Form N–8b–2, and Form N–CEN.

A. Reasons for and Objectives of the Proposed Actions

As described more fully above, proposed rule 6c–11 would allow ETFs that meet the conditions of the rule to form and operate without the expense and delay of obtaining an exemptive order from the Commission. The Commission's objective is to create a consistent, transparent and efficient regulatory framework for ETFs and to facilitate greater competition and innovation among ETFs. The Commission also believes the proposed disclosure amendments would provide useful information to investors who purchase and sell ETF shares in secondary markets. Finally, the goal of the proposed amendments to Form N–CEN is for the Commission to be able to better monitor reliance on rule 6c–11 and to assist the Commission with its accounting, auditing and oversight functions.

B. Legal Basis

The Commission is proposing new rule 6c–11 pursuant to the authority set forth in sections 6(c), 22(c), and 38(a) of the Investment Company Act [15 U.S.C. 80a–6(c), 22(c), and 80a–37(a)]. The Commission is proposing amendments to registration Form N–1A under the authority set forth in sections 6, 7(a), 10 and 19(a) of the Securities Act of 1933 [15 U.S.C. 77f, 77g(a), 77j, 77s(a)], and sections 8(b), 24(a), and 30 of the Investment Company Act [15 U.S.C. 80a–8(b), 80a–24(a), and 80a–29]. The Commission is proposing amendments to registration Form N–8b–2 under the authority set forth in section 8(b) and 38(a) of the Investment Company Act [15 U.S.C. 80a–8(b) and 80a–37(a)]. The Commission is proposing amendments to Form N–CEN under the authority set forth sections 8(b), 30(a), and 38(a) of the Investment Company Act [15 U.S.C. 80a–8(b), 80a–29(a), and 80a–37(a)].

C. Small Entities Subject to the Rule

An investment company is a small entity if, together with other investment companies in the same group of related investment companies, it has net assets of $50 million or less as of the end of its most recent fiscal year.[604] Commission staff estimates that, as of December 2017, there are approximately 8 open-end ETFs that may be considered small entities.[605] Commission staff estimates there are no UIT ETFs that would be considered small entities subject to the proposed disclosures for Form N–8B–2.[606]

D. Projected Reporting, Recordkeeping, and Other Compliance Requirements

The proposed amendments would amend current reporting requirements for ETFs considered small entities.

1. Rule 6c–11

Proposed rule 6c–11 would require an ETF to disclose on its website: (i) Portfolio holding information and information regarding a published basket on each business day; (ii) the ETF's current NAV per share, market price, and premium or discount, each as of the end of the prior business day; (iii) if an ETF's premium or discount is greater than 2% for more than seven consecutive trading days, a discussion of the factors that are reasonably believed to have materially contributed to the premium or discount; and (iv) a table and line graph showing the ETF's premiums and discounts.[607] We also are proposing to require that ETFs preserve and maintain copies of all written authorized participant agreements, as well as records setting forth the following information for each basket exchanged with an authorized participant: (i) The names and quantities of the positions composing the basket; (ii) identification of the basket as a ''custom basket'' and a record stating that the custom basket complies with the ETF's policies and procedures (if applicable); (iii) cash balancing amounts (if any); and (iv) the identity of the authorized participant conducting the transaction.[608] Proposed rule 6c–11 would also require ETFs relying on the proposed rule to adopt and implement written policies and procedures that govern the construction of baskets and the process that will be used for the acceptance of basket assets.[609] ETFs using custom baskets under the proposed rule must adopt custom basket policies and procedures that include certain enumerated requirements.[610]

We estimate that approximately 8 ETFs are small entities that would comply with proposed rule 6c–11, and we do not believe that their costs would differ from other ETFs. As discussed above, we estimate that an ETF would incur an annual burden of approximately 36.97 hours, at an average time cost of approximately $11,758.97, and an external cost of $666.65.[611]

2. Disclosure and Reporting Requirements

We are proposing amendments to Form N–1A and Form N–8B–2 designed to provide investors who purchase ETF shares in secondary market transactions with tailored information regarding ETFs, including information regarding costs associated with an investment in ETFs. Specifically, proposed amendments to Form N–1A would require new disclosure regarding fees and expenses, such a brokerage

[603] *See* 5 U.S.C. 603(a).

[604] 17 CFR 270.0–10(a).

[605] This estimate is derived from an analysis of data reported on Form N–1A with the Commission for the period ending December, 2017.

[606] This estimate is derived from an analysis of data reported on Forms S–6 and N–8B–2 with the Commission for the period ending December 2017.

[607] *See* proposed rule 6c–11(c)(1)(iii) and (iv).

[608] *See supra* section II.C.5.a.

[609] Proposed rule 6c–11(c)(3).

[610] Proposed rule 6c–11(c)(3).

[611] *See supra* footnote 561 and accompanying text.

commission and financial intermediary fees, and additional information on certain trading costs.[612] In addition, we are proposing to include instructions in Form N–1A requiring an ETF to provide bid-ask spread information on the ETF's website and an interactive calculator, in a clear and prominent format on the ETF's website, to allow investors to customize certain hypothetical calculations to their specific investing situation.[613] Proposed amendments to Form N–8B–2 mirror proposed disclosures for Form N–1A. We are also proposing amendments to Form N–CEN that would require ETFs to report on Form N–CEN if they are relying on rule 6c–11. The proposed Form N–CEN amendments are designed to assist us with monitoring reliance on rule 6c–11 as well with our accounting, auditing and oversight functions, including compliance with the PRA.

All ETFs would be subject to the proposed disclosure and reporting requirements, including ETFs that are small entities. We estimate that 8 ETFs are small entities that would be required to comply with the proposed disclosure and reporting requirements.[614]

As discussed above, we estimate that each ETF, including ETFs that are small entities, would incur a one-time burden of an additional 10 hours, at a time cost of an additional $3,355 to draft and finalize the required disclosure and amend its registration statement.[615] We further estimate that ETFs, including ETFs that are small entities, would incur a one-time average burden of 10 hours associated with implementing the interactive calculator on its website, at a time cost of $3,355, as required by proposed Instruction 5(e) to Item 3. In the aggregate, we estimate that ETFs, including ETFs that are small entities, would incur a one-time burden of an additional 20 hours, at a time cost of an additional $6,710, to comply with the proposed Form N–1A disclosure requirements for ETFs.[616]

We also estimate that each ETF, including ETFs that are small entities, would incur an ongoing burden of an additional 5 hours, at a time cost of an additional $1,677.50, each year to review and update the proposed disclosures. We further estimate that each ETF, including ETFs that are small entities, would incur an ongoing burden of an additional 5 hours, at a time cost of an additional $1,677.50, to maintain the interactive calculator on its website. In aggregate, we estimate that each ETF, including ETFs that are small entities, would incur an annual ongoing burden of an additional 10 hours, at a time cost of an additional $3,355, to comply with the proposed Form N–1A disclosure requirements. We do not estimate any change to the external costs associated with the proposed amendments to Form N–1A.[617]

As discussed above, because the amendments made to Form N–8B–2 mirror those made on Form N–1A, we believe that UIT ETFs, including UIT ETFs that are small entities, would incur the same costs as all ETFs associated with updating their registration statements. However, none of the UIT ETFs are small entities.

E. Duplicative, Overlapping or Conflicting Federal Rules

Commission staff has not identified any federal rules that duplicate, overlap, or conflict with the proposed regulations.

F. Significant Alternatives

The RFA directs the Commission to consider significant alternatives that would accomplish our stated objectives, while minimizing any significant economic impact on small entities. We considered the following alternatives for small entities in relation to the proposed regulations:

- Exempting ETFs that are small entities from the proposed disclosure, reporting or recordkeeping requirements, to account for resources available to small entities;
- establishing different disclosure, reporting or recordkeeping requirements or different frequency of these requirements, to account for resources available to small entities;
- clarifying, consolidating, or simplifying the compliance requirements under the amendments for small entities; and
- using performance rather than design standards.

We do not believe that exempting any subset of ETFs, including small entities, from proposed rule 6c–11 or proposed form amendments would permit us to achieve our stated objectives. Nor do we believe establishing different disclosure, reporting or recordkeeping requirements or different frequency of these requirements for small entities would permit us to achieve our stated objectives. Similarly, we do not believe that we can establish simplified or consolidated compliance requirements for small entities under the proposed rule without compromising our objectives. As discussed above, the conditions necessary to rely on proposed rule 6c–11 and the reporting, recordkeeping and disclosure requirements are designed to provide investor protection benefits, including, among other things, tailored information regarding ETFs, including information regarding costs associated with an investment in ETFs. These benefits should apply to investors in smaller funds as well as investors in larger funds. Similarly, we do not believe it would be in the interest of investors to exempt small ETFs from the proposed disclosure and reporting requirements or to exempt small ETFs from the proposed recordkeeping requirements. We believe that all ETF investors, including investors in small ETFs, would benefit from disclosure and reporting requirements that permit them to make investment choices that better match their risk tolerances. We further note that the current disclosure requirements for reports on Form N–1A and Form N–8B–2 do not distinguish between small entities and other funds.[618]

Finally, we believe that proposed rule 6c–11 and related disclosure and reporting requirements appropriately use a combination of performance and design standards. Proposed rule 6c–11 provides ETFs that satisfy the requirements of the rule with exemptions from certain provisions of the Act necessary for ETFs to operate. Because the provisions of the Act from which ETFs would be exempt provide important investor and market protections, the conditions of the proposed rule must be specifically designed to ensure that these investor and market protections are maintained. However, where we believe that flexibility is beneficial, we proposed performance-based standards that provide a regulatory framework, rather than prescriptive requirements, to give funds the opportunity to adopt policies and procedures tailored to their specific

[612] *See supra* footnote 572 and accompanying text.

[613] Proposed Instruction 5(e) to Item 3 of Form N–1A.

[614] *See supra* footnote 605.

[615] *See supra* footnote 576 and accompanying text.

[616] *See supra* footnote 576 and accompanying text.

[617] *Id.*

[618] *See* Reporting Modernization Adopting Release, *supra* footnote 147, at section V.E (noting that small entities currently follow the same requirements that large entities do when filing reports on Form N–SAR, Form N–CSR, and Form N–Q, and stating that the Commission believes that establishing different reporting requirements or frequency for small entities (including with respect to proposed Form N–PORT and proposed Form N–CEN) would not be consistent with the Commission's goal of industry oversight and investor protection).

needs without raising investor or market protection concerns.[619]

G. General Request for Comment

The Commission requests comment regarding this analysis. We request comments on the number of small entities that would be subject to the proposed ETF regulations and whether the proposed ETF regulations would have any effects that have not been discussed. We request that commenters describe the nature of any effects on small entities subject to the proposed ETF regulations and provide empirical data to support the nature and extent of such effects. We also request comment on the estimated compliance burdens of the proposed ETF regulations and how they would affect small entities.

VI. Consideration of Impact on the Economy

For purposes of the Small Business Regulatory Enforcement Fairness Act of 1996, or ''SBREFA,'' [620] the Commission must advise OMB whether a proposed regulation constitutes a ''major'' rule. Under SBREFA, a rule is considered ''major'' where, if adopted, it results in or is likely to result in:

- An annual effect on the economy of $100 million or more;
- A major increase in costs or prices for consumers or individual industries; or
- Significant adverse effects on competition, investment or innovation.

We request comment on whether our proposal would be a ''major rule'' for purposes of SBREFA. We solicit comment and empirical data on:

- The potential effect on the U.S. economy on an annual basis;
- Any potential increase in costs or prices for consumers or individual industries; and
- Any potential effect on competition, investment, or innovation.

Commenters are requested to provide empirical data and other factual support for their views to the extent possible.

VII. Statutory Authority

The Commission is proposing new rule 6c–11 pursuant to the authority set forth in sections 6(c), 22(c), and 38(a) of the Investment Company Act [15 U.S.C. 80a–6(c), 80a–22(c), and 80a–37(a)]. The Commission is proposing amendments to registration Form N–1A under the authority set forth in sections 6, 7(a), 10 and 19(a) of the Securities Act of 1933 [15 U.S.C. 77f, 77g(a), 77j, 77s(a)], and sections 8(b), 24(a), and 30 of the Investment Company Act [15 U.S.C. 80a–8(b), 80a–24(a), and 80a–29]. The Commission is proposing amendments to registration Form N–8B–2 under the authority set forth in section 8(b) and 38(a) of the Investment Company Act [15 U.S.C. 80a–8(b) and 80a–37(a)]. The Commission is proposing amendments to Form N–CEN under the authority set forth in sections 8(b), 30(a), and 38(a) of the Investment Company Act [15 U.S.C. 80a–8(b), 80a–29(a), and 80a–37(a)].

List of Subjects

17 CFR Part 239

Reporting and recordkeeping requirements, Securities.

17 CFR Parts 270 and 274

Investment companies, Reporting and recordkeeping requirements, Securities.

Text of Proposed Rules and Form Amendments

For reasons set out in the preamble, title 17, chapter II of the Code of Federal Regulations is proposed to be amended as follows:

PART 239—FORMS PRESCRIBED UNDER THE SECURITIES ACT OF 1933

■ 1. The authority citation for part 239 continues to read, in part, as follows:

Authority: 15 U.S.C. 77c, 77f, 77g, 77h, 77j, 77s, 77z–2, 77z–3, 77sss, 78c, 78*l,* 78m, 78n, 78o(d), 78o–7 note, 78u–5, 78w(a), 78*ll,* 78mm, 80a–2(a), 80a–3, 80a–8, 80a–9, 80a–10, 80a–13, 80a–24, 80a–26, 80a–29, 80a–30, and 80a–37; and sec. 107 Pub. L. 112–106, 126 Stat. 312, unless otherwise noted.

* * * * *

PART 270—RULES AND REGULATIONS, INVESTMENT COMPANY ACT OF 1940

■ 2. The authority citation for part 270 continues to read, in part, and is amended by adding a sectional authority for § 270.6c–11 to read as follows:

Authority: 15 U.S.C. 80a–1 *et seq.,* 80a–34(d), 80a–37, 80a–39, and Pub. L. 111–203, sec. 939A, 124 Stat. 1376 (2010), unless otherwise noted.

* * * * *

Section 270.6c–11 is also issued under 15 U.S.C. 80a–6(c) and 80a–37(a).

* * * * *

■ 3. Section 270.6c–11 is added to read as follows:

§ 270.6c–11 Exchange-traded funds.

(a) *Definitions.* For purposes of this section:

Authorized participant means a member or participant of a clearing agency registered with the Commission, which has a written agreement with the exchange-traded fund or one of its service providers that allows the authorized participant to place orders for the purchase and redemption of creation units.

Basket means the securities, assets or other positions in exchange for which an exchange-traded fund issues (or in return for which it redeems) creation units.

Business day means any day the exchange-traded fund is open for business, including any day when it satisfies redemption requests as required by section 22(e) of the Act (15 U.S.C. 80a–22(e)).

Cash balancing amount means an amount of cash to account for any difference between the value of the basket and the net asset value of a creation unit.

Creation unit means a specified number of exchange-traded fund shares that the exchange-traded fund will issue to (or redeem from) an authorized participant in exchange for the deposit (or delivery) of a basket and a cash balancing amount if any.

Custom basket means:

(i) Baskets that are composed of a non-representative selection of the exchange-traded fund's portfolio holdings; or

(ii) Different baskets used in transactions on the same business day.

Exchange-traded fund means a registered open-end management company:

(i) That issues (and redeems) creation units to (and from) authorized participants in exchange for a basket and a cash balancing amount if any; and

(ii) Whose shares are listed on a national securities exchange and traded at market-determined prices.

Exchange-traded fund share means a share of stock issued by an exchange-traded fund.

Foreign investment means any security, asset or other position of the ETF issued by a foreign issuer as that term is defined in § 240.3b–4 of this title, and for which there is no established United States public trading market, as that term is used in 17 CFR 227.201 (Item 201 of Regulation S–K under the Securities Act of 1933).

Market price means:

(i) The official closing price of an exchange-traded fund share; or

(ii) If it more accurately reflects the market value of an exchange-traded

[619] *See e.g., supra* section II.C.5 (noting that proposed rule 6c–11 would provide an ETF with the flexibility to use ''custom baskets'' if the ETF has adopted written policies and procedures that set forth detailed parameters for the construction and acceptance of custom baskets that are in the best interests of the ETF and its shareholders).

[620] Public Law 104–121, Title II, 110 Stat. 857 (1996) (codified in various sections of 5 U.S.C., 15 U.S.C. and as a note to 5 U.S.C. 601).

fund share at the time as of which the exchange-traded fund calculates current net asset value per share, the price that is the midpoint between the national best bid and national best offer as of that time.

National securities exchange means an exchange that is registered with the Commission under section 6 of the Securities Exchange Act of 1934 (15 U.S.C. 78f).

Portfolio holdings means the securities, assets or other positions held by the exchange-traded fund.

Premium or discount means the positive or negative difference between the market price of an exchange-traded fund share at the time as of which the current net asset value is calculated and the exchange-traded fund's current net asset value per share, expressed as a percentage of the exchange-traded fund share's current net asset value per share.

(b) *Application of the Act to Exchange-Traded Funds.* If the conditions of paragraph (c) of this section are satisfied:

(1) *Redeemable security.* An exchange-traded fund share is considered a ''redeemable security'' within the meaning of section 2(a)(32) of the Act (15 U.S.C. 80a–2(a)(32)).

(2) *Pricing.* A dealer in exchange-traded fund shares is exempt from section 22(d) of the Act (15 U.S.C. 80a–22(d)) and § 270.22c–1(a) with regard to purchases, sales and repurchases of exchange-traded fund shares at market-determined prices.

(3) *Affiliated transactions.* (i) A person who is an affiliated person of an exchange-traded fund (or who is an affiliated person of such a person) solely by reason of the circumstances described in paragraphs (b)(3)(i)(A) and (B) of this section is exempt from sections 17(a)(1) and 17(a)(2) of the Act (15 U.S.C. 80a–17(a)(1) and (a)(2)) with regard to the deposit and receipt of baskets:

(A) Holding with the power to vote 5% or more of the exchange-traded fund's shares; or

(B) Holding with the power to vote 5% or more of any investment company that is an affiliated person of the exchange-traded fund.

(4) *Postponement of redemptions.* If an exchange-traded fund includes a foreign investment in its basket, and if a local market holiday, or series of consecutive holidays, or the extended delivery cycles for transferring foreign investments to redeeming authorized participants prevents timely delivery of the foreign investment in response to a redemption request, the exchange-traded fund is exempt, with respect to the delivery of the foreign investment, from the prohibition in section 22(e) of the Act (15 U.S.C. 80a–22(e)) against postponing the date of satisfaction upon redemption for more than seven days after the tender of a redeemable security if the exchange-traded fund delivers the foreign investment as soon as practicable, but in no event later than 15 days after the tender of the exchange-traded fund shares. The exemption provided in paragraph (b)(4) of this section will expire and no longer be effective on [date ten years from effective date of rule].

(c) *Conditions.* (1) Each business day, an exchange-traded fund must disclose prominently on its website, which is publicly available and free of charge:

(i) Before the opening of regular trading on the primary listing exchange of the exchange-traded fund shares and before the exchange-traded fund starts accepting orders for the purchase or redemption of creation units:

(A) The portfolio holdings that will form the basis of the next calculation of current net asset value per share;

(B) A basket applicable to orders for the purchase or redemption of creation units to be priced based on the next calculation of current net asset value; and

(C) The estimated cash balancing amount, if any;

(ii) The exchange-traded fund's current net asset value per share, market price, and premium or discount, each as of the prior business day;

(iii) A table showing the number of days the exchange-traded fund's shares traded at a premium or discount during the most recently completed calendar year and the most recently completed calendar quarters since that year (or the life of the exchange-traded fund, if shorter);

(iv) A line graph showing exchange-traded fund share premiums or discounts for the most recently completed calendar year and the most recently completed calendar quarters since that year (or the life of the exchange-traded fund, if shorter); and

(v) If the exchange-traded fund's premium or discount is greater than 2% for more than seven consecutive trading days, a discussion of the factors that are reasonably believed to have materially contributed to the premium or discount, which must be maintained on the website for at least one year thereafter; and

(vi) The exchange-traded fund must present the description, amount, value and unrealized gain/loss in the manner prescribed within 17 CFR 210.12–12, 210.12–12A, 210.12–13, 210.12–13A, 210.12–13B, 210.12–13C, and 210.12–13D (Article 12 of Regulation S–X) for each portfolio holding or basket asset required to be disclosed pursuant to paragraphs (c)(1)(i) of this section.

(2) An exchange-traded fund must reflect changes in the exchange-traded fund's portfolio holdings in the first calculation of net asset value per share on the first business day following the trade date.

(3) An exchange-traded fund must adopt and implement written policies and procedures that govern the construction of baskets and the process that will be used for the acceptance of baskets; *provided, however,* if the exchange-traded fund utilizes a custom basket:

(i) These written policies and procedures also must:

(A) Set forth detailed parameters for the construction and acceptance of custom baskets that are in the best interests of the exchange-traded fund and its shareholders, including the process for any revisions to, or deviations from, those parameters; and

(B) Specify the titles or roles of the employees of the exchange-traded fund's investment adviser who are required to review each custom basket for compliance with those parameters.

(4) The exchange-traded fund may not seek, directly or indirectly, to provide returns that exceed the performance of a market index by a specified multiple, or to provide returns that have an inverse relationship to the performance of a market index, over a fixed period of time.

(5) Notwithstanding the definition of exchange-traded fund in paragraph (a) of this section, an exchange-traded fund is not prohibited from selling (or redeeming) individual shares on the day of consummation of a reorganization, merger, conversion or liquidation.

(d) *Recordkeeping.* The exchange-traded fund must maintain and preserve for a period of not less than five years, the first two years in an easily accessible place:

(1) All written agreements (or copies thereof) between an authorized participant and the exchange-traded fund or one of its service providers that allows the authorized participant to place orders for the purchase or redemption of creation units;

(2) For each basket exchanged with an authorized participant, records setting forth:

(i) The names and quantities of the positions composing the basket exchanged for creation units;

(ii) If applicable, identification of the basket as a custom basket and a record stating that the custom basket complies with policies and procedures that the

exchange-traded fund adopted pursuant to paragraph (c)(3)(i) of this section;

(iii) Cash balancing amount, if any; and

(iv) Identity of authorized participant transacting with the exchange-traded fund.

PART 274—FORMS PRESCRIBED UNDER THE INVESTMENT COMPANY ACT OF 1940

■ 4. The general authority citation for part 274 continues to read, in part, as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s, 78c(b), 78*l,* 78m, 78n, 78o(d), 80a–8, 80a–24, 80a–26, 80a–29, and Pub. L. 111–203, sec. 939A, 124 Stat. 1376 (2010), unless otherwise noted.

* * * * *

■ 5. Form N–1A (referenced in §§ 239.15A and 274.11A) is amended as follows:

■ a. In General Instruction A revise the definition of ''Exchange-Traded Fund.''

■ b. In General Instruction A, remove the definition of ''Market Price.''

The additions and revisions read as follows:

Note: The text of Form N–1A does not, and this amendment will not, appear in the *Code of Federal Regulations.*

Form N–1A

* * * * *

GENERAL INSTRUCTIONS

* * * * *

A. Definitions

* * * * *

''Exchange-Traded Fund'' means a Fund or Class, the shares of which are listed and traded on a national securities exchange, and that has formed and operates under an exemptive order granted by the Commission or in reliance on rule 6c–11 [17 CFR 270.6c–11] under the Investment Company Act.

* * * * *

■ 6. Amend Item 3 of Form N–1A to read as follows:

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Item 3. Risk/Return Summary: Fee Table

Include the following information, in plain English under rule 421(d) under the Securities Act, after Item 2:

Fees and Expenses of the Fund

This table describes the fees and expenses that you may pay if you buy, hold and sell shares of the Fund. You may pay other fees not described below, such as brokerage commissions and other fees to financial intermediaries, which are not reflected in the tables and examples below. You may qualify for sales charge discounts if you and your family invest, or agree to invest in the future, at least $[ ] in [name of fund family] funds. More information about these and other discounts is available from your financial intermediary and in [identify section heading and page number] of the Fund's prospectus and [identify section heading and page number] of the Fund's statement of additional information.

Shareholder Fees (fees paid directly from your investment)

Maximum Sales Charge (Load) Imposed on Purchases (as a percentage of offering price)	_____%
Maximum Deferred Sales Charge (Load) (as a percentage of_____)	_____%
Maximum Sales Charge (Load) Imposed on Reinvested Dividends [and other Distributions] (as a percentage of_____)	_____%
Redemption Fee (as a percentage of amount redeemed, if applicable)	_____%
Exchange Fee	_____%
Maximum Account Fee	_____%

Annual Fund Operating Expenses (expenses that you pay each year as a percentage of the value of your investment)

Management Fees	_____%
Distribution [and/or Service] (12b-1) Fees	_____%
Other Expenses	_____%
_____	_____%
_____	_____%
Total Annual Fund Operating Expenses	_____%

Example

This Example is intended to help you compare the cost of investing in the Fund with the cost of investing in other mutual funds.

The Example assumes that you invest $10,000 in the Fund for the time periods indicated and then redeem all of your shares at the end of those periods. The Example also assumes that your investment has a 5% return each year and that the Fund's operating expenses remain the same.

	1 year	3 years	5 years	10 years
Although your actual costs may be higher or lower, based on these assumptions your costs would be:	$	$	$	$
You would pay the following expenses if you did not redeem your shares:	$	$	$	$

The Example above does not reflect sales charges (loads) on reinvested dividends [and other distributions]. If these sales charges (loads) were included, your costs would be higher.

Exchange-Traded Fund Trading Information and Related Costs

What information do I need to know about how the Exchange-Traded Fund ("ETF") trades?

Individual shares of an ETF may only be bought and sold in the secondary market through a broker or dealer at a market price. The market price can change throughout the day due to the supply of and demand for ETF shares, and changes in the value of the Fund's underlying investments, among other reasons. Because ETF shares trade at market prices rather than net asset value, shares may trade at a price greater than net asset value (premium) or less than net asset value (discount).

What costs are associated with trading shares of an ETF?

An investor may incur costs when buying or selling shares on an exchange that are ***in addition to*** the costs described above. Examples include brokerage commissions, costs attributable to the bid-ask spread, and costs attributable to premiums and discounts.

What is the bid-ask spread?

The bid-ask spread is the difference between the highest price a buyer is willing to pay to purchase shares of the Fund (bid) and the lowest price a seller is willing to accept for shares of the Fund (ask). The bid-ask spread can change throughout the day due to the supply of or demand for ETF shares, the quantity of shares traded, and the time of day the trade is executed,

among other factors. For the ETF's most recent fiscal year ended [___], the median bid-ask spread was

XX.XX%.

How does the bid-ask spread impact my return on investment?

The impact of the bid-ask spread depends on your trading practices. For example, based on the ETF's fiscal year-end data, purchasing $10,000 worth of ETF shares and then immediately thereafter selling $10,000 worth of ETF shares (*i.e.*, a "round-trip"), your cost, in dollars, would be as follows:

For a SINGLE round-trip (each trade being $10,000)	
Assuming mid-range spread cost:	$ ____
Assuming high-end spread cost:	$ _____

But what if I plan to trade ETF shares frequently?

Based on the ETF's most recent fiscal year-end data, completing 25 round-trips of $10,000 each, your cost, in dollars, would be as follows:

For 25 round-trips (each trade being $10,000)	
Mid-range spread cost:	$ _____
High-end spread cost:	$ _____

Where can I get more trading information for the ETF?

The ETF's website at [www.[Series-SpecificLandingPage.com]] includes recent information on the Fund's net asset value, market price, premiums and discounts, as well as an interactive calculator you can use to determine how the bid-ask spread would impact your specific investment.

Portfolio Turnover

The Fund pays transaction costs, such as commissions, when it buys and sells securities (or "turns over" its portfolio). A higher portfolio turnover rate may indicate higher transaction costs and may result in higher taxes when Fund shares are held in a taxable account. These costs, which are not reflected in annual fund operating expenses or in the example, affect the Fund's performance. During the most recent fiscal year, the Fund's portfolio turnover rate was _____% of the average value of its portfolio.

BILLING CODE 8011–01–C

* * * * *

■ 7. Amend Instruction 1 of Item 3 of Form N–1A as follows:

* * * * *

Instructions

1. *General*

(a) Round all dollar figures to the nearest dollar and all percentages to the nearest hundredth of 1%.

(b) Include the narrative explanations in the order indicated. A Fund may modify the narrative explanations if the explanation contains comparable information to that shown. The narrative explanation regarding sales charge discounts is only required by a Fund that offers such discounts and should specify the minimum level of investment required to qualify for a discount as disclosed in the table required by Item 12(a)(1).

(c) Include the caption ''Maximum Account Fees'' only if the Fund charges these fees. A Fund may omit other captions if the Fund does not charge the fees or expenses covered by the captions.

(d)

(i) If the Fund is a Feeder Fund, reflect the aggregate expenses of the Feeder Fund and the Master Fund in a single fee table using the captions provided. In a footnote to the fee table, state that the table and Example reflect the expenses of both the Feeder and Master Funds.

(ii) If the prospectus offers more than one Class of a Multiple Class Fund or more than one Feeder Fund that invests in the same Master Fund, provide a separate response for each Class or Feeder Fund.

(e) If the Fund is an Exchange-Traded Fund, exclude any fees charged for the purchase and redemption of the Fund's creation units.

* * * * *

■ 8. Amend Instruction 5 of Item 3 of Form N–1A to read as follows:

* * * * *

5. *Exchange-Traded Fund Trading Information and Related Costs.*

(a) Include the median bid-ask spread for the Fund's most recent fiscal year only if the Fund is an Exchange-Traded Fund. However, do not include the median bid-ask spread for any Exchange-Traded Fund that had its initial listing on a national securities exchange after the beginning of the most recently completed fiscal year. For an Exchange-Traded Fund that had an initial listing after the beginning of the most recently completed fiscal year, explain that the Exchange-Traded Fund did not have a sufficient trading history to report trading information and related costs. Information should be based on the most recently completed fiscal year end. The Fund also must provide information on the Fund's website, which is publicly accessible, free of charge, that investors can use to obtain the bid/ask spread information required in this Item.

(b) Bid-Ask Spread (Median). Calculate the median bid-ask spread by dividing the difference between the ask and the bid by the midpoint of the ask and the bid for each ten-second interval throughout each trading day of the Exchange-Traded Fund's most recent fiscal year. Once the bid-ask spread for each ten-second interval throughout the fiscal year is determined, sort the spreads from lowest to highest. If there is an odd number of spread intervals, then the median is the middle number. If there is an even number of spread intervals, then the median is the average between the two middle numbers. Express the spread as a percentage, rounded to the nearest hundredth percent.

(c) Determine the mid-range spread cost for each number of transactions in the table according to the following formula:

$(S_{Mid}/2) * \$10{,}000 * T$

Where:

S_{Mid} = Median spread as calculated in Instruction 5(b) during most recently completed calendar year, expressed as a percentage;

T = Number of Transactions (1 and 25).

(d) Determine the high-end spread cost for each number of transactions in the table according to the following formula:

$(S_{High}/2) * \$10{,}000 * T$

Where:

S_{High} = High-end spread is calculated by dividing the difference between the ask and the bid by the midpoint of the ask and the bid for each ten-second interval throughout each trading day of the Exchange-Traded Fund's most recently completed fiscal year. Once the bid-ask spread for each ten-second interval throughout the fiscal year is determined, sort the spreads from lowest to highest. The high end spread is the number closest to the 95th percentile, expressed as a percentage. If two numbers are equally close to the 95th percentile, use the average of the two numbers;

T = Number of Transactions (1 and 25).

(e) Provide an interactive calculator in a clear and prominent format on the Fund website which uses the calculations in Instructions 5(a)–(d) to Item 3 to provide the information required by Q&As 3, 4 and 5.

* * * * *

■ 9. Amend Item 6 of Form N–1A as follows:

* * * * *

Item 6. Purchase and Sale of Fund Shares

(a) *Purchase of Fund Shares.* Disclose the Fund's minimum initial or subsequent investment requirements.

(b) *Sale of Fund Shares.* Also disclose that the Fund's shares are redeemable and briefly identify the procedures for redeeming shares (*e.g.,* on any business day by written request, telephone, or wire transfer).

(c) *Exchange-Traded Funds.* If the Fund is an Exchange-Traded Fund, the Fund may omit the information required by this Item.

* * * * *

■ 10. Amend Items 11(a)(1) and 11(g) of Form N–1A as follows:

* * * * *

Item 11. Shareholder Information

(a) *Pricing of Fund Shares.* Describe the procedures for pricing the Fund's shares, including:

(1) An explanation that the price of Fund shares is based on the Fund's net asset value and the method used to value Fund shares (market price, fair value, or amortized cost); except that if the Fund is an Exchange-Traded Fund, an explanation that the price of Fund shares is based on a market price.

* * * * *

(g) *Exchange-Traded Funds.* If the Fund is an Exchange-Traded Fund, the Fund may omit from the prospectus the information required by Items 11(a)(2), (b), and (c).

* * * * *

■ 11. Remove Item 27(b)(7)(iv) of Form N–1A and instructions thereto.

■ 12. Amend Instruction 1(e)(ii) of Item 27(d)(1) of Form N–1A as follows:

* * * * *

Instructions

* * * * *

1. *General.*

* * * * *

(e) If the fund is an Exchange-Traded Fund:

* * * * *

(ii) Exclude any fees charged for the purchase and redemption of the Fund's creation units.

* * * * *

■ 13. Amend Form N–8B–2 (referenced in §§ 239.16 and 274.12) as follows:

The additions and revisions read as follows:

Note: The text of Form N–8B–2 does not, and this amendment will not, appear in the *Code of Federal Regulations.*

Form N–8B–2

* * * * *

GENERAL INSTRUCTIONS FOR FORM N–8B–2

* * * * *

Definitions

* * * * *

Exchange-Traded Fund (ETF): The term ''Exchange-Traded Fund'' or ''ETF'' means a trust, the shares of which are listed and traded on a national securities exchange, and that has formed and operates under an exemptive order granted by the Commission.

* * * * *

Information Concerning Loads, Fees, Charges, and Expenses

13.

* * * * *

(h) If the trust is an Exchange-Traded Fund, furnish an explanation indicating that an ETF investor may pay additional fees not described by any other item in this form, such as brokerage commissions and other fees to financial intermediaries.

(i) If the trust is an Exchange-Traded Fund, furnish the disclosures and information set forth in Item 3 of Form N–1A [referenced in 17 CFR 274.11A], in the section of that Item titled ''Exchange-Traded Fund Trading Information and Related Costs.'' Provide information specific to the trust as necessary, utilizing the ETF-specific methodology set forth in the Instructions to Form N–1A Item 3.

* * * * *

■ 14. Amend Items C.7. and E.2. Form N–CEN (referenced in § 274.101):

The additions read as follows:

Note: The text of Form N–CEN does not, and this amendment will not, appear in the *Code of Federal Regulations.*

FORM N–CEN

ANNUAL REPORT FOR REGISTERED INVESTMENT COMPANIES

* * * * *

Part C. Additional Questions for Management Investment Companies

* * * * *

Item C.7.

* * * * *

k. Rule 6(c)–11 (17 CFR 270.6c–11):

* * * * *

Part E. Additional Questions for Exchange-Traded Funds and Exchange-Traded Managed Funds

* * * * *

Item E.2.

* * * * *

Instruction. The term ''authorized participant'' means a member or participant of a clearing agency registered with the Commission, which has a written agreement with the Exchange-Traded Fund or Exchange-Traded Managed Fund or one of its service providers that allows the authorized participant to place orders for the purchase and redemption of creation units.

* * * * *

By the Commission.

Dated: June 28, 2018.

Brent J. Fields,

Secretary.

[FR Doc. 2018–14370 Filed 7–30–18; 8:45 am]

BILLING CODE 8011–01–P

FEDERAL REGISTER

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Part V

The President

Notice of July 27, 2018—Continuation of the National Emergency With Respect to Lebanon

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Title 3—

The President

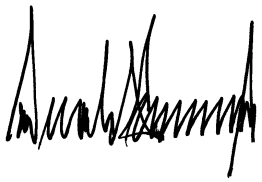
Notice of July 27, 2018

Continuation of the National Emergency With Respect to Lebanon

On August 1, 2007, by Executive Order 13441, the President declared a national emergency with respect to Lebanon pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701–1706) to deal with the unusual and extraordinary threat to the national security and foreign policy of the United States constituted by the actions of certain persons to undermine Lebanon's legitimate and democratically elected government or democratic institutions; to contribute to the deliberate breakdown in the rule of law in Lebanon, including through politically motivated violence and intimidation; to reassert Syrian control or contribute to Syrian interference in Lebanon; or to infringe upon or undermine Lebanese sovereignty. Such actions contribute to political and economic instability in that country and the region.

Certain ongoing activities, such as Iran's continuing arms transfers to Hizballah—which include increasingly sophisticated weapons systems—serve to undermine Lebanese sovereignty, contribute to political and economic instability in the region, and continue to constitute an unusual and extraordinary threat to the national security and foreign policy of the United States. For this reason, the national emergency declared on August 1, 2007, and the measures adopted on that date to deal with that emergency, must continue in effect beyond August 1, 2018. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing for 1 year the national emergency with respect to Lebanon declared in Executive Order 13441.

This notice shall be published in the *Federal Register* and transmitted to the Congress.



THE WHITE HOUSE,
July 27, 2018.

[FR Doc. 2018–16550
Filed 7–30–18; 11:15 am]
Billing code 3295–F8–P

FEDERAL REGISTER

Vol. 83 Tuesday,
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Part VI

The President

Proclamation 9770—National Korean War Veterans Armistice Day, 2018

Federal Register
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Tuesday, July 31, 2018

Presidential Documents

Title 3—

The President

Proclamation 9770 of July 26, 2018

National Korean War Veterans Armistice Day, 2018

By the President of the United States of America

A Proclamation

This year marks the 65th anniversary of the signing of the armistice that ended the fighting of the Korean War. For 3 brutal years, our Armed Forces and allies fought valiantly to stop the spread of communism and defend freedom on the Korean Peninsula. On National Korean War Veterans Armistice Day, we remember the bravery and sacrifices of those who fought and died for this noble cause.

On the Korean Peninsula, our brave Soldiers, Sailors, Marines, Airmen, and Coast Guardsmen fought with skill and resolve against tyranny and oppression. Justice, liberty, and democracy prevailed, but victory came at a tremendous cost. More than 33,000 Americans were killed in action during the Korean War, and more than 103,000 were wounded. Thousands more were captured and held as prisoners of war. Many are still missing in action. We will never forget these valiant patriots or their families, who have endured unimaginable loss.

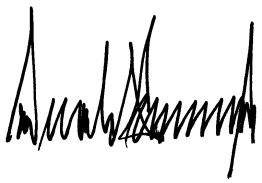
More than six decades after the cease-fire on the Korean Peninsula, our relationship with South Korea continues to flourish. We have forged a powerful friendship built on respect, a mutual desire for economic prosperity, and an unwavering commitment to democratic values and peace through strength.

In contrast, our relationship with North Korea has been hostile, due to continued threats to our allies, their development of weapons of mass destruction and ballistic missile programs, and ongoing human rights violations. Last month's historic summit with Chairman Kim Jong Un in Singapore, however, has offered a renewed sense of hope for the future—including the promise of complete denuclearization of the Korean Peninsula. During this summit, I raised my concern for the many American families who have been unable to properly bury the loved ones they lost during the Korean War and bring closure to this chapter in their lives. As a result, Chairman Kim and I announced our commitment to the recovery and repatriation of the remains of Americans missing in action. My Administration will fulfill our Nation's solemn duty to bring our patriots home with dignity and honor.

Today, we honor our Korean War Veterans for their immeasurable contributions to the cause of liberty. We also salute members of the armed forces, past and present, who have maintained an allied presence on the Korean Peninsula since the 1953 armistice. Their efforts to stave off aggression are worthy of our highest respect and gratitude.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim July 27, 2018, as National Korean War Veterans Armistice Day. I call upon all Americans to observe this day with appropriate ceremonies and activities that honor and give thanks to our distinguished Korean War Veterans.

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



[FR Doc. 2018–16555
Filed 7–30–18; 11:15 am]
Billing code 3295–F8–P

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S. 490/P.L. 115–219

To reinstate and extend the deadline for commencement of construction of a hydroelectric project involving the Gibson Dam. (July 27, 2018; 132 Stat. 1556)

S. 931/P.L. 115–220

To designate the facility of the United States Postal Service located at 4910 Brighton Boulevard in Denver, Colorado, as the ''George Sakato Post Office''. (July 27, 2018; 132 Stat. 1558)

S. 2734/P.L. 115–221

To designate the Federal building and United States courthouse located at 1300 Victoria Street in Laredo, Texas, as the ''George P. Kazen Federal Building and United States Courthouse''. (July 27, 2018; 132 Stat. 1559)

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